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Assessment and Determination of Practical Considerations for Wide-scale Utilization of Elastometric Half-facepiece Respirators during a Pandemic or Outbreak Situation

May 2013

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RS2011-IG13

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Assessment and Determination of Practical Considerations for Wide-Scale Utilization of Elastomeric Half-Facepiece Respirators during a Pandemic or Outbreak Situation

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- Speech Intelligibility scores, from the MRT, for the N95 FFR and EHFR were analyzed using the paired t-test, which showed there was a significant difference in communication interference between the two respirators, subjects had higher scores for the N95 FFR than for the EHFR. Both exceeded the minimum communication criteria of 70% as set by NIOSH.
- For subjects that did not don the respirator prior to the study and those that indicated they donned it during the study, there were significant differences over time for interference with communication and alarm. For surveys 3 and 4, interference with communication scores were significantly lower compared with the average scores for surveys 1 and 2.
- ICU audits identified several challenges with respect to allocating dedicated storage space for clean and dirty respirators and incorrect handling of EHFRs at the end of shifts.
- Themes regarding reasons for choosing not to use an EHFR were identified. These were associated with comfort, availability, communication interference and cleaning protocols.
- The EHFR cleaning and disinfection process differed from common practice in SPD. It was more time consuming than anticipated and the lack of these resources and systems complicated the reprocessing schedule and equipment tracking.
- Logistics of using EHFRs related to equipment storage, reprocessing, education requirements and communication and patient care impacts were identified.

EXECUTIVE SUMMARY

Respiratory protection has been recommended by best practice organizations to protect health care workers during a pandemic. Because of high demand during a pandemic or wide-scale outbreak, availability of N95 Filtering Facepiece Respirators (N95-FFRs) from supplier and manufacturers can become extremely limited. Due to the large number of respirators required for a large health authority during a pandemic or outbreak, stockpiling large quantities of disposable respirators may be challenging due to storage requirements, stock rotation, and limited typical usage (in relation to the usage during a pandemic).

The purpose of this study was to assess the feasibility of utilizing reusable elastomeric half-facepiece respirators in departments with high demand for respiratory protection during a pandemic or wide-scale outbreak. Elastomeric half-facepiece respirators with P100 filters (EHFRs) represent a potential reusable respirator option as they can be cleaned and disinfected between uses. The study objectives were to:

1. Assess and compare the acceptability of N95 FFRs and EHFRs for use by nursing staff in three Intensive Care Units (ICUs).
2. Assess the practical implications associated with EHFR usage in these three ICUs, including selection, storage between uses, and between shift storage.
3. Evaluate the process and impact of cleaning and disinfecting the EHFR in sterile processing departments (SPD).
4. Identify the logistics (including barriers and facilitating factors) to be addressed in a hospital when implementing the use of EHFR on a wide-scale basis.

The study was conducted, over a 6-month period, in the ICU and SPD at three large acute care hospitals. The study utilized several tools including surveys and audits (ICU and SPD) to gather data on speech intelligibility, staff perceptions regarding EHFR use and EHFR handling and reprocessing information. In order to compare ICU nurse perception changes over time, the average scores for surveys 1 and 2 were compared with the average scores of surveys 3 and 4. The surveys and department audits were

repeated four times. 107 ICU nurses consented to participate as subjects. Subjects were asked to utilize a 3M 6000 series EHFR for all situations where they would normally have used an N95-FFR.

The results for each objective are as follows:

Objective 1:

- Speech Intelligibility scores, from the Modified Rhyme Test (MRT), for the 3M 1860/1860S N95 FFR and 3M 6000 series EHFR were analyzed using the paired t-test, which showed there was a **significant difference in communication interference** between the two respirators, subjects had **higher scores for the N95 FFR (**mean = 92.58%) than for the EHFR (mean = 86.60%). However **both exceeded the minimum communication criteria** of 70% as set by NIOSH.
- For subjects that did not don the respirator prior to the study, there were significant differences over time for interference with communication and alarm. For surveys 3 and 4, interference with communication scores were significantly lower (median = 2) compared with the average scores for surveys 1 and 2 (median = 2.5) for those nurses who donned the respirator during the study. This was consistent with the differences over time for these two factors amongst the subjects that indicated they had donned the EHFR during the study.

Objective 2:

- During the surveys, subjects were asked to rate how easy it was to store and clean an EHFR, survey responses were neutral to positive. However ICU audits identified several **challenges with respect to allocating dedicated storage space for clean and dirty respirators and incorrect handling of EHFRs at the end of shifts**. Themes were also identified from the surveys regarding **reasons for choosing not to use an EHFR**. These were associated with **comfort, availability, communication interference and cleaning protocols**.

Objective 3:

- A time-in-motion study and the SPD audits identified that the **EHFR cleaning and disinfection process differs from common practice in SPD**. It was **more time consuming** than originally

anticipated and there was **no consistent equipment transport systems** within each site. The lack of these resources and systems complicated the reprocessing schedule and equipment tracking. Due to low EHFR usage we are unable to comment on the impact of the cleaning and disinfection protocols on the EHFR integrity over time.

Objective 4:

- Logistics of using EHFRs related to equipment storage, reprocessing, education requirements and communication and patient care impacts were identified. Equipment **storage both during and between use posed several challenges**. To facilitate use of EHFR and limit staff frustration it is important to designate storage areas that will remain consistent throughout the usage period, for the clean or dirty EHFRs and filters. **Procedures and personnel resources for transporting EHFRs within the site must be established**. As EHFRS are reusable, education and training on use, cleaning, reprocessing and maintenance must be conducted, requiring additional time and resources beyond that of N95 FFR fit-testing and education. In addition in the event EHFR are to be used during a pandemic or outbreak it will be imperative to have casual and part-time staff trained and fit-tested as well. This will require targeted planning as due to limited shifts worked it was difficult to recruit them to participate as subjects. Although the speech intelligibility results met minimum criteria the survey data indicated that subjects perceived EHFRs contributed to communication interference with co-workers and patients – this would need to be addressed. Resources need to be utilized to educate potential EHFR users on why this alternative respirator is being implemented, what previous research on EHFR use has been conducted and to address concerns about communication and/or alarming patients.

Keywords*: reusable respirator, elastomeric half-facepiece respirator, pandemic planning, outbreak management, pandemic stockpiling, speech intelligibility.*

1. RESEARCH PROBLEM/CONTEXT

Respiratory protection is required to protect healthcare workers when caring for patients who are potentially ill with an airborne infectious disease. Healthcare workers often employ the use of respirators as personal protective equipment (PPE), specifically the N95 filtering facepiece respirator (N95 FFR), in these situations as well as in the case of a pandemic.

N95 FFRs are the primary choice of respiratory protection for a number of reasons. They are disposed after each use and therefore do not require cleaning or reprocessing. They are light in weight and less cumbersome to don and doff as straps do not require any adjustment nor are there any filter cartridges to be manipulated. However, due to high demand during a pandemic or wide-scale outbreak, availability of N95 FFRs from supplier and manufacturers can become extremely limited. At the same time, stockpiling large quantities of N95 FFRs is challenging due to storage requirements, stock rotation and limited typical usage as compared to use during a pandemic. Due to these factors and the fact that N95 FFRs cannot be disinfected for re-use, consideration needs to be given to other respiratory protection options.

This research provides information on whether elastomeric half-facepiece respirators (EHFRs) with P100 filters, which can be cleaned and disinfected between uses, represent a potential reusable respirator option during a pandemic or outbreak.

2. RATIONALE AND SIGNIFICANCE OF RESEARCH

Pandemic planning guidelines from several associations state that N95 FFRs, or equivalent level protection, may be required for certain situations where there is close contact with confirmed or suspected pandemic patients[1-5]. In addition, similar requirements for respiratory protection were implemented during SARS in 2003[2]. Under similar circumstances in the future, where a novel respiratory syndrome is identified and route of transmission is unknown, respiratory protection would be required.

Alternative respiratory protection, such as an EHFR, should be considered and may be required for situations where a worker cannot be successfully fit-tested to any of the organization's N95 FFR.

Reusable respirators, in particular EHFRs, offer several advantages over N95 FFRs such as less waste, enhanced capacity to complete a user seal check, higher level of protection and potential for cost savings over time. However, they are not widely utilized, generally because of several concerns, including:

- Adverse perception by visitors and patients when seeing staff wearing an EHFR.
- Physiological impact and anxiety associated with wearing an EHFR.
- Comfort associated with use of an EHFR.
- Difficulty for staff to communicate while wearing an EHFR.
- Storage of the devices on the unit.
- Challenges with effective cleaning and disinfection of the devices.
- Additional resources (time and personnel) required for use and cleaning/disinfecting.

The high demand and low availability of N95 FFRs during the recent H1N1 pandemic has necessitated the need to assess and evaluate if, and what role, EHFRs might play in a pandemic or outbreak situation. For ongoing and future pandemic and outbreak planning, it is essential to fully evaluate the practical implications of wide-scale use of reusable respirators in the healthcare setting.

3. CRITICAL REVIEW OF EXISTING LITERATURE

In the early 1990s, with the introduction of the OSHA policy requiring the use of high efficiency respiratory protection for healthcare workers in contact with active tuberculosis patients, some organizations utilized elastomeric half-facepiece respirators within the United States[6]. In the BC health authorities, EHFRs were not regularly used for protection against airborne infectious diseases, and were only used by staff when unable to fit available N95 FFR models. *We have been unable to find any recent published studies where the wide-scale use of reusable respirators has been assessed in the healthcare setting for pandemic or outbreak situations.*

Physiological Impact and Anxiety

Reberge et al evaluated the physiological impact of wearing an EHFR on health care workers over the course of one hour while the participants completed tasks to simulate usual work rates[7]. They found that EHFR imposed little additional physiological impact. They did however note the potential for carbon dioxide retention that may cause hypercapnia, symptoms of which include flushed skin, headache or lethargy in some users and suggested further investigation of this potential issue.

Wu et al compared anxiety levels caused while wearing an N95 FFR or an EHFR while performing a series of tasks in an experimental setting[8]. They found a significantly higher level of anxiety caused while wearing the EHFR compared to the N95 FFR. However, as noted by the authors, participants only wore the respirator for a short duration and with longer term use, anxiety levels may change.

Communication

An additional concern is the ability to effectively communicate while wearing an EHFR. Radonovich et al (2010) recently assessed speech intelligibility associated with various N95 FFRs and EHFRs worn by healthcare workers[9]. Their study involved 16 nurses. Both N95 FFRs and EHFRs were found to decrease speech intelligibility. The study included one N95 FFR model (3M 1860), and one EHFR model (3M 7500 series). The level of decreased speech intelligibility was fairly similar between the 3M 1860 and the 3M 7500 series. This study had a small number of subjects and did not include several of the N95 FFRs and EHFR models commonly used in BC healthcare, including the 3M 1860S (N95 FFR), 3M 1870 (N95 FFR), and 3M 6000 series (EHFR).

Stockpiling Respiratory Protection

Reusable respirators, such as an EHFR, represent the opportunity to decrease the quantity of pandemic stock. Prior to the H1N1 pandemic, Fraser Health Authority utilized an average of approximately 75,000 N95 FFRs per year – approximately 1,440 N95 FFRs per week. During the peak of the pandemic, over 19,000 N95 FFRs were being used per week, a 13x increase over baseline usage. Analysis has indicated that in order to meet this demand for a future pandemic, up to 500,000 N95 FFRs

may need to be stockpiled. To simply rotate through that level of stock based on normal usage would take almost 7 years – provided that the organization stays with the existing N95 FFR makes and models.

Cleaning and Disinfection

In November 2009, in response to the potential need to implement the use of EHFRs, occupational hygienists and infection control practitioners from each of the BC health authorities, under the coordination of the Provincial Infection Control Network of BC (PICNet), developed specific cleaning and disinfecting protocols for EHFRs (Appendix A). The practical application of these guidelines has not been evaluated in a real-world (or simulated) setting.

This study aimed to assess whether it is feasible to implement and use elastomeric respirators in several departments currently using N95 FFRs. Through observation and self-reports, the practicality of use was evaluated including information on storage, use (including user perceptions), cleaning and associated limitations. In addition, the impact of cleaning and disinfecting reusable respirators in Sterile Processing Departments (SPD) was evaluated.

4. OBJECTIVES

1. Assess and compare the acceptability of N95 filtering facepiece respirators (N95 FFRs) and elastomeric half-facepiece respirators (EHFRs) for use by nursing staff in three Intensive Care Units (ICUs). Factors considered included: comfort, communication, storage and confidence in fit and protection.

2. Assess the practical implications associated with EHFR usage in these three ICUs, including selection, storage between uses, and between shift storage.

3. Evaluate the process and impact of cleaning and disinfecting the EHFR in sterile processing departments. Aspects considered were impacts on workflow, workload and documentation needs.

4. Identify the logistics (including barriers and facilitating factors) to be addressed in a hospital when implementing the use of EHFR on a wide-scale basis, including equipment transport, storage and tracking; education and fit-testing; and communication/patient care impacts.

5. METHODOLOGY

The study was conducted at three large acute care hospitals within Fraser Health - Abbotsford Regional Hospital (ARH), Surrey Memorial Hospital (SMH) and Royal Columbian Hospital (RCH) in the Intensive Care Units and Sterile Processing Departments. These sites were selected because they have the largest ICU departments and thus more likely to have patients on airborne precautions and requiring them to wear respiratory protection. Nursing staff in the respective Intensive Care Units (ICUs) at these sites were requested to participate in this study. Nurses were selected as the subject group because of all the staff in the ICU (Respiratory technologists, Care aides, physicians etc) nurses would use respiratory protection most frequently.

Approval was obtained from the Fraser Health Research Ethics Board.

5.1. Respirator Selection

EHFR model selection was made based on two factors: (1) the respirator filters need to be washable, (2) the types of EHFR already used within BC health authorities. Only two of the EHFR models currently available have filters that are washable, the 3M 6000 and 3M 7500 series. Of these the 3M 6000 series is most commonly utilized across BC health authorities and therefore was selected for this study.

A supply of N95 FFRs was left in the department for non-nursing staff (e.g. respiratory therapy, physicians) that were not included in this study. In addition, any participant who felt that the use of the EHFR compromised specific patient care, based on professional judgment, was able to use an N95 FFR as per normal practice.

5.2. Initial Contact

As staff are most likely to read messages and/or requests for participation sent from their management Managers at each site were asked to circulate the Advertisement for this study (Appendix B) to their staff. This was done on November 21, 2011. The advertisement provided information on the purpose of the study, supporting and funding agencies, the study length, extent of staff participation required and

benefits of the study. Recruitment efforts were done via email and posting in department communication binders or notice boards.

5.3. Education and Training Session

The education and training sessions were scheduled at least two weeks after the initial contact was established in order to allow enough time for nurses on various shift schedules to be informed of the research project. The sessions were advertised as well as promoted by the department Managers, Clinical Nurse Educators and Patient Care Coordinators. The number of education days offered at ARH, SMH and RCH were 6, 13 and 11 respectively. Each day was divided into several 30 minute sessions during which one-on-one training was conducted. The time per session was limited in order to minimize impact of the research activities on department workload and patient care. All sessions were conducted in rooms located within or immediately adjacent to the participating departments. The following sections describe each component of the education and training sessions.

5.3.1. PowerPoint Presentation Part 1

Nurses from ARH, SMH and RCH, who volunteered to attend, were shown a PowerPoint® presentation (Appendix C) and then were provided with an opportunity to ask questions. Participants were advised about the features and capability of an EHFR that qualified it to be an alternative to the N95 FFR.

5.3.2. Consent

On completion of the PowerPoint presentation nurses were asked if they would participate in this study and those who agreed were asked to sign the Letter of Consent (Appendix D).

5.3.3. Speech Intelligibility on N95 FFR

Speech intelligibility was assessed using the Modified Rhyme Test (MRT), as mentioned in the NIOSH procedure TEB-CBRN-APR-STP-0313 (Appendix E). This test quantified the level of communication interference associated with the N95 FFR and EHFR worn by the ICU nurses. The speech intelligibility procedure, for this study, was similar to that of the study conducted by Radonovich et al in 2009. Two

modifications were made to the MRT due to resource and time limitations. All MRTs were conducted by the Research Assistant, who also acted as the listener. The modifications were:

- Only one listener, versus three, was used to record answers from the word lists as well as monitor the sound level meter. In order to minimize any impact on the research findings the Research Assistant checked the background noise prior to and midway through each education and training session.
- The MRT was not conducted without the respirator. The Research Assistant interacted with each subject for 10 to 15 minutes prior to conducting any speech intelligibility tests, thus allowing her to orient herself to subject's normal speech. Therefore it was assumed that intelligibility would be 100% when no respirator was worn.

<u>Procedure followed for the MRT was as follows:</u>

1. Room was set-up as per the NIOSH document (Appendix F)
2. The word lists were divided into 2 sets as they had different answer sheets.
3. The participant was asked to randomly choose a word list and the respective answer sheet was then gathered by the listener. The participant then donned an N95 FFR. Both the participant and listener then took their assigned positions to perform the MRT.

5.3.4. PowerPoint Presentation Part 2

Subjects were then oriented and trained on the EHFR. Specifically the donning, doffing and seal check procedures were reviewed and demonstrated. How and where to obtain an EHFR in their department was detailed and the requirement to use the respirator size to which they had been fit-tested was emphasized.

5.3.5. Fit-testing

Subjects were asked to select the N95 FFR to which they had been last fit-tested, in order to perform the N95 MRT. N95 FFR fit-testing was not conducted during these education and training sessions. This

decision was made because of time limitations and the fact that whether staff had been recently fit-tested on an N95 FFR was not imperative to the study research questions.

The subject was then fit-tested for an EHFR 3M Model 6000 series respirator. All three sizes of respirators (small, medium, and large) were available during the fit-test sessions. The 3M Bitter Bitrex qualitative fit-test procedure was utilized in accordance with the WorkSafeBC Occupational Health and Safety Regulation[10] and CSA Z94.4-02 (R2007) Selection, Use and Care of Respirators[11].

5.3.6. Speech Intelligibility on EHFR

The MRT was now repeated while the subject wore the EHFR. It was conducted using the same word list as used during the N95 FFR MRT. The answers for the EHFR speech intelligibility test were recorded on a new answer sheet.

5.3.7. Storage, Cleaning and Disinfection of the EHFR

Departments were provided with three times as many EHFR as staff that worked during each shift to ensure adequate supplies were always available across both work shifts. This took into account the anticipated 24 hour reprocessing turnaround time for SPD. The EHFRs and filters were stored in separate covered bins and additional bins were provided for dirty EHFRs and used filters. The cleaning procedures implemented were as per '*The Recommendations for the Use of Reusable Half-Facepiece Elastomeric Respirators in Healthcare Settings*' document developed by PICNet. The training also included department specific details on equipment storage and handling. Procedures reviewed were how to:

- properly label & store respirators during their shifts.
- clean the EHFR during their shifts.
- handle the EHFR at the end of shift their shifts.

The EHFR filters were to be wiped and returned to the designated filter supply bin located in the soiled utility room. The respirators were to be left in a separate container, within the soiled utility room, from which they would be sent to the SPD for cleaning & disinfection between shifts.

5.4. Data Collection

5.4.1. Speech Intelligibility Test

Analysis of individual speech intelligibility was conducted based on the NIOSH procedure TEB-CBRN-APR-STP-0313, where an Overall Performance Rating of 70% was utilized to determine whether a respirator allows for acceptable speech intelligibility[12]. The answer sheet for word lists 7A – 12A was requested and received from NIOSH, as it was not readily available in the online procedure documentation[13].

5.4.2. Surveys

The survey tool (Appendix G and H) were utilized to assess the overall staff perception associated with usage of N95 FFRs and EHFRs respectively as well as changes in staff perception over time. A personal anonymous code (PAC) was used to ensure the confidentiality of results while allowing the research team to compare individuals' survey responses over time. This 5 character PAC was created by requesting the subjects to answer the following questions at the beginning of each survey:

First letter of your father's last name	
First letter of your mother's first name	
How many letters in your first name (enter 9 if >9)	
Last number of your year of birth	
First letter of the town of your birth	

The survey was offered, via an online link to Survey Monkey and paper copies, four times through the course of this six-month study. The intervals were 2 weeks, 1 month, 3 months and 6 months after the study was launched.

All survey data was transferred into an Excel datasheet and analyzed using Statistical Product and Service Solutions (SPSS), a statistical software program. The data analysis methodology is described in

section 5.5. Unfortunately the control data had to be excluded from the research due to errors made in documentation of the subjects PACs.

5.4.3. Audits

5.4.3.1 ICU Audits

Audits were conducted by the Research Assistant, in each ICU, each time a survey was distributed. The audits were conducted to assess EHFR and filter availability (adequate numbers, consistency of storage location, appropriate storage etc), usage of the EHFRs and also whether used/dirty EHFR were being sent to SPD for reprocessing. This data was documented by the Research Assistant using the Observation Tool (Appendix I) and then tabulated for each audit.

5.4.3.2. SPD Audits

SPD Audits were conducted by the Research Assistant, each time a survey was distributed to ICU nurses. A total of 4 audits were conducted at each site. Each audit was completed in consultation with the SPD Co-ordinator. The purpose of the audits was to:

- evaluate the process and impact of cleaning and disinfecting the EHFR on the SPD.
- track the time and resources required for collecting soiled EHFRs from the ICU cleaning/disinfecting in SPD and returning clean EHFRs to the ICU.
- identify resources associated with cleaning/disinfecting EHFRs in SPD.
- ensure there is no adverse impact of the cleaning/disinfection process on the EHFR or its components.

Two logs for tracking EHFR SPD drop-off and pick-up were provided to the SPD departments at the commencement of the study (Appendices J & K). Use of these logs was reviewed during each audit. Findings were documented by the Research Assistant and tabulated for each audit.

5.5. Data Analysis

With the survey perception questions serving as dependent variables, site, work experience and reported frequency of respirator use were used as the independent variables. Open-ended questions

were reviewed to identify trends with respect to factors or situations affecting staff's ability to use the reusable respirators and the frequency of these occurrences.

We used SPSS® Statistics 19 to analyze the data for this report. We report means, medians and standard deviations for continuous variables and proportions for categorical variables. Comparisons within subjects were completed using paired t-test for the Speech data and Wilcoxon Signed Ranks Test for the survey data.

6. RESEARCH FINDINGS

A total of 107 nurses (30 from ARH, 27 from RCH and 50 from SMH) consented to participate as subjects. The demographics of the subjects were obtained from the survey data. Of the subjects that responded (N=88), 94% were females, which is representative of the ICU nurse population. There was a broad range of years of experience amongst the subject population, most worked full-time on 12-hour rotating shifts. Table I depicts the demographics of the study sample.

Table I: Demographics of Subject Population (N = 88)

Gender	**RCH**	**ARH**	**SMH**	**All sites N= 88**
	n=32	**n=28**	**n=28**	**n (%)**
Female	13	7	12	32 (94)
Male	0	2	0	2 (6)
Employment Status				
Full-time	9	9	10	28 (80.0)
Part-time	0	3	2	5 (14.3)
Casual	0	2	0	2 (5.70)
Shiftwork				
Day	5	2	2	9 (26.5)
Night	1	0	0	1 (2.90)
Rotate	7	7	10	24 (70.6)
Years of experience	**N=19**	**N=11**	**N=5**	**N= 35**
Range	3 – 40	4 - 32	1 -17	1 - 40
Mean	14.89	11.7	7.20	12.8
Median	14	10	8	10
Mode	4	10	-	4
Standard Deviation	10.88	7.9	6.18	9.6

6.1. Assess and compare the acceptability of N95 filtering facepiece respirators (N95 FFRs) and elastomeric half-facepiece respirators (EHFRs) for use by nursing staff in three Intensive Care Units (ICUs)

Speech Intelligibility Results

During speech intelligibility testing, subjects were asked to select the N95 FFR to which they had been previously fit-tested. Although available N95 FFR models were the 3M 1860, 1860S or 1870, all subjects selected the 3M 1860 or 1860S. The MRT scores for the N95 FFR and EHFR were analyzed using the paired t-test, which shows a significant difference between the two respirators. The NIOSH Speech Intelligibility test has set the minimum criteria as 70% for communication requirement. Subjects had higher scores for the N95 FFR (mean = 92.58, standard deviation = 5.02) than for the EHFR (mean = 86.60, standard deviation = 7.24), $t(106) = 10.42$, $p < .001$, effect size=.7. The effect size ($d = .7$) was found to be greater than Cohen's (1988) convention for a large effect ($d = .5$). As was found in the Radonovich study, results from our study show that the speech intelligibility was lower when wearing the EHFR **compared with** the average intelligibility of the N95 FFR (OR = 0.185, 95% CI [0.0976, 0.3523])[9].The results were consistent when data from each hospital was analyzed separately. See Appendix L for MRT scores of all subjects.

EHFR Survey Results

A total of 88 out of the 107 consenting subjects responded to at least 1 out of the 4 surveys issued during this study. The number of subjects that responded to 2, 3 or 4 surveys was 17, 8 and 2 respectively. Survey response by frequency and percentage, based on the total number of subjects who responded to each survey is reported in Table II.

Table II: Survey response rate for study population

	Subjects n (%)
Survey 1	27 (31)
Survey 2	31 (35)
Survey 3	29 (33)
Survey 4	30 (34)

To allow for average response calculations and comparisons between subject responses the survey response categories (Strongly Disagree through to Strongly Agree) were assigned numerical values as follows: Strongly Disagree = 1; Disagree = 2; Neutral = 3; Agree = 4 and Strongly Agree = 5.

In order to compare perception changes over time, the survey responses needed to be grouped due to low response rates. Survey scores were compared between the average scores for surveys 1 and 2 and the average scores for surveys 3 and 4. This grouping was considered on the basis that surveys 1 and 2 were offered within the first month of the study period, while surveys 3 and 4 represented the latter half.

In order to control for previous experience with the use of an EHFR, subjects were asked whether they had worn a reusable respirator prior to the commencement of this study. We used Wilcoxon test for those who responded to the question, 15 indicated they had worn an EHFR prior to the study. For the group who did not don the respirator prior to the study, there were significant differences over time for interference with communication and alarm. The trend was that nurses scored the two variables lower at survey 3 and 4 compared with survey 1 and 2, however this difference does not appear to be a substantial barrier to relying on EHFRs during a pandemic or outbreak situation. No differences were observed among nurses who reported donning the respirator prior to the study (See Table III for results from Wilcoxon Ranks Test).

Data gathered from the surveys show that 21 subjects had reported using the EHFR at least once during the study. Of those, 20 subjects indicated they had worn an EHFR 1-10 times and one subject had worn an EHFR 21-50 times. For the purpose of analysis, the mean and standard deviation for survey questions related to availability, comfort and communication with an EHFR was calculated based on average of responses only. Since the population was not normally distributed, the data was further analyzed using the Wilcoxon Signed Ranks test. Analysis with the test indicated that there was significant difference between the donned versus not donned during the study groups, for the questions regarding communication interference. For surveys 3 and 4, interference with communication scores were

significantly lower (median = 2) compared with the average scores for surveys 1 and 2 (median = 2.5), z = -2.239, $p < .05$, but only for those nurses who donned the respirator during the study. The response trends for those who had donned an EHFR during the study versus those who did not are provided in Table IV.

6.2. Assess the practical implications associated with EHFR usage in these three ICUs, including selection, storage between uses, and between shift storage

During the surveys, subjects were asked to rate how easy it was to store and clean an EHFR in between uses on a scale of 1 to 5, ranging from strongly disagree to strongly agree. Although survey responses were neutral to positive (rated 3 or higher), as depicted in Tables III and IV, the ICU audits identified that storing the EHFR, in between uses, can be challenging as there is very limited counter space and storage at the nurse's station outside the patient room. Due to similar reasons, it was challenging to identify and dedicate space for storing respirator supplies in both the clean supplies and soiled utility rooms. The audits identified that the storage location within the clean supply rooms actually changed during the study. Other issues identified during the ICU Audits were:

- Staff concerns about the cleaning procedure used by sterile processing. Namely with respect to how the fabric straps were being effectively cleaned and disinfected.
- Staff leaving filters on dirty respirators at the end of their shift instead of wiping the filters, at the end of their shift, and returning them to the 'Clean filters container' within the soiled utility room. The Research Assistant discussed this practice error with the Clinical Nurse Educators and Patient Care Coordinators, who would then reinforce proper reprocessing practices. Nonetheless, the research assistant still found filters on EHFRs in the 'Dirty respirator container' within the soiled utility room.
- Porters or Care Aides were not trained to check that filters had been removed from the respirators prior to delivery to SPD.

- Porters or Care Aides were not regularly moving the filters stored in the clean filter bin within the soiled utility room back into the filter supply container kept in the clean supplies room.
- Dirty Respirators were not brought to SPD for processing on a regular basis, as identified during audits with the Patient Care Coordinator.

On the surveys, 16 subjects noted that they chose not to use an EHFR. Themes that appeared from their responses included issues related to (1) comfort, (2) availability, (3) communication interference and (4) cleaning protocols. With respect to comfort subjects noted EHFRs were uncomfortable to wear with glasses, left impression on their nose and caused headaches because of pressure on their sinuses. This is consistent with complaints documented in other research on N95 FFR and EHFR use which included facial heat, pain, and pressure[14, 15, 16, 17]. Regarding availability subjects identified challenges in obtaining an EHFR when doing break relief, having to re-enter the patient room without time to complete the wipe of the EHFR and others noted that since there was an adequate supply of N95 FFRs they did not have to use an EHFR. Several subjects indicated that their colleagues could not hear them when they wore an EHFR. Finally a few staff indicated that they were concerned with the cleaning protocols specifically that the fabric straps would get contaminated during removal and could not be cleaned with an alcohol wipe during their shift.

6.3. Evaluate the process and impact of cleaning and disinfecting the EHFR in sterile processing departments

The cleaning and disinfecting procedure for EHFRs was based on the PICNet document as well as 3M's 'Guidelines for cleaning, sanitizing and disinfecting Reusable Respirators and Powered Air Purifying Respirators (PAPRs)'. See Appendix M for 3M guidelines.

Prior to implementation of EHFR use at the sites, Time-in-Motion Studies were conducted at each site in order to determine how the departments could implement the required cleaning and disinfection procedures. The respirators had to be soaked in the cleaning solution, then scrubbed and rinsed in running lukewarm water. This procedure was then repeated with the disinfectant solution before the

respirators were air dried. According to the 3M guidelines the EHFRs cannot withstand temperatures greater than 120°F and therefore the SPD driers (140°F temperature) could not be utilized. Both the soaking and drying practices required for reprocessing the EHFRs differ from how the majority of other medical equipment is processed in SPD. Subsequently the need for additional supplies including soaking/cleaning bins, timers and brushes was identified. In addition, determinations of how much detergent or disinfectant needed to be used based on the size of the soaking containers and dilution requirements had to be established. These values varied from one site to another because different sized containers had to be used based on the department layout.

During the time in motion study, it was noticed that the respirators did not submerge but instead would float in the cleaning and disinfecting solutions. In order to address this issue, it was decided to follow the recommended cleaning and disinfection procedures; however do this for each side of the respirator. Therefore for cleaning and disinfecting it was soaked for 2 minutes and 10 minutes per side respectively. This meant the cleaning procedure time was double what was originally anticipated. The SPD Coordinators indicated that the turnaround time (to the ICUs) for the EHFRs remained 24 hours as originally determined. Site specific step by step procedures were then developed and posted for SPD staff to refer to as needed. These procedures included instructions on the use of the drop-off and pick-up logs. These logs were to be maintained to document how many respirators were received for cleaning as well as the number returned to the unit. See Appendix N for site specific procedures and the log forms. The following observations were made regarding the impact on the sterile processing department:

- SPD would not pick-up dirty respirators from the unit as they were concerned about cross contamination from blood and body fluids that might cover other equipment deposited in the existing bins that were picked up by SPD. SPD asked that ICU deliver the respirators to SPD instead. As a result, the ICUs had to add this task to Care Aide or Porter responsibilities. But due to workload and staff shortages, this new task was not performed on a regular basis.

- Two of the three SPDs would not deliver the clean EHFRs back to the unit due to short staffing on their end and thus this task was also added to Care Aide or Porter responsibilities.
- EHFRs delivered or dropped off at SPD, would not be labeled with the department name and would end up sitting on the shelf for a few days until claimed.
- Drop-off and pick-up logs were not being utilized by two of the SPDs and thus little data on EHFR use and turnaround time was gathered from the audits. The research assistant brought this to the attention of the SPD Coordinator. But despite ongoing reinforcement by the Coordinator, SPD staff failed to document this information.

SPDs at all three sites had different ways of operating. ARH was the only site that had an existing equipment tracking system in place into which they incorporated tracking of EHFR reprocessing. SPD staff at ARH would document the number of EHFRs dropped off for processing and have the ICU staff initial the drop-off log sheet. Similarly, they would have an ICU staff initial the pick-up log sheet when processed EHFRs were returned to the department. This way they could track the turnaround time for the EHFRs being processed. Also, the logs included an area for documenting damage to equipment during processing as well as equipment that has gone missing.

The original intent was to evaluate the impact of the cleaning and disinfection protocol on the EHFRs, over time. However, due to low usage we are unable to comment on whether the cleaning regiment would cause any deterioration to the EHFRs with more frequent reprocessing.

6.4. Identify the logistics (including barriers and facilitating factors) to be addressed in a hospital when implementing the use of EHFR on a wide-scale basis

Findings from the first three objectives were used to determine the practical implications of using EHFRs including logistics related to equipment storage and reprocessing, education and fit-test requirements, as well as communication and patient care impacts.

Equipment storage and reprocessing posed several challenges in setting up the research activities and appropriately maintaining supplies. As the N95 FFRs were not being completely replaced with EHFRs

additional storage space for the EHFRs and filters had to be identified. It was imperative to have assistance from a department representative (Care Aide or Supervisor) to determine an appropriate location. Nonetheless, clean supplies tended to move around in the clean supplies room and not necessarily kept adjacent to each other (EHFRs, clean filters & Ziploc bags for storage during shift use), which made it more challenging for subjects to grab their supplies at the start of their shift. In order to facilitate use of EHFR it is important to designate storage areas that will remain consistent throughout the usage period, for the clean EHFRs and filters, as well as the dirty EHFRs. This will minimize staff confusion, frustration and/or choosing to use alternate protection.

Existing procedures did not include a process for transporting EHFRs between the ICU and SPD departments therefore a system including personnel resources has to be established. This requires discussion with the ICU and SPD managers and a commitment for resourcing the equipment delivery & pick-up activities. These process factors indicate that additional supervision and/or intervention is required to ensure EHFR use and storage instructions are being followed. For example the ICU audits found that staff continued to leave the filters on the respirators, in the dirty supplies bin, at the end of the day – someone would need to be designated to monitor this on a regular basis.

Wherever possible it is recommended that storage and reprocessing procedures be embedded into existing systems. This includes storing EHFRs on carts in the unit where N95 FFRs are currently being stocked and using existing equipment tracking systems instead of trying to implement new ones. This could alleviate the scenarios identified by some of the subjects regarding instances where the nurse was in the process of cleaning their respirator when they had to go back into the patient room. As there was no additional EHFR readily available (extra supplies were stored in the clean supplies room and not on the unit supply carts) the nurse chose to use an N95 FFR to re-enter the patient room. ICU Audits identified that dirty EHFRs were not being sent down to SPD on a daily basis due to lack of coverage by Porters or Care Aides and because this was a new process/task. Also, SPD staff did not record the number of EHFRs received for processing or delivered on completion. This impacted the ability to track

processing/turnover time and with increased number of departments potentially using EHFRs during a pandemic the impact of poor tracking could significantly affect respirator availability.

Education & Fit-testing

As EHFRs are reusable, their use requires that cleaning, reprocessing and equipment maintenance activities be conducted. Subsequently the education and training portion of fit-testing sessions is more time consuming, requiring an additional 10 to 15 minutes to complete. In the event of a pandemic or need to implement EHFR, group sessions could be coordinated. In this context, education and fit-testing appears to be a barrier, however other research suggests education and training programs will help users better understand the need to use available protective measures[18].

Consideration should be made to the fact that it was challenging for the ICU nurses on shift to obtain coverage for their patient care activities so that they could attend the education and fit-test sessions. Even though funding was available for ICU nurse backfill there remained significant challenges with (a) lack of additional specialized ICU nurse availability to provide coverage and (b) difficulty to ensure the nurse covering the subject was provided with all necessary patient care history. In addition it will be imperative to have casual and part-time staff trained and fit-tested as well. This will require targeted planning as due to limited shifts worked it was difficult to recruit them to participate as subjects. This suggests that should EHFR use be part of pandemic planning education and training on EHFR use and/or fit-testing be conducted well in advance of a pandemic.

Communication & Patient Care Impacts

The MRT scores from the EHFRs in this research were above the minimum communication requirements as prescribed by NIOSH and similar to those found in the Radonovich study[9]. However the perception of communication interference was evident in the survey responses and has also been identified in previous studies[9, 19]. The Harber et al study evaluated the impact of EHFRs and N95 FFRs, on subjective tolerance, in a variety of work type activities and in the laboratory setting and reported an intermediate impact with interference of speech[19].

In order to facilitate use of the EHFRs staff should be educated regarding why alternative respirators are being implemented, what research has been conducted to date on use of EHFRs in healthcare settings and specifically address concerns about communication and/or alarming patients. The issue of alarming patients could be of higher significance in departments such as emergency and pediatrics and should be considered when planning for EHFR usage.

Subjects that normally wear prescription glasses commented that they had a difficult time wearing EHFRs because the glasses did not sit well on the EHFR nosepiece and affected their visual acuity during patient care. Whether alternate EHFR styles could address this issue should be further explored.

Summary of Learnings

- Speech Intelligibility scores, showed that subjects had significantly higher scores for the N95 FFR. However both exceeded the minimum communication criteria.
- There are challenges with implementation in allocating dedicated storage space for clean and dirty respirators and incorrect handling of EHFRs at the end of shifts.
- Staff chose not to use an EHFR due to comfort, availability, communication interference and cleaning protocols.
- EHFR cleaning and disinfection process differ from common practice in SPD. It was more time consuming than originally anticipated and there was no consistent equipment transport systems within each site.
- Equipment storage both during and between use posed several challenges.
- Procedures and personnel resources for transporting EHFRs within the site must be established.

Limitations

One of the limitations of this study was that our subject enrollment and survey response rates were lower than anticipated. This could be the result of several factors. Firstly, staff shortages and unexpected events in the ICUs which limited shift coverage and thereby staff ability to attend education and training sessions. It was difficult to target casual and part-time staff for this study, as they work very

limited shifts. A small percentage of the staff at all sites was either off on maternity or medical leave and therefore could also not be targeted. No incentives were offered to participants to enroll or to continue participating in the consecutive surveys. If budget had allowed the ability to offer participants an incentive it may have resulted in higher participation rates at both the initial intake and ongoing during the study period. Due to resource limitations only nursing staff were eligible to participate, while other department staff such as the Respiratory Therapists and Care Aides, were excluded from this study. In hindsight it may have been beneficial to include them to allow for a larger potential subject pool. Many of these staff indicated they would have liked to have been able to participate. The time over which the four surveys were distributed was scheduled too close together within the 6 month study period. This led to survey 1 and 2 being distributed back to back and staff may have thought it was the same survey or the process too onerous and disregarded the second participation request. Increasing the length of future studies, would provide more opportunity for the participants to wear the EHFR, increase the periods between the survey distributions and provide their opinions as well as increase potential for detecting changes of perception over time.

7. Implications for Future Research on Occupational Health

Findings from this study suggest that further research to evaluate some of the recommended procedures to be used in a wide-scale implementation of EHFRs would be beneficial. This includes evaluating the effectiveness of the recommended EHFR cleaning procedures, which would aid in improving staff confidence in the protocols and comfort in using reusable respirators. Evaluating other EHFR models to determine whether acceptability and/or speech intelligibility differs between EHFR models. Expand this research to include different user groups such as Respiratory Technologists and Physicians. Further evaluating potential barriers and facilitators with respect to implementing the use of EHFRS in relation to logistics and stockpiling, respirator turnover and impacts on the warehouse. Evaluating different EHFR cleaning methodologies with the manufacturer with goal of finding an effective cleaning protocol that is less time consuming.

8. APPLICATION FOR POLICY AND PREVENTION

The results of this study will be of interest to numerous stakeholders within the healthcare industry and Fraser Health specifically including Acute care managers, directors and frontline staff, EHFR manufacturers, logistics coordinators and warehousing leadership, Workplace Health and Infection Control.

Results from the MRT indicate that speech intelligibility was within acceptable ranges for both N95 and EHFR. Therefore based on Speech Intelligibility an EHFR could be used as an effective alternative during outbreak or pandemic situations. However the survey and audit findings indicate that some management factors need to be evaluated and addressed prior to any implementation of EHFRs.

A full evaluation of the impact on SPD needs to be completed for each site. The impact of EHFR implementation will vary by site and can be affected by the physical size of the department, layout and existing infrastructure. The evaluation should also include a review of the existing equipment tracking systems across the organization and determination of the best system for tracking EHFR reprocessing.

Provision for additional resources needs to be made. These resources include equipment for cleaning EHFRs in SPD, potential increased SPD staffing needs, as well as increased supervision in EHFR user departments (e.g. ICU) and SPDs. This is necessary to ensure equipment is being handled and transported appropriately within each site, ultimately ensuring adequate supplies are always available.

Based on the study findings, consideration will be made for inclusion of EHFRs in the Fraser Health pandemic stockpile. This will be included as an item for discussion during the next Fraser Health Pandemic Plan update and revision. As the Fraser Health Pandemic Plan was drafted by a multidisciplinary working group it will also be an appropriate venue for discussions regarding the increased resources needed for effective implementation of EHFRs.

9. KNOWLEDGE TRANSLATION AND EXCHANGE

There are several groups potentially affected by the outcomes of this research.

Front Line Nursing Staff in ICUs and SPDs – A brief summary report will be provided to these staff via e-mail and through department communication binders. Also, survey and audit findings and overall recommendations will be forwarded to Fraser Health Executive and other policy makers.

Joint Occupational Safety & Health Committees – A copy of this report and a summary presentation will be made to all JOSH Committees across Fraser Health at the Fraser Health JOSH Committee Conference.

Health Care Safety Professionals Association of British Columbia (HCSPA) – The principal investigator and research assistant will provide an overview to the HCSPA. This will allow each member to take and apply the findings at each of their sites.

Policy Makers – A copy of this report will be sent to several key organizations involved with policy decisions, such as the Health Shared Services of BC, Ministry of Health, Directors of BC Health Authority Workplace Health departments and British Columbia Nurses Union.

WorkSafeBC – A copy of this report will be shared with the Health Care officers in the Health Care Industry Labor Services department.

Ministry of Health Services (MOH) and British Columbia Centre for Disease Control (BCCDC) – Results of the study will be shared with the MOH and BCCDC, as they can utilize the results of the findings to assist in their pandemic planning efforts for the province.

Results of this study will also be shared with the Community and Hospital Infection Control Association of BC (CHICA BC) and The Provincial Infection Control Network (PICNet).

Peer-Reviewed Publications - Results of the study will be submitted to a peer reviewed scientific publication e.g. *Journal of Occupational and Environmental Hygiene* (official journal of the American Industrial Hygiene Association and the American Conference of Governmental Industrial Hygienists), American Journal of Infection Control and/or the Journal of Infectious Diseases.

Presentations - A submission to present the research findings will be made for the American Industrial Hygiene Conference and Exposition (AIHCe) 2014.

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Table III

Grouped survey response means for donned EHFR prior to study and not donned prior to the study (significance from Wilcoxon Ranks Test, p < 0.05)

	Donned prior to study (n = 15)			Did not don prior to study (n = 73)		
	Median (Mean)		p-value	Median (Mean)		p-value
	Survey 1 & 2	Survey 3 & 4		Survey 1 & 2	Survey 3 & 4	
A reusable respirator is readily available for me to use at the beginning of my shift.	3.50 (3.50)	4.00 (3.80)	0.317	4.00 (3.88)	4.00 (3.85)	0.931
The process of wiping the respirator DURING the shift after exiting the isolation room is not onerous.	3.00 (2.89)	3.00 (3.33)	0.317	3.00 (2.96)	3.00 (2.90)	0.651
My reusable respirator can be easily stored during my shift.	3.00 (3.22)	3.00 (3.22)	0.564	3.00 (3.50)	3.50 (3.43)	0.589
The reusable respirator is comfortable to wear.	3.00 (2.78)	3.00 (3.00)	1.000	3.00 (2.68)	3.00 (2.75)	0.958
The reusable respirator does not interfere with my ability to provide patient care.	3.00 (2.89)	3.00 (2.83)	0.180	3.00 (2.90)	3.00 (2.85)	0.717
The reusable respirator does not interfere with the ability of coworkers, patients, or visitors, to understand what I am saying.	3.00 (2.67)	3.00 (2.22)	0.180	3.00 (2.63)	3.00 (2.46)	0.044
The use of the reusable respirator does not alarm or concern patients.	3.00 (2.89)	3.00 (3.00)	1.000	3.00 (2.99)	3.00 (2.85)	0.023
I feel that I know enough to wear the elastomeric half-facepiece respirator (EHFR) safely.	4.00 (3.80)	4.00 (3.56)	1.000	3.00 (3.32)	3.00 (3.17)	0.501
I feel the EHFR fits adequately.	3.00 (3.50)	4.00 (3.56)	0.317	3.00 (3.35)	3.00 (3.28)	0.944
I feel the seal check can adequately identify it is fitting me properly.	4.00 (3.78)	4.00 (3.67)	1.000	3.50 (3.42)	3.00 (3.32)	0.892
I feel confident that the respirator fits me properly.	3.00 (3.45)	4.00 (3.56)	0.317	3.00 (3.31)	3.00 (3.30)	0.796
I feel this respirator offers me more protection than I need.	3.00 (2.94)	3.00 (3.11)	0.317	3.00 (3.13)	3.00 (3.04)	0.713

Table IV

Grouped survey response means for donned EHFR during the study and not donned during the study (significance from Wilcoxon Ranks Test, $p < 0.05$)

	Donned during study			Did not don during study		
	Median (Mean)		p-value	Median (Mean)		p-value
	Survey 1 & 2	Survey 3 & 4		Survey 1 & 2	Survey 3 & 4	
A reusable respirator is readily available for me to use at the beginning of my shift.	4.00 (3.94)	4.00 (4.13)	1.000	4.00 (3.71)	4.00 (3.67)	1.00
The process of wiping the respirator DURING the shift after exiting the isolation room is not onerous.	3.00 (2.88)	3.00 (2.84)	1.000	3.00 (2.98)	3.00 (3.06)	0.222
My reusable respirator can be easily stored during my shift.	4.00 (3.44)	3.5 (3.39)	0.851	3.00 (3.45)	3.00 (3.38)	1.000
The reusable respirator is comfortable to wear.	3.00 (2.71)	3.00 (2.45)	0.524	3.00 (2.70)	3.00 (2.97)	0.317
The reusable respirator does not interfere with my ability to provide patient care.	3.00 (2.97)	2.50 (2.68)	0.276	3.00 (2.85)	3.00 (2.95)	0.102
The reusable respirator does not interfere with the ability of coworkers, patients, or visitors, to understand what I am saying.	2.50 (2.53)	2.00 (1.92)	0.025	3.00 (2.71)	3.00 (2.73)	0.317
The use of the reusable respirator does not alarm or concern patients.	3.00 (3.06)	3.00 (2.71)	0.059	3.00 (2.91)	3.00 (2.97)	0.180
I feel that I know enough to wear the elastomeric half-facepiece respirator (EHFR) safely.	4.00 (3.65)	4.00 (3.53)	0.877	3.00 (3.30)	3.00 (3.02)	0.216
I feel the EHFR fits adequately.	4.00 (3.65)	4.00 (3.42)	0.535	3.00 (3.22)	3.00 (3.23)	0.141
I feel the seal check can adequately identify it is fitting me properly.	4.00 (3.62)	4.00 (3.58)	0.356	3.00 (3.41)	3.00 (3.26)	0.258
I feel confident that the respirator fits me properly.	3.00 (3.44)	4.00 (3.47)	0.809	3.00 (3.28)	3.00 (3.26)	0.655
I feel this respirator offers me more protection than I need.	3.00 (3.09)	3.00 (2.97)	0.194	3.00 (3.093)	3.00 (3.10)	0.131

Appendix A

Recommendations for the Use of Reusable Half-Facepiece Elastomeric Respirators in Healthcare Settings

Recommendations for the Use of Reusable Half-Facepiece Elastomeric Respirators in Healthcare Settings

November 19, 2009

Preamble

During the current pandemic H1N1 (pH1N1) outbreak, the Public Health Agency of Canada (PHAC) has recommended that healthcare providers tailor their use of N95 respirators based on a point of care risk assessment while providing care to patients suspected or confirmed to have pH1N1. An N95 respirator should be worn if the healthcare provider is likely to be exposed to aerosol generating medical procedures. While it remains a priority to ensure that N95 respirators are used appropriately by healthcare providers, some Health Authorities are already experiencing shortages of these respirators. A contingency plan for the use of half-facepiece reusable elastomeric respirators as alternative protection is required in the event that a disposable N95 respirator is not available or an adequate fit cannot be obtained.

The Provincial Infection Control Network (PICNet) facilitated a collaborative discussion between Occupational Health and Safety and Infection Prevention and Control representatives from each of the Health Authorities in British Columbia to address this. This group reached consensus on a process for the use, cleaning and disinfection of reusable half-facepiece respirators. This contingency plan is reliant on well defined preparatory actions within each Health Authority. These include:

1) As much as possible, restricting the use half-facepiece respirators to specific units within the facility. The group recommends choosing intensive care units, operating rooms and nursing units with negative pressure rooms. (Note: other units providing care for patients with suspected or confirmed pH1N1 should follow point of care risk assessments and use disposable N95 respirators as appropriate).
2) Working with existing Sterile Processing Departments (SPD) to develop a process for the reprocessing of half-facepiece respirators either in SPD or on the unit.
3) Ensuring that individuals responsible for cleaning and reprocessing half-facepiece respirators are properly trained to do so.
4) Ensuring site specific processes for cleaning, storage and quality assurance are established and followed.

The processes listed below are for discussion purposes within each Health Authority and can be used as a template on any unit where the use of reusable half-facepiece respirators is deemed appropriate. These processes comply with the Canadian Standard Association recommended procedures for cleaning and sanitizing reusable elastomeric respirators.

Participants in this discussion group were:

Fraser Health: Quinn Danyluk Kathleen McWhinney, Petra Welsh
Interior Health: Stacey Grant
Northern Health: Deanna Hembroff, Jennifer Hogan
Occupational Health and Safety Agency for Healthcare: Nena Benic
Provincial Health Services Authority: Robyn Hunter, Alison Jones
Provincial Infection Control Network: Joanne Archer, Bruce Gamage
Providence Health Care: Howard Green
Vancouver Coastal Health: Graham Rhodes
Vancouver Island Health Authority: Dan Costello, Andrea Griffiths

Elastomeric Respirators: Daily Use

Applicability: Half-Facepiece Elastomeric Respirator issued to Healthcare worker for individual, full-day use.

Respirators are not to be shared between individuals during a shift.

Whether the respirator is permanently assigned to an individual or whether the respirator is only shared between shifts, the respirator must undergo the End of Day Cleaning and Disinfection Process.

Individuals must receive annual education, training, and fit-testing in order to use any of the respirators listed in this document.

Manufacturer	3M	North
Make	Elastomeric Respirator	Elastomeric Respirator
Model	6000, 7500 Series	7700 Series
Filter	P100 (7093)	P100 (7580P100)

Scope: Use of a fit-tested Half-Facepiece Elastomeric Respirator with P100 filters for provision of care to a patient where an N95 respirator is required but is either not available or an adequate fit cannot be obtained.

Process	Steps
1. Inspection of elastomeric respirator prior to donning	1.1 Ensure respirator components are dry 1.2 Label respirator on elastic straps with your name (do not write on the strap or apply tape) 1.3 Ensure filter gaskets are properly seated and in good condition 1.4 Ensure respirator filters are within expiry date and properly attached to respirator ▪ If new filter, document expiry date (1 year expiry) on back of filter with permanent marker ▪ If marked expiry date is fading, reapply with a permanent marker 1.6 Check face piece for cracks, tears and dirt 1.7 Check facial seal area for distortion 1.8 Examine inhalation and exhalation valves for signs of distortion, cracking, or tearing 1.9 Check head straps are intact and have good elasticity 1.10 Examine all parts for signs of cracking or fatiguing 1.11 If signs of damage, refer to your organization's process for removing the respirator from service
2. Donning personal protective equipment (PPE) before entering room or in anteroom	2.1 Perform hand hygiene 2.2 Apply gown (as per routine practices) 2.3 Apply elastomeric respirator and perform user seal check in accordance with your organization's *Instructions for Fitting: Elastomeric Half-Facepiece Style Respirator* 2.4 Apply protective eyewear 2.5 Apply new pair gloves (gloves to cover the sleeve cuff of gown if is worn)
3. Doffing PPE before exiting patient room	3.1 Remove gloves and gown 3.2 Perform hand hygiene
4. Exit room to hallway (or anteroom if provided)	4.1 Open door with paper towel, or 4.2 Open door and perform hand hygiene
5. Doffing PPE in hallway or anteroom	5.1 Remove eye protection (handle using side straps) 5.2 Perform hand hygiene
6. Quick cleaning of elastomeric respirator between patients, for single day usage	6.1 Don new pair of non-sterile gloves 6.2 Remove elastomeric respirator (handle using side straps) 6.3 Wipe interior and exterior of respirator and filters using only 70% alcohol wipe or *3M Respirator Cleaning Wipe* 6.4 Place respirator in clean area to dry and store between uses 6.5 If last use of the day – remove name label and put in appropriate bin for cleaning and disinfection 6.6 Remove gloves 6.7 Perform hand hygiene

Elastomeric Respirators: End of Day Cleaning and Disinfection

Applicability: Half-Facepiece Elastomeric Respirator issued to healthcare worker for individual full-day use

Manufacturer	3M	North
Make	Half-face piece Respirator	Half-face piece Respirator
Model	6000, 7500 Series	7700 Series
Filter	P100 (7093)	P100 (7580P100)

Scope: The cleaning and disinfection of respirators (for use by different staff members) should be done in an area dedicated to such activities, either in a separate department or separate area. The staff following this next section must be appropriately trained in equipment cleaning. The manufacturers' guidelines should accompany this document.

Process	Steps
1. Cleaning of elastomeric respirators	1.1 Don appropriate PPE for cleaning and disinfection ▪ latex, nitrile or chemical resistant gloves ▪ water resistant gown ▪ full face shield 1.2 Remove the P100 filters and wipe exterior surface of filters with 70% alcohol wipe or *3M Respirator Cleaning Wipe* 1.3 Allow filters to dry and store in appropriate container 1.4 Prepare cleaning solution according to instructions on container of neutral detergent (e.g. Measure 5 ml of *Neutrawash* for each 1 litre of warm water – mix) 1.5 Completely immerse respirator in neutral detergent solution ▪ Time: 2 mins ▪ Temperature: lukewarm 1.6 Scrub crevices under water with brushes, swabs, or pipe cleaners for 30 seconds or until visible soil is removed (whichever is longer) 1.7 Disposable equipment must be used once then thrown away ▪ Non-disposable brushes must be reprocessed according to brush manufacturer's instructions after each use 1.8 Rinse in warm tap water. 1.9 Remove excess water prior to disinfection
2. Disinfection of elastomeric respirators	2.1 Don appropriate PPE for cleaning and disinfection (may use same PPE if steps 7 and 8 are done as a continuous process ▪ latex or nitrile gloves ▪ water resistant gown ▪ full face shield 2.2 Measure hospital grade disinfectant as per protocol for your facility. If using bleach use mixing instructions to obtain 50 ppm solution (e.g.: 1ml of household bleach to 1 litre of water) 2.3 Completely immerse respirator in disinfectant solution ▪ Time: 10 min ▪ Temperature:lukewarm 2.4 Scrub respirator crevices, openings and holes under water with brushes, swabs, or pipe cleaners for 1 minute minimum. ▪ Disposable equipment must be used once then thrown away ▪ Non-disposable brushes must be reprocessed according to brush manufacturer's instructions after each use 2.5 Rinse respirator in warm tap water 2.6 Dry completely 2.7 Ensure filter gaskets are properly seated and in good condition ▪ Inspect filter gaskets for signs of damage ▪ If damaged, remove respirator from service & follow your facilities process for gasket replacement ▪ Ensure appropriate filters (e.g. P100) are within expiry date (within 1 year) & reinstall
3. Storage	3.1 Store respirators in a leak-proof, rigid container or in individual bags 3.2 Ensure labelling to document that respirator has been disinfected (can label bags to document clean elastomeric respirator) 3.3 Store bags/containers in designated clean, storage area

Appendix B

Advertisement – Elastomeric Half-facepiece Research Project

ELASTOMERIC HALF-FACEPEICE RESEARCH PROJECT

WHAT IS THIS STUDY ABOUT?

A large number of respirators are required by health authorities during a pandemic or outbreak. Although N95 filtering facepiece respirators (FFRs) are the primary choice of respiratory protection, they cannot be disinfected for re-use and must be disposed of after each patient. At the same time, stockpiling large quantities of N95 FFRs is not practical due to storage requirements, stock rotation and limited typical usage.

This research will provide much needed information on whether Elastomeric Half-facepiece respirators (EHFRs) represent a potential reusable respirator option, during a pandemic or outbreak, as they can be cleaned and disinfected between uses.

WHY INTENSIVE CARE UNIT STAFF?

Front line staff in Intensive Care Units are exposed to airborne biological hazards, such as tuberculosis, on a regular basis. Due to the nature of their job, they are required to use N95 FFRs when working with their clients. The number of N95s required by a single ICU staff, on shift, can increase considerably during an outbreak, and result in an overall shortage of available respirators. So, it is essential to fully evaluate the practical implications of wide-scale use of reusable respirators in a healthcare setting.

BENEFITS TO INTENSIVE CARE UNITS

- **Receive a Fit-Test.** Participation in this study will provide you with a fit-test on an N95 or Elastomeric Half-facepeice respirator. This will ensure you know which type/model fits you adequately if you need to use one.
- **Pandemic Preparedness**. The education and training will help prepare you for a pandemic. Being fit-tested is required to ensure pandemic preparedness.
- **Research Participation.** Your participation in this study will provide valuable information in this area.

WHAT IS THE TIME FRAME?

This project will occur over a one-year period, commencing October 2011.

Staff education and training, for the respirator fit-testing, will require approximately 30 minutes. As the study continues, participants are required to complete respirator perception surveys which will require approximately 5 minutes each time.

WHAT DO I NEED TO DO TO PARTICIPATE?

We are requesting that ALL intensive care nursing staff from BUH, ARH, RCH and SMH participate in this study.

- Let your Supervisor/Manager know if you are willing to participate. Those staff who do not participate in this study will still require a N95 respirator fit-test as part of our pandemic planning.
- As this is a research study, all participants are required to complete a Consent Form that is available from your Supervisor/Manager.

WHAT SUPPORT DOES THIS STUDY HAVE?

This study has support from the following organizations/agencies:

- BC Nurses Union, Ministry of Health Services, Health Shared Services Organization of BC, Health Care Safety Professional Association of BC, Provincial Infection Control Network of BC and Community and Hospital Infection Control Association of BC
- WorkSafeBC
- Fraser Health Ethics Review Boards

WHERE CAN I GET MORE INFORMATION

Rita Ciconte, MSc
Program Leader, Safety & Prevention
Workplace Health

Telephone: 604.412.6134
Email: rita.ciconte@fraserhealth.ca

Quinn Danyluk, MSc CIH
Manager, Safety and Prevention
Workplace Health

Telephone: 604.613.7736
email: quinn.danyluk@fraserhealth.ca

BRITISH COLUMBIA Nurses' Union

WORK SAFE BC
WORKING TO MAKE A DIFFERENCE

Appendix C

PowerPoint Presentation

ASSESSMENT AND DETERMINATION OF PRACTICAL CONSIDERATIONS FOR WIDE-SCALE UTILIZATION OF ELASTOMERIC HALF-FACEPIECE RESPIRATORS DURING A PANDEMIC OR OUTBREAK SITUATION

WorkSafeBC Focus on Tomorrow, Innovation at Work Grant

Issue to be addressed…

- Although N95 filtering facepiece respirators are the primary choice of respiratory protection, because of high demand during a pandemic or wide-scale outbreak, availability from supplier and manufacturers can become extremely limited.
- Stockpiling larger quantities of disposable respirators is not practical due to storage requirements, stock rotation, and limited typical usage (in relation to the usage during a pandemic).

RESEARCH QUESTION

Is it feasible to utilize reusable elastomeric half-facepiece respirators with P100 filters (EHFRs) in place of N95 filtering facepiece respirators during a pandemic or wide-scale outbreak in departments which have a high demand for respiratory protection against biological hazards?

OBJECTIVES

1. Assess and compare the acceptability of N95s & EHFRs for use by nursing staff
2. Evaluate the process and impact of cleaning and disinfecting the EHFR in sterile processing departments
3. Identify the logistics to be addressed in a hospital when implementing the use of EHFR on a wide-scale basis
4. Identify the logistics (barriers and facilitators) to be addressed in a hospital when implementing the use of EHFR on a wide-scale basis.

RESEARCH DESIGN

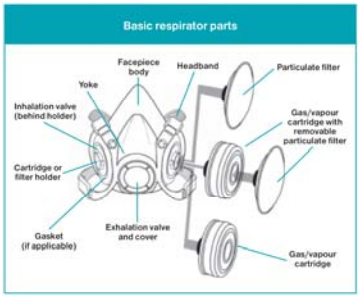
- Study to be conducted in 3 acute care hospitals:
  - Abbotsford Regional Hospital & Cancer Centre
  - Royal Columbian
  - Surrey Memorial
- Departments involved:
  - Intensive Care Unit
  - Sterile Processing
- Subjects:
  - ICU nurses

Project Supporters

- British Columbia Nurses' Union – Project Supporter
- Ministry of Health Services
- Health Shared Services Organization of BC
- Provincial Infection Control Network of BC (PICNet)
- Community and Hospital Infection Control Association of BC (CHICA BC)
- Health Care Safety Professional Association of British Columbia

THANK-YOU FOR YOUR SUPPORT!

PARTS OF A HALF-FACEPIECE RESPIRATOR



FIT-CHECK: NEGATIVE PRESSURE CHECK

FIT-CHECK: POSITIVE PRESSURE CHECK

FIT TEST

CLEANING, MAINTENANCE, & STORAGE

Appendix D

Letter of Consent – Subject Information and Consent Form: Intensive Care Unit

3935 Kincaid Street
Burnaby, BC
V5G 2X6
Tel: 604-412-6134

SUBJECT INFORMATION AND CONSENT FORM: INTENSIVE CARE UNIT

TITLE OF STUDY: ***Assessment and Determination of Practical Considerations for Wide-Scale Utilization of Elastomeric Half-Facepiece Respirators During a Pandemic or Outbreak Situation***

Fraser Health Principal Investigator:
Rita Ciconte, MSc
Program Leader, Safety & Prevention
Workplace Health

Tel: 604-412-6134 (M-F, 0800-1600 hours)

Fraser Health Co-Principal Investigator:
Quinn A Danyluk, MSc, CIH
Manager, Safety and Prevention
Workplace Health

Tel: 604-613-7736 (M-F, 0800-1600 hours)

Funding Agency: WorkSafeBC Research Secretariat and Workers Compensation Board of Nova Scotia

This study is being carried out at the Intensive Care Units of Burnaby Hospital (BUH), Abbotsford Regional Hospital (ARH), Royal Columbian Hospital (RCH) and Surrey Memorial Hospital (SMH).

INTRODUCTION:
N95 filtering facepiece respirators (N95 FFR) are used in acute care sites to prevent the spread of airborne organisms during many potential high-risk procedures. However, the availability of N95 FFRs, from suppliers and manufacturers, can become extremely limited during a pandemic or wide-scale outbreak. You are being invited to participate because you are a nursing staff member in one of the acute care facilities participating in the study and you normally wear N95 FFRs as required for your job. The goal is to find out whether it is feasible to utilize reusable elastomeric half-facepiece respirators with P100 filters (EHFRs), during these situations, as they can be cleaned and disinfected between uses.

YOUR PARTICIPATION IS VOLUNTARY:
It is up to you to decide if you want to take part in this study. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study and why the research is being done, what you will undergo during the study and the possible benefits, risks and discomforts.

If you wish to participate, you will need to sign this form. If you do decide to take part in this study, you are still free to leave at any time and without giving any reasons. If you do not wish to participate, you do not have to provide any reason for your decision not to participate.

Please take the time to read the following information carefully before you decide.

WHO IS CONDUCTING THE STUDY?
There are two researchers overseeing the study who are occupational hygienists – Rita Ciconte and Quinn Danyluk. Rita and Quinn will be assisted by a research assistant, Sona Jassal, who is also an occupational hygienist. All three are part of the Workplace Health team

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Burnaby, BC
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at Fraser Health. WorkSafeBC is the funding agency of the study; they provide funding for studies that improve workplace health and safety relevant to BC workplaces.

BACKGROUND:
A large number of respirators are required by health authorities during a pandemic or outbreak. Although N95 FFRs are the primary choice of respiratory protection, they cannot be disinfected for re-use and must be disposed of after each patient. This issue cannot be fully addressed by stock piling large quantities due to storage requirements and stock rotation.

WHAT IS THE PURPOSE OF THE STUDY?
There are four objectives of this study. They are to:

1. Assess and compare the acceptability of N95 FFRs and EHFRs for use by the nursing staff in an ICU.
2. Determine the practical implications associated with EHFR usage, selection and storage.
3. Evaluate the process and impact of cleaning and disinfecting the EHFR in the Sterile Processing Department (SPD).
4. Identify the barriers and facilitating factors that need to be addressed in a hospital when considering implementing the use of EHFR on a wide-scale basis.

WHO CAN PARTICIPATE IN THE STUDY?
Nursing staff from pre-selected acute care facilities are eligible to participate in the study as using N95 FFRs is a regular part of their job. It is up to you if you want to be a part of this study and all of the results will be confidential. For the purpose of the survey, a unique identifier will be created for each participant to ensure confidentiality of the results.

WHO SHOULD NOT PARTICIPATE IN THE STUDY?
People with medical conditions such as chronic obstructive pulmonary disease (COPD), emphysema, and shortness of breath will not be a part of this study. It is not advisable for people with these conditions to use EHFR respirators.

WHAT DOES THE STUDY INVOLVE?

If You Decide to Join This Study

- You will be asked to complete a fit-test form that reviews conditions that impact the use of a respirator as well as documents the model and size of respirator to which you are successfully fit-tested.
- You will get respirator education by watching a presentation and via hands on training.
- You will put on at least one of the N95 FFR models (1870, 1860, 1860S) and perform a modified rhyme test, to assess speech intelligibility.
- You will then be fit tested on an EHFR using Bitrex salt solution that allows for taste threshold screening. On achieving a successful fit, you will be asked to participate in the modified rhyme test, while wearing the EHFR.
- You will then be asked to complete an N95 survey on the spot and an EHFR Survey at an interval of 2 weeks, 1 month, 3 months and 6 months. An electronic copy of the survey will be e-mailed to you by the department manager.

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TIME REQUIREMENTS

The time required per person for the training and fit test is approximately 30 minutes. Each of the four online surveys disseminated following fit test completion, will require approximately 5 minutes each to complete.

WHAT ARE MY RESPONSIBILITIES?

- You should not eat, drink (except water), smoke or chew gum at least 15 minutes before your appointment. If you are male, you are asked to be clean-shaven at the time of your fit-testing appointment.
- Complete the four online surveys during the progress of this study.

WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

- If you have never worn a respirator before, you may feel a little bit nervous at first because there is some resistance to breathing when wearing an N95 or EHFR respirator.
- Claustrophobia is the fear of being in enclosed or narrow places. If you are claustrophobic, you may feel some symptoms of claustrophobia during fit-testing.
- The Bitrex® spray is very bitter tasting. Some people exposed to Bitrex® may feel side effects such as mild irritation to the nose and throat.
- After you do a respirator fit-test, some people may have flushed cheeks.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

Annual fit-testing is required as part of your normal work duties. This study will allot more time to education, training, and fit-testing than you would normally receive and as a result provide more information to you. By joining this study, you will have a chance to inform the researchers of any change in your perception regarding the practicality of using EHFRs with increased usage. This data will then be compared against similar surveys completed by BUH ICU nursing staff, who will be using only N95 FFRs during this study.

RIGHTS AND COMPENSATION:

By signing this form, you do not give up any of your legal rights and you do not release the study co-principal investigators or other participating institutions from their legal and professional duties. There will be no costs to you for participation in this study.

WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

Your participation in this research is entirely voluntary. You may withdraw from this study at any time. If you decide to enter the study and to withdraw at any time in the future, there will be no penalty or loss of benefits to which you are otherwise entitled. The study investigators may decide to discontinue the study at any time, or withdraw you from the study at any time, if they feel that it is in your best interest. If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment in the study will be retained for analysis.

CONFIDENTIALITY:

Your confidentiality will be respected. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate by

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representatives of the Fraser Health Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a subject in this study. Only this number will be used on any research–related information about you during the course of this study, so that your identity [i.e. your name or any other information that could identify you] as a subject in this study will be kept confidential. Information that directly discloses your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique identifier that is used on your research-related information will not be removed or released without your consent unless required by law.

CONTACT:

If you have any questions you can contact one of the researchers below:

Rita Ciconte at 604-412-6134
Quinn Danyluk at 604-613-7736
Sona Jassal at 604-614-7163

If you have any concerns about your rights as a research control and/or your experience while participating in this study, contact Dr. Marc Foulkes and/or Dr. Allan Belzberg, Research Ethics Board (REB) co-Chairs by calling 604-587-4681. You may discuss these rights with the co-chairmen of the Fraser Health REB.

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TITLE OF STUDY: ***Assessment and Determination of Practical Considerations for Wide-Scale Utilization of Elastomeric Half-Facepiece Respirators During a Pandemic or Outbreak Situation***

CONSENT TO PARTICIPATE:

- I have read and understood the subject information and consent form and am consenting to participate in the study "Assessment and Determination of Practical Considerations for Wide-Scale Utilization of Elastomeric Half-Facepiece Respirators During a Pandemic or Outbreak Situation".
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the result will only be used for scientific objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me (if applicable).
- I have read this form and I freely consent to participate in this study.
- I have been told that I will receive a dated and signed copy of this form.

Printed name of subject: _____

Signature of subject: _____

Date: _____

_____

Printed name of Principal Investigator/Designate: _____

Signature of Principal Investigator/Designate: _____

Date: _____

Appendix E

Speech Intelligibility Tool – Determination of Communication Performance Test for Speech Conveyance and Intelligibility of Chemical, Biological, Radiological, and Nuclear (CBRN) Full-Facepiece Air-Purifying Respirator (APR) Standard Testing Procedure (NIOSH Procedure No. TEB-CBRN-APR-STP-0313)

National Institute for Occupational Safety and Health National Personal Protective Technology Laboratory P.O. Box 18070 Pittsburgh, PA 15236	
Procedure No. TEB-CBRN-APR-STP-0313	Revision: 2.0 / Date: 31 October 2007

UNCONTROLLED COPY

DETERMINATION OF COMMUNICATION PERFORMANCE TEST FOR SPEECH CONVEYANCE AND INTELLIGIBILITY OF CHEMICAL BIOLOGICAL RADIOLOGICAL AND NUCLEAR (CBRN) FULL-FACEPIECE AIR-PURIFYING RESPIRATOR (APR) STANDARD TESTING PROCEDURE

1. PURPOSE

1.1. This test establishes the procedures for ensuring that the level of speech conveyance and intelligibility provided by the Communication Performance Test on Chemical Biological Radiological and Nuclear (CBRN) Full Facepiece Air-Purifying Respirator (APR) submitted for Approval, or Extension of Approval, or examined during Certified Product Audits, meet the minimum certification standards set forth in 42 CFR Part 84, Subpart G, Section 84.63(a)(c)(d) and the Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Full-Facepiece Air-Purifying Respirator (APR) dated 3-7-2003.

1.2. The purpose of this test is to quantify the performance of a respirator in transmitting intelligible speech of a human test subject. This is accomplished by determining a listener's ability to comprehend single-syllable words spoken by a subject wearing the respirator.

2. GENERAL

2.1. This STP describes the Communication Performance Tests for Speech Conveyance and Intelligibility of the CBRN APR in sufficient detail that a person knowledgeable in the appropriate technical field can select equipment with the necessary resolution, select the appropriate human subject test panel, conduct the test, and determine whether or not the product passes the test.

2.2. The Communication Performance Test shall be performed through the use of the Modified Rhyme Test (MRT) to evaluate a listener's ability to comprehend single words from a speaker. Both listeners and speakers shall be in combinations of masked and unmasked postures during the MRT to provide an indication of speech transmission and intelligibility.

2.3. This test is considered a human factors test that requires participation of 8 test subjects to quantify the performance rating of a respirator to transmit intelligible speech.

Approvals:			
First Level	Second Level	Third Level	Fourth Level

UNCONTROLLED COPY

3. EQUIPMENT/MATERIALS

3.1. Test Subjects

3.1.1. Test administrators: Shall have successfully completed the CDC/ATSDR Scientific Ethics Training, DHHS/NIH Human Participant Protections Education for Research Teams or an equivalent course.

3.1.1.1. Administrator 1 shall have the duties of monitoring the test speakers' speech. Administrator 1 shall also monitor the actions of the listener group to make sure they are responding to the test speaker and not misbehaving during the test.

3.1.1.2. Administrator 2 shall monitor the dBA level of the test speaker and give verbal or nonverbal feedback as to loudness of his/her speech. Administrator 2 shall also record the dBA level on the Respirator Communication Performance Test Data Collection Sheet (see 8.4).

3.1.2. Eight test subjects are required for this test. All procedures and requirements specified in the NIOSH Human Subject Review Board (HSRB) Protocol HSRB-04-NPPTL-02XP entitled, "Protocol for the Certification and Quality Assurance Testing of Respirators" shall be followed and met.

3.1.3. The eight test subjects shall be divided into two groups, a listener group comprised of three subjects (at least one female and one male) and a speaker group comprised of five subjects (at least one female and one male).

3.1.4. All test speakers and listeners shall be fluent in English. In addition, these subjects shall have no obvious or strong regional or foreign accents.

3.1.5. The eight test subjects shall be trained in the donning and use of the respirator per manufacturer's instructions by the test administrator.

3.1.6. Each subject shall be sized and fitted for the respirator per manufacturer's instructions. Where an individual is qualified to wear multiple sizes of the respirator, the subject shall select the respirator size that provides the most comfortable fit.

3.1.7. The subjects shall have normal hearing as defined in the HSRB Protocol (see 3.1.2.).

3.1.8. The test subjects shall not have any facial hair or conditions that may cause interference with the seal of the respirator facepiece.

3.2. Test Equipment

3.2.1. Permanent Marker

3.2.2. Measuring tape, foot & inch, minimum 20 feet length.

3.2.3. Test laboratory that permits an unobstructed 10 +1/-0 ft distance between test speaker and the listener group when facing one another. Figure 1 contains a diagram of the subject and equipment positioning for the Modified Rhyme Test setup.

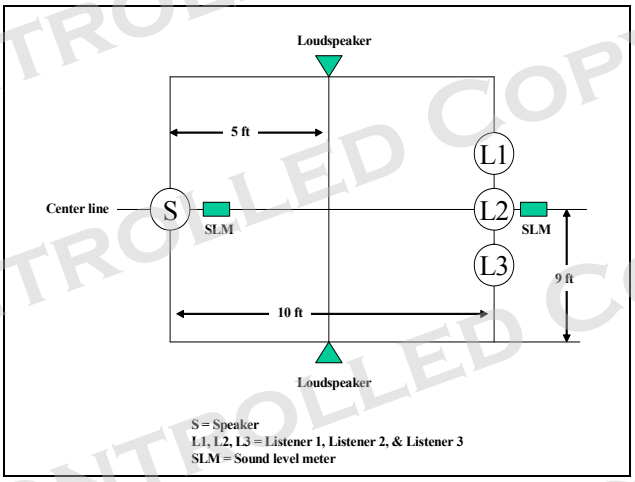

Figure 1. Modified Rhyme Test setup diagram

3.2.4. Noise Plug, Precision Pink Noise Test Generator (GTC Industries) or equivalent for producing pink noise in the frequency range of 20.0 Hz to 50.0 kHz. Accuracy: 3dB per octave rolloff from 20 Hz to 20 KHz.
Pink noise is defined as an audio test signal that contains all the frequencies in the audio spectrum with equal energy in each octave. Pink noise contains less energy in the higher audio frequencies than in the lower ones.

Figure 2. Noise Plug, Precision Pink Noise Generator (GTC Industries)

3.2.5. The stereo amplifier is positioned outside the room and used to transmit and amplify the background noise.

3.2.6. The two loudspeakers are positioned midway between test speaker and listeners. Details of the exact positioning of the speaker equipment are further defined in Section 5.3.2

3.2.7. Two Type 2 digital sound level meters (Sper Scientific, LTD, Model 840029) with an "A" weighting decibel scale of 30 to 130 dB or equivalent. One sound

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level meter will be positioned in front of the Test Speaker and the second sound level meter will be positioned at head level beside listener L2 (see figure 1).

Figure 3. Sper Scientific LTD digital sound level meter, Model 840029

3.2.8. Sper Scientific, LTD Acoustical calibrator (model 840031) or equivalent is used to calibrate the sound level meters.

Figure 4. Acoustical calibrator (Sper Scientific model 840031)

3.2.9. Twelve word lists from the Modified Rhyme Test (MRT). These twelve word lists are separated onto individual sheets to be used by the test speakers during the test (see 8.1)

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3.2.10. Test listeners' multiple choice answer pages on the laptops or equivalent. Modified Rhyme Test listener responses are recorded and scored using laptops that have been programmed for this application; otherwise, the manual method using the multiple choice answer sheets can be employed (see 8.2).

3.2.11. Sound and/or audiovisual recording device for recording speech.

4. TESTING REQUIREMENTS AND CONDITIONS

4.1. Prior to beginning any testing, all measuring equipment to be used must have been calibrated in accordance with the testing laboratory's procedure and schedule. All measuring equipment utilized for this testing must have been calibrated using a method traceable to the National Institute of Standards and Technology (NIST) when available.

4.2. Any laboratory using this procedure to supply certification test data as a contractor to NIOSH will be subject to the provisions of the NIOSH Supplier Qualification Program (SQP). This program is based on the tenets of *ISO/IEC 17025, the NIOSH Manual of Analytical Methods* and other NIOSH guidelines. An initial complete quality system audit and follow on audits are requirements of the program. Additional details of the Program and its requirements can be obtained directly from the Institute.*
***Note** 4.2 does not apply to Pretest data from applicants as required under 42 CFR 84.64.

4.3. Precision and accuracy (P&A) must be determined for each instrument in accordance with laboratory procedures and NIOSH/NPPTL guidance. Sound practice requires, under *NIOSH Manual of Analytical Methods*, demonstrating a tolerance range of expected data performance of a plus or minus 25% of a 95% confidence interval of the stated standard requirement. NIOSH/NPPTL P&A tolerance can be higher but not lower.

4.4. Normal laboratory safety practices must be observed.

4.4.1. All electrical equipment cables and wires must be covered or fastened securely to the floor by a rug or tape to eliminate trip hazards.

4.4.2. Worktables must be maintained free of clutter and non-essential test equipment.

4.4.3. All large test equipment such as the stereo amplifier, speakers, and noise generator shall be securely anchored to eliminate toppling hazards.

5. PROCEDURES

5.1. Fill in the Pretest data on the Respirator Communication Performance Test Data Collection Sheet (see 8.3).

5.2. Record the background noise of the room without any external noise, at the center listener's head position, on the Respirator Communication Performance Test Data Collection Sheet.

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5.3. Test Equipment Set-Up.

5.3.1. Room Selection.

The room selected to perform the MRT shall be of ample size to comfortably house all the test equipment indicated in Figure 1 and the personnel associated with the test. It shall be free of external noise interference.

5.3.2. Equipment Positioning

The test equipment shall be arranged in accordance with the diagram of Figure 1. The loudspeakers shall be positioned such that their forward axes are oriented toward one another at a height of approximately 29.5 inches from the floor and they are 9 +0.5/-0 ft from the center of the sound field between the test speaker and listeners. The laptops will be placed directly in front of the listeners at a convenient distance away.

5.4. Training of the Test Speakers.

5.4.1. Without the listeners in the room, one subject at a time will be seated in the test speaker's position and be given an individual MRT word list from section 8.1. A sound level meter will be positioned in front of the test speaker at a convenient distance as a guide concerning the loudness of their voice during reading of the word list. The sound level meter shall be set to display "A"-weighted sound levels.

5.4.2. Test administrator 1 shall be seated beside the test speaker to monitor the reading of the word list. The administrator shall instruct the test speaker to read, without placing any unusual emphasis on any stimulus word, at a rate of approximately one phrase every 6 seconds, using the introductory phrase "The word is (list word)". In addition, the test speaker shall be directed to communicate each word without using any visual gestures, such as hand signals, and without repeating any of the list words.

5.4.3. Test administrator 2 shall be seated in the center test listener's position and instruct the test speaker to begin reading the word list at a voice level of 75 to 85 dBA.

5.4.4. During the reading of the word list, test administrator 2 will monitor the "A"-weighted output volume of the speaker and provide feedback as to the loudness of the speaker's performance throughout the reading of the word list. Test administrator 1 will provide feedback to the test speaker regarding the pronunciation of the list words and the rate of performance. Additional training will be done if warranted per the judgment of the test administrators. These procedures will be completed without the use of a respirator and without any background noise above ambient conditions.

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5.4.5. Additionally, training with background noise of 60 ± 2 dBA consisting of a pink noise will also be completed according to the above procedures in section 5.4.

5.5. Training of the Test Listeners.

5.5.1. The three test listeners shall be seated facing a single test speaker at a distance of 10 ft. The listeners shall be seated next to one another with approximately one foot between them. Each listener will be given a laptop with a list of multiple choice words for recording his or her responses. Alternate means for recording the test listener's, responses such as paper answer sheets, are acceptable (see 8.2).

5.5.2. An MRT word list will be provided to a trained test speaker. The test speaker will be instructed to communicate the word list to the test listeners as was done during speaker training.

5.5.3. As a group, listeners will be instructed to listen attentively as the test speaker reads 50 words to them each with the introductory phrase "The word is (list word)." The test listeners shall be directed to select, or make a best guess of the word, that was perceived to be spoken from the six possible response words provided to them on the laptops. Test listeners shall also be instructed to provide a "thumbs-up" hand signal to the speaker as a cue to say the next phrase.

5.5.4. During the reading of the word list, administrator 2 will monitor the A-weighted output volume of the speaker at the listening position and provide feedback as to the loudness throughout the reading of the word list. In addition, test administrator 1 will provide the test speaker feedback regarding the rate of performance. Administrator 1 will also monitor the actions of the listener group and provide additional instructions as needed. Additional training will be done if warranted per the judgment of the test administrators. These procedures will be completed without the use of a respirator and without any background noise above ambient conditions.

5.5.5. Additionally, training with background noise of 60 ± 2 dBA consisting of a pink noise will also be completed according to the above procedures.

5.6. Conducting the Test.

5.6.1. The noise generator shall be turned on and set to produce 60 ±2 dBA of pink noise, as measured by the sound level meter at the center test listener's head position without listeners present. This value shall be recorded on the Respirator Communication Performance Test Data Collection Sheet.

5.6.2. The three test listeners shall be seated in the listening position with a laptop located conveniently in front of them.

5.6.3. A test speaker will then be positioned in the speaking position and present one complete MRT word list to the listening panel. A different test speaker shall then

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be used to present the next MRT trial. Test speakers will continue to rotate among the speaker test panel until all trials have been completed.

5.6.4. Data will be obtained without the respirator and with the respirator worn and operated per the manufacturer's instructions by both speakers and listeners. All conditions shall be randomly assigned and a different word list shall be used for each test. A test matrix of the MRT conditions is provided in Table 2 to assist the test administrator in establishing the sequence of testing.

Table 2. MRT Trial Matrix

Trial #	Speaker	With or Without Mask	Word list
1	1	No mask	11A
2	2	No mask	3A
3	3	Masked	5A
4	4	Masked	7A
5	5	No mask	4A
6	2	Masked	12A
7	4	No mask	5A
8	1	Masked	1A
9	5	Masked	8A
10	3	No mask	6A

5.6.5. Background noise levels shall be monitored at the center test listener's head position and recorded, on the Respirator Communication Performance Test Data Collection Sheet, at the beginning, middle, and end of each MRT session by administrator 2.

5.6.6. The test speakers shall be monitored and recorded during the test to determine if the test speakers conform to the word list specified for each trial by test administrator 1. Test administrator 1 shall also make note of any improperly pronounced or misspoken words by the test speakers.

5.6.7. A total of 10 MRT trials shall be performed. The 10 trials will result in a total of 15 MRT scores (five per listener) for the unworn mask condition and 15 scores for the worn condition.

5.7. Data Analysis.

5.7.1. Use the Respirator Communication Performance Test Data Collection Sheets, to assist with the analysis of the ten MRT for each listener.

5.7.2. The number of correct responses shall be adjusted for chance or guessing made possible by the multiple-choice form of the answer sheet using the equation:

$$\text{Adjusted Score} = \text{Number of Correct Listener Responses} - \frac{\text{Number of Wrong Listener Responses}}{5}$$

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5.7.3. Determine the Number of Words Spoken Correctly by the speakers from either the Test Administrators notes or if necessary, by listening to the Audio recorder tapes.

5.7.4. Listener performance on the MRT shall be scored in terms of the percentage of words correctly identified using the equation for both the masked and unmasked posture:

% Correct = (Adjusted Score/Number of Words Spoken Correctly) * 100

5.7.5. Average Unmasked and Average Masked % Correct Scores shall be calculated for each individual listener.

5.7.6. Each individual listener's Average Masked % Correct Score shall be divided by their Average Unmasked % Correct Score to calculate a Performance Rating using the equation:

$$\text{Performance Rating (\%)} = \left(\frac{\text{Average Masked \% Correct Score}}{\text{Average Unmasked \% Correct Score}} \right) \text{x } 100$$

5.7.7. The performance rating of all listeners shall then be averaged to determine the Overall Performance Rating of the CBRN APR using the following Equation:

$$\text{Overall Performance Rating (\%)} = \frac{\text{Performance Rating (\%)}_{L1} + \text{Performance Rating (\%)}_{L2} + \text{Performance Rating (\%)}_{L3}}{3}$$

6. PASS/FAIL CRITERIA

6.1. The criterion for passing this test is set forth in 42 CFR, Part 84, Subpart G, Section 84.63(a)(c)(d) and the Statement of Standard for Chemical, Biological, Radiological and Nuclear (CBRN) Full-Facepiece Air-Purifying Respirator (APR) dated 3-7-2003.

6.2 A candidate CBRN APR must obtain an Overall Performance Rating greater than or equal to 70% to meet the Communication requirement.

7. RECORDS/TEST SHEETS

7.1. All test data shall be recorded on the Respirator Communication Performance Test Data Collection Sheets.

8. ATTACHMENTS

8.1. CBRN APR Communication Performance Word List Test Sheets

8.2. CBRN APR Communication Performance Test Listener Data Sheet

8.3. Respirator Communication Performance Test Data Collection Sheet

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Section 8.1
CBRN APR Communication Performance Word List Test Sheets

List 1A

1. The word is **but**
2. The word is **kit**
3. The word is **peak**
4. The word is **pig**
5. The word is **cold**
6. The word is **sick**
7. The word is **pat**
8. The word is **beat**
9. The word is **hot**
10. The word is **fit**
11. The word is **sung**
12. The word is **sent**
13. The word is **rest**
14. The word is **mat**
15. The word is **top**
16. The word is **sack**
17. The word is **day**
18. The word is **heal**
19. The word is **name**
20. The word is **pay**
21. The word is **must**
22. The word is **pun**
23. The word is **hen**
24. The word is **cud**
25. The word is **book**
26. The word is **late**
27. The word is **led**
28. The word is **same**
29. The word is **pin**
30. The word is **feel**
31. The word is **soil**
32. The word is **fizz**
33. The word is **park**
34. The word is **bash**
35. The word is **till**
36. The word is **male**
37. The word is **dud**
38. The word is **sin**
39. The word is **tack**
40. The word is **case**
41. The word is **bang**
42. The word is **thaw**
43. The word is **ray**
44. The word is **dig**
45. The word is **team**
46. The word is **win**
47. The word is **seek**
48. The word is **bun**
49. The word is **feat**
50. The word is **sip**

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List 2A

1. The word is **bus**
2. The word is **kick**
3. The word is **peas**
4. The word is **fig**
5. The word is **hold**
6. The word is **lick**
7. The word is **pass**
8. The word is **beach**
9. The word is **pot**
10. The word is **bit**
11. The word is **sub**
12. The word is **went**
13. The word is **west**
14. The word is **map**
15. The word is **cop**
16. The word is **sap**
17. The word is **pay**
18. The word is **heath**
19. The word is **tame**
20. The word is **pale**
21. The word is **gust**
22. The word is **pus**
23. The word is **then**
24. The word is **cuss**
25. The word is **cook**
26. The word is **lace**
27. The word is **bed**
28. The word is **save**
29. The word is **pit**
30. The word is **reel**
31. The word is **boil**
32. The word is **fib**
33. The word is **bark**
34. The word is **bad**
35. The word is **fill**
36. The word is **gale**
37. The word is **duck**
38. The word is **sit**
39. The word is **tap**
40. The word is **cane**
41. The word is **sang**
42. The word is **saw**
43. The word is **race**
44. The word is **dim**
45. The word is **teak**
46. The word is **din**
47. The word is **seethe**
48. The word is **run**
49. The word is **meat**
50. The word is **dip**

List 3A

1. The word is **bug**
2. The word is **kin**
3. The word is **peach**
4. The word is **rig**
5. The word is **gold**
6. The word is **tick**
7. The word is **pan**
8. The word is **beak**
9. The word is **got**
10. The word is **hit**
11. The word is **sup**
12. The word is **rent**
13. The word is **best**
14. The word is **math**
15. The word is **hop**
16. The word is **sad**
17. The word is **gay**
18. The word is **heap**
19. The word is **fame**
20. The word is **page**
21. The word is **bust**
22. The word is **puff**
23. The word is **ten**
24. The word is **cup**
25. The word is **took**
26. The word is **lake**
27. The word is **shed**
28. The word is **safe**
29. The word is **pig**
30. The word is **eel**
31. The word is **toil**
32. The word is **fill**
33. The word is **lark**
34. The word is **bath**
35. The word is **will**
36. The word is **tale**
37. The word is **dung**
38. The word is **sill**
39. The word is **tang**
40. The word is **cave**
41. The word is **rang**
42. The word is **jaw**
43. The word is **raze**
44. The word is **dip**
45. The word is **teal**
46. The word is **pin**
47. The word is **seem**
48. The word is **fun**
49. The word is **heat**
50. The word is **rip**

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List 4A

1. The word is **bun**
2. The word is **kill**
3. The word is **peace**
4. The word is **big**
5. The word is **told**
6. The word is **kick**
7. The word is **pad**
8. The word is **bean**
9. The word is **lot**
10. The word is **kit**
11. The word is **sum**
12. The word is **bent**
13. The word is **vest**
14. The word is **man**
15. The word is **mop**
16. The word is **sat**
17. The word is **say**
18. The word is **hear**
19. The word is **game**
20. The word is **pave**
21. The word is **dust**
22. The word is **puck**
23. The word is **men**
24. The word is **cuff**
25. The word is **hook**
26. The word is **lane**
27. The word is **fed**
28. The word is **sale**
29. The word is **pip**
30. The word is **peel**
31. The word is **coil**
32. The word is **fit**
33. The word is **mark**
34. The word is **bat**
35. The word is **bill**
36. The word is **bale**
37. The word is **dub**
38. The word is **sing**
39. The word is **tam**
40. The word is **cape**
41. The word is **hang**
42. The word is **law**
43. The word is **rake**
44. The word is **dill**
45. The word is **tease**
46. The word is **fin**
47. The word is **seen**
48. The word is **gun**
49. The word is **seat**
50. The word is **hip**

List 5A

1. The word is **buck**
2. The word is **king**
3. The word is **peat**
4. The word is **dig**
5. The word is **fold**
6. The word is **wick**
7. The word is **pack**
8. The word is **bead**
9. The word is **not**
10. The word is **wit**
11. The word is **sun**
12. The word is **tent**
13. The word is **test**
14. The word is **mad**
15. The word is **pop**
16. The word is **sass**
17. The word is **way**
18. The word is **heat**
19. The word is **same**
20. The word is **pane**
21. The word is **just**
22. The word is **pup**
23. The word is **pen**
24. The word is **cut**
25. The word is **shook**
26. The word is **lay**
27. The word is **red**
28. The word is **sane**
29. The word is **pill**
30. The word is **keel**
31. The word is **oil**
32. The word is **fig**
33. The word is **hark**
34. The word is **ban**
35. The word is **hill**
36. The word is **pale**
37. The word is **dun**
38. The word is **sick**
39. The word is **tab**
40. The word is **cake**
41. The word is **fang**
42. The word is **raw**
43. The word is **rate**
44. The word is **did**
45. The word is **teach**
46. The word is **sin**
47. The word is **seed**
48. The word is **sun**
49. The word is **neat**
50. The word is **tip**

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List 6A

1. The word is **buff**
2. The word is **kid**
3. The word is **peal**
4. The word is **wig**
5. The word is **sold**
6. The word is **pick**
7. The word is **path**
8. The word is **beam**
9. The word is **tot**
10. The word is **sit**
11. The word is **sud**
12. The word is **dent**
13. The word is **nest**
14. The word is **mass**
15. The word is **shop**
16. The word is **sag**
17. The word is **may**
18. The word is **heave**
19. The word is **came**
20. The word is **pace**
21. The word is **rust**
22. The word is **pub**
23. The word is **den**
24. The word is **cub**
25. The word is **look**
26. The word is **lame**
27. The word is **wed**
28. The word is **sake**
29. The word is **pick**
30. The word is **heel**
31. The word is **foil**
32. The word is **fin**
33. The word is **dark**
34. The word is **back**
35. The word is **kill**
36. The word is **sale**
37. The word is **dug**
38. The word is **sip**
39. The word is **tan**
40. The word is **came**
41. The word is **gang**
42. The word is **paw**
43. The word is **rave**
44. The word is **din**
45. The word is **tear**
46. The word is **tin**
47. The word is **seep**
48. The word is **nun**
49. The word is **beat**
50. The word is **lip**

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List 7A

1. The word is **lick**
2. The word is **beat**
3. The word is **puff**
4. The word is **cook**
5. The word is **tip**
6. The word is **rave**
7. The word is **hang**
8. The word is **till**
9. The word is **math**
10. The word is **sale**
11. The word is **same**
12. The word is **peal**
13. The word is **kit**
14. The word is **sat**
15. The word is **sin**
16. The word is **gold**
17. The word is **buff**
18. The word is **lay**
19. The word is **nun**
20. The word is **must**
21. The word is **pad**
22. The word is **din**
23. The word is **sit**
24. The word is **win**
25. The word is **teak**
26. The word is **dent**
27. The word is **sub**
28. The word is **led**
29. The word is **tot**
30. The word is **dub**
31. The word is **pip**
32. The word is **seen**
33. The word is **way**
34. The word is **west**
35. The word is **pace**
36. The word is **bat**
37. The word is **mop**
38. The word is **big**
39. The word is **tab**
40. The word is **case**
41. The word is **name**
42. The word is **soil**
43. The word is **fin**
44. The word is **cuff**
45. The word is **heal**
46. The word is **hark**
47. The word is **heat**
48. The word is **then**
49. The word is **law**
50. The word is **bean**

List 8A

1. The word is **wick**
2. The word is **neat**
3. The word is **puck**
4. The word is **took**
5. The word is **rip**
6. The word is **ray**
7. The word is **sang**
8. The word is **will**
9. The word is **man**
10. The word is **gale**
11. The word is **safe**
12. The word is **peas**
13. The word is **kid**
14. The word is **sass**
15. The word is **sick**
16. The word is **hold**
17. The word is **but**
18. The word is **lane**
19. The word is **bun**
20. The word is **just**
21. The word is **pan**
22. The word is **dig**
23. The word is **bit**
24. The word is **pin**
25. The word is **tease**
26. The word is **sent**
27. The word is **sup**
28. The word is **red**
29. The word is **not**
30. The word is **dung**
31. The word is **pig**
32. The word is **seem**
33. The word is **day**
34. The word is **rest**
35. The word is **page**
36. The word is **bash**
37. The word is **shop**
38. The word is **fig**
39. The word is **tam**
40. The word is **cane**
41. The word is **same**
42. The word is **toil**
43. The word is **fill**
44. The word is **cuss**
45. The word is **feel**
46. The word is **bark**
47. The word is **heath**
48. The word is **ten**
49. The word is **thaw**
50. The word is **bead**

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List 9A

1. The word is **pick**
2. The word is **meat**
3. The word is **pub**
4. The word is **look**
5. The word is **sip**
6. The word is **rake**
7. The word is **fang**
8. The word is **bill**
9. The word is **mat**
10. The word is **male**
11. The word is **sane**
12. The word is **peach**
13. The word is **kill**
14. The word is **sack**
15. The word is **sill**
16. The word is **cold**
17. The word is **bug**
18. The word is **lace**
19. The word is **sun**
20. The word is **gust**
21. The word is **pass**
22. The word is **dim**
23. The word is **fit**
24. The word is **fin**
25. The word is **teach**
26. The word is **went**
27. The word is **sum**
28. The word is **wed**
29. The word is **hot**
30. The word is **dud**
31. The word is **pill**
32. The word is **seethe**
33. The word is **pay**
34. The word is **vest**
35. The word is **pace**
36. The word is **back**
37. The word is **top**
38. The word is **rig**
39. The word is **tap**
40. The word is **cave**
41. The word is **game**
42. The word is **foil**
43. The word is **fit**
44. The word is **cup**
45. The word is **eel**
46. The word is **park**
47. The word is **heap**
48. The word is **pen**
49. The word is **paw**
50. The word is **beam**

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List 10A

1. The word is **kick**
2. The word is **feat**
3. The word is **pup**
4. The word is **book**
5. The word is **lip**
6. The word is **rate**
7. The word is **bang**
8. The word is **fill**
9. The word is **mass**
10. The word is **tale**
11. The word is **sale**
12. The word is **peak**
13. The word is **king**
14. The word is **sag**
15. The word is **sip**
16. The word is **told**
17. The word is **bun**
18. The word is **lake**
19. The word is **gun**
20. The word is **bust**
21. The word is **pat**
22. The word is **did**
23. The word is **kit**
24. The word is **tin**
25. The word is **tear**
26. The word is **bent**
27. The word is **sun**
28. The word is **shed**
29. The word is **pot**
30. The word is **duck**
31. The word is **pin**
32. The word is **seed**
33. The word is **gay**
34. The word is **test**
35. The word is **pave**
36. The word is **bath**
37. The word is **pop**
38. The word is **pig**
39. The word is **tan**
40. The word is **cape**
41. The word is **came**
42. The word is **boil**
43. The word is **fib**
44. The word is **cud**
45. The word is **keel**
46. The word is **lark**
47. The word is **heave**
48. The word is **den**
49. The word is **saw**
50. The word is **beat**

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List 11A

1. The word is **tick**
2. The word is **heat**
3. The word is **pus**
4. The word is **hook**
5. The word is **dip**
6. The word is **raze**
7. The word is **gang**
8. The word is **hill**
9. The word is **mad**
10. The word is **bale**
11. The word is **save**
12. The word is **peace**
13. The word is **kin**
14. The word is **sad**
15. The word is **sit**
16. The word is **fold**
17. The word is **bus**
18. The word is **late**
19. The word is **run**
20. The word is **rust**
21. The word is **pack**
22. The word is **dill**
23. The word is **wit**
24. The word is **din**
25. The word is **teal**
26. The word is **rent**
27. The word is **sung**
28. The word is **bed**
29. The word is **lot**
30. The word is **dug**
31. The word is **pick**
32. The word is **seek**
33. The word is **say**
34. The word is **best**
35. The word is **pay**
36. The word is **ban**
37. The word is **hop**
38. The word is **dig**
39. The word is **tang**
40. The word is **cake**
41. The word is **fame**
42. The word is **coil**
43. The word is **fig**
44. The word is **cut**
45. The word is **peel**
46. The word is **mark**
47. The word is **heal**
48. The word is **men**
49. The word is **jaw**
50. The word is **beach**

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List 12A

1. The word is **sick**
2. The word is **seat**
3. The word is **pun**
4. The word is **shook**
5. The word is **hip**
6. The word is **race**
7. The word is **rang**
8. The word is **kill**
9. The word is **map**
10. The word is **pale**
11. The word is **sake**
12. The word is **peat**
13. The word is **kick**
14. The word is **sap**
15. The word is **sing**
16. The word is **sold**
17. The word is **buck**
18. The word is **lame**
19. The word is **fun**
20. The word is **dust**
21. The word is **path**
22. The word is **dip**
23. The word is **hit**
24. The word is **sin**
25. The word is **team**
26. The word is **tent**
27. The word is **sud**
28. The word is **fed**
29. The word is **got**
30. The word is **dun**
31. The word is **pit**
32. The word is **seep**
33. The word is **may**
34. The word is **nest**
35. The word is **pane**
36. The word is **bad**
37. The word is **cop**
38. The word is **wig**
39. The word is **tack**
40. The word is **came**
41. The word is **tame**
42. The word is **oil**
43. The word is **fizz**
44. The word is **cub**
45. The word is **reel**
46. The word is **dark**
47. The word is **hear**
48. The word is **hen**
49. The word is **raw**
50. The word is **beak**

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Section 8.2
CBRN APR Communication Performance Test Listener Data Sheet

NIOSH Application Number _____Date: _____

Respirator Manufacture: _____ ; MRT/Sheet# _____

Respirator Type: _____ ; Speakers Respirator Number, if worn _____ (Indicate if unworn)

Listener's Respirator (circle one): Unworn Worn If Worn, Listeners Respirator Number _____

Listener #:_____ Listening Position:_ Speaker #:_____ MRT Word List#:_____

1	but	bug	bus	14	map	mat	math	27	wed	fed	bed	40	cake	came	Cave
	buff	bun	buck		mad	mass	man		led	shed	red		cane	case	cape
2	kin	kid	kick	15	hop	cop	shop	28	sane	sake	safe	41	fang	bang	hang
	king	kit	kill		mop	pop	top		save	same	sale		sang	gang	rang
3	peak	peach	peas	16	sack	sad	sap	29	pit	pin	pig	42	law	saw	paw
	peal	peace	peat		sag	sat	sass		pill	pick	pip		jaw	raw	thaw
4	dig	wig	big	17	say	pay	may	30	heel	peel	keel	43	rake	rate	ray
	fig	pig	rig		gay	way	day		feel	eel	reel		raze	race	rave
5	fold	sold	gold	18	heath	heave	heap	31	toil	boil	foil	44	dip	dim	din
	hold	cold	told		heat	heal	hear		coil	oil	soil		dill	did	dig
6	kick	lick	sick	19	tame	came	fame	32	fig	fizz	fit	45	tear	teal	teak
	tick	wick	pick		same	name	game		fib	fin	fill		team	tease	teach
7	path	pack	pass	20	page	pane	pace	33	mark	bark	dark	46	tin	fin	sin
	pat	pad	pan		pave	pale	pay		lark	hark	park		win	pin	din
8	beat	beak	beach	21	dust	gust	must	34	bash	bat	ban	47	seethe	seek	seen
	beam	bean	bead		bust	just	rust		back	bath	bad		seed	seep	seem
9	pot	hot	lot	22	pun	puff	pup	35	will	hill	kill	48	run	bun	fun
	not	tot	got		pub	pus	puck		bill	fill	till		sun	nun	gun
10	fit	hit	bit	23	then	den	ten	36	pale	sale	bale	49	neat	beat	seat
	sit	kit	wit		pen	hen	men		gale	male	tale		meat	feat	heat
11	sup	sub	sud	24	cuss	cud	cup	37	duck	dud	dung	50	lip	hip	dip
	sum	sun	sung		cut	cub	cuff		dun	dug	dub		sip	rip	tip
12	dent	tent	rent	25	hook	shook	book	38	sit	sip	sill				
	went	sent	bent		took	cook	look		sick	sin	sing		**Score**		
13	best	west	nest	26	late	lake	lay	39	tack	tan	tab				
	vest	test	rest		lame	lane	lace		tang	tam	tap				

1

sick	kick
tick	wick
pick	lick

2

feat	heat
neat	meat
seat	beat

3

pup	pun
puff	pus
puck	pub

4

look	hook
took	shook
cook	book

5

rip	lip
hip	dip
tip	sip

6

ray	rate
raze	rave
race	rake

7

rang	hang
fang	gang
bang	sang

8

bill	hill
kill	will
fill	till

9

math	mass
mad	man
map	mat

10

male	pale
tale	gale
sale	bale

11

save	safe
sane	same
sale	sake

12

peach	peas
peal	peak
peace	peat

13

kin	kit
kill	kid
kick	king

14

sat	sap
sass	sag
sack	sad

15

sin	sit
sip	sick
sill	sing

16

sold	cold
told	hold
gold	fold

17

but	bun
bus	buck
bug	buff

18

lay	late
lane	lake
lame	lace

19

fun	run
gun	bun
nun	sun

20

dust	gust
bust	just
must	rust

21

pan	pack
pat	pad
pass	path

22

dill	din
dim	dip
dig	did

23

wit	sit
bit	kit
fit	hit

24

fin	win
sin	din
pin	tin

25

tear	teach
teak	tease
teal	team

26

sent	rent
dent	went
bent	tent

27

sum	sup
sud	sub
sung	sun

28

led	bed
fed	red
wed	shed

29

tot	hot
got	not
lot	pot

30

duck	dung
dun	dud
dub	dug

31

pig	pip
pill	pit
pin	pick

32

seep	seethe
seek	seed
seen	seem

33

way	pay
gay	say
day	may

34

vest	best
test	nest
rest	west

35

pale	pace
pay	pane
pave	page

36

ban	back
bath	bash
bad	bat

37

shop	mop
cop	top
pop	hop

38

rig	fig
dig	wig
pig	big

39

tam	tap
tack	tang
tan	tab

40

cake	came
cave	case
cape	cane

41

name	game
tame	same
fame	came

42

soil	coil
oil	toil
foil	boil

43

fin	fit
fib	fig
fizz	fill

44

cut	cud
cub	cuff
cuss	cup

45

keel	reel
eel	heal
feel	peel

46

mark	lark
dark	hark
bark	park

47

heath	hear
heap	heave
heal	heat

48

den	then
hen	men
ten	pen

49

thaw	raw
law	jaw
saw	paw

50

bead	beach
beat	bean
beak	beam

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Section 8.3
CBRN APR Communication Performance Test Data Collection Sheet

TN # : _____ MRT Trial # : _____ Speaker ID # : _____

Word List # : _____ Please Circle: Masked Unmasked

Number of words correctly spoken by the MRT Speaker: _____

Listener #1 ID: _____

1. % of Words Answered Correctly = _____
2. Adjusted Score = _____

Listener #2 ID: _____

1. % of Words Answered Correctly = _____
2. Adjusted Score = _____

Listener #3 ID: _____

1. % of Words Answered Correctly = _____
2. Adjusted Score = _____

Background Noise (w/o pink noise): _____

Pink Noise Before Session: _____

Pink Noise Middle of Session: _____

Pink Noise After Session: _____

Revision History

Revision	Date	Reason for Revision
0	15 September 2004	Historic document
1.1	22 December 2005	Update header and format No changes to method
2.0	31 October 2007	Significant changes – Section 4.3 added to address required precision and accuracy of instrumentation; changes to Table 2; additional word lists, and deleted instructions specific to having the test performed by a third-party laboratory.

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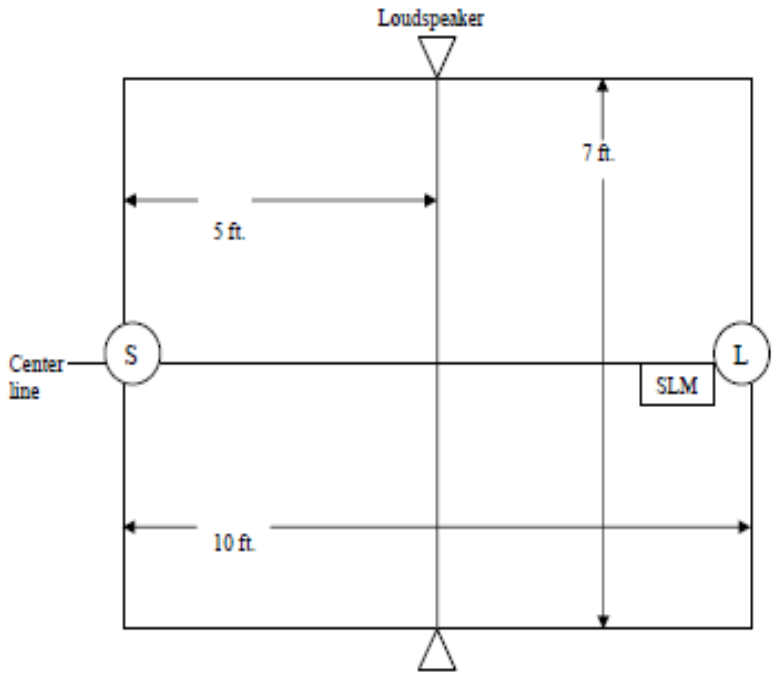
Appendix F

Room set-up for Modified Rhyme Test



Legend:
S – Speaker
L – Listener
SLM – Sound level meter

Appendix G

Survey for ICU Staff – N95 FFRs

Survey for ICU Staff – N95 Respirators

Personal Anonymous Code

Please complete the following to create your Personal Anonymous Code. Since you are the only one who knows the answers to these questions, it will ensure anonymity but will allow any future surveys to be linked to this one – without anyone knowing your identity. This code will only be used for the purposes of this project.

First letter of your father's last name	
First letter of your mother's first name	
How many letters in your first name (enter 9 if >9)	
Last number of your year of birth	
First letter of the town of your birth	

Site:	❑ ARH ❑ RCH ❑ SMH	**Date:**	

Gender: ❑ Female ❑ Male
Status: ❑ Full-time ❑ Part-time ❑ Casual

Years of healthcare experience: _____

Years in current position: _____

N95s Respirators in Use in Fraser Health

Prior to this study, have you ever worn an N95 respirator?	❑ Yes ❑ No
Have you been fit-tested to an N95 respirator in the past year?	❑ Yes ❑ No

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
An N95 respirator that I have fit-tested to is readily available for me to use at the beginning of my shift					
The N95 respirator is comfortable to wear					
The N95 respirator does not interfere with my ability to provide patient care					
The N95 respirator does not interfere with the ability of coworkers, patients, or visitors, to understand what I am saying					
The use of the N95 respirator does not alarm or concern patients or visitors					

Appendix H

Survey for ICU Staff – Reusable Respirators

Survey for ICU Staff – Reusable Respirators

Personal Anonymous Code

Please complete the following to create your Personal Anonymous Code. Since you are the only one who knows the answers to these questions, it will ensure anonymity but will allow any future surveys to be linked to this one – without anyone knowing your identity. This code will only be used for the purposes of this project.

First letter of your father's last name	
First letter of your mother's first name	
How many letters in your first name (enter 9 if >9)	
Last number of your year of birth	
First letter of the town of your birth	

Site: ❑ ARH ❑ RCH ❑ SMH **Date:**

Gender: ❑ Female ❑ Male

Status: ❑ Full-time ❑ Part-time ❑ Casual

Shiftwork: ❑ Day ❑ Night ❑ Both (rotate)

Years of healthcare experience: _____

Years in current position: _____

Prior to this study, have you ever worn a reusable respirator? ❑ Yes ❑ No

Since the beginning of this study, approximately how many times have you worn a reusable respirator?
❑ None ❑ 1-10 ❑ 11-20 ❑ 21-50 ❑ >50

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
A reusable respirator is readily available for me to use at the beginning of my shift					
The process of wiping the respirator DURING the shift after exiting the isolation room is <u>not</u> onerous					
My reusable respirator can be easily stored during my shift					
The reusable respirator is comfortable to wear					
The reusable respirator does not interfere with my ability to provide patient care					
The reusable respirator does not interfere with the ability of coworkers, patients, or visitors, to understand what I am saying					
The use of the reusable respirator does not alarm or concern patients or visitors					
I feel that I know enough to wear the elastomeric half-facepiece respirator (EHFR) safely					
I feel the EHFR fits adequately					

	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
I feel the fit check can adequately identify it is fitting me properly					
I fell confident that the respirator fits me properly					
I feel this respirator offers me more protection than I need					

Were there any times since the last survey that you were unable to wear a reusable respirator?

❑ Yes ❑ No

If so, please describe the reason(s) why: _____

_____

_____

Appendix I

Audit / Observation Tool - ICU

Audit / Observation Tool - ICU

To be initiated at shift change.

Site:	❑ ARH ❑ RCH ❑ SMH	**Date:**	
Time:			

CURRENT SHIFT

1. Are there any patients on airborne precautions or other precautions requiring staff to wear respiratory protection?

   ❑ Yes ❑ No

   Number of patients on airborne precautions: _____

   Number of staff using EHFRs: _____

2. Number of ICU staff working in department during this shift: _____

3. Number of clean* reusable respirators available at the beginning of the shift: _____

   (*found in the respirator bins labeled "CLEAN"; respirators that have been cleaned and disinfected in SPD)

   Is this number sufficient based on the number of airborne precautions, number of ICU staff, and rotation?

   ❑ Yes ❑ No

Comments:

PREVIOUS SHIFT (refer to SPD staff log sheet located in ICU on soiled respirator container):

4. Were there any reusable respirators used during the previous shift?

   ❑ Yes – how many ____ ❑ No

   If yes, what time were they picked up? _____

Comments:

5. Are respirators appropriately labeled/identified with the individual staff member's name during the shift?

   Number of respirators in use: ____

   Number appropriately labeled: ____

   Number NOT appropriately labeled: ____

Comments:

Appendix J

Drop-off Log for SPD Staff – Reusable Respirators

Drop-off Log for SPD Staff – Reusable Respirators

Site:	❑ ARH	❑ RCH	❑ SMH

Month:		
Date	**Drop-off time**	**Number of respirators**

Appendix K

Pick-up Log for SPD Staff – Reusable Respirators

Pick-up Log for SPD Staff – Reusable Respirators

Site:	❑ ARH	❑ RCH	❑ SMH

Month:		
Date	**Pick-up time**	**Number of respirators**

Appendix L

MRT scores for all subjects

MRT Scores for ARH

EHFR SIZE	N95 Score	EHFR Score
Small	47	46
Small	45	46
Medium	48	45
Small	48	41
Medium	47	46
Medium	47	46
Small	48	46
Medium	46	45
Medium	43	34
Small	46	40
Small	50	45
Small	45	45
Small	46	42
Small	44	43
Small	40	34
Small	47	35
Medium	49	43
Medium	47	42
Small	47	44
Small	43	39
Small	46	45
Small	47	44
Medium	50	49
Small	47	39
Small	49	46
Small	45	44
Small	48	40
Small	40	35
Medium	44	42
Small	39	35

MRT Scores for SMH

EHFR SIZE	N95 Score	EHFR Score
Small	45	34
Small	47	41
Small	47	41
Medium	45	42
Small	45	43
Medium	49	46
Small	46	46
Small	50	43
Medium	44	44
Medium	48	48
Small	42	45
Small	49	48
Small	50	48
Medium	49	47
Small	49	48
Small	48	45
Small	47	41
Medium	46	40
Small	48	42
Small	46	39
Medium	46	46
Small	47	44
Small	43	43
Medium	47	47
Small	44	43
Medium	49	46
Medium	44	45
Medium	44	43
Small	47	42
Small	45	44
Small	43	46
Small	47	45
Small	47	43
Medium	44	42
Small	44	44
Medium	47	45
Small	49	50
Small	45	45
Small	50	47
Medium	50	50
Small	50	47
Small	44	43
Medium	47	50
Medium	49	48
Medium	49	50
Medium	40	44
Small	45	39
Small	46	42
Small	50	47
Small	47	44

MRT Scores for RCH

EHFR SIZE	N95 Score	EHFR Score
Small	45	38
Medium	49	45
Medium	47	43
Large	49	46
Small	47	44
Small	44	41
Small	47	43
Medium	49	47
Small	48	44
Small	43	38
Small	46	37
Medium	45	38
Small	43	42
Medium	45	39
Medium	48	47
Small	46	42
Small	44	45
Medium	50	40
Medium	48	43
Small	48	45
Medium	47	44
Small	46	45
Small	47	44
Small	46	44
Small	46	42
Small	45	40
Small	38	36

Appendix M

3M Guidelines for cleaning, sanitizing and disinfecting Reusable Respirators and Powered Air Purifying Respirators (PAPRs)

3M Canada Company
Compagnie 3M Canada

P. O. Box / C.P. 5757
London, Ontario N6A 4T1

June 16, 2009

Guidelines for cleaning, sanitizing and disinfecting Reusable Respirators and Powered Air Purifying Respirators (PAPRs)

3M has received a number of inquiries regarding the use of respiratory protection for exposure to Influenza A (H1N1) and cleaning instructions for reusable respirator and powered air purifying respirators (PAPRs). At this time, Health Canada has not provided specific instructions for cleaning equipment nor disinfecting product specific for Influenza A (H1N1). Information is provided below regarding a few types of disinfectant products. Your facility should review this information thoroughly prior to selecting the disinfecting product for your equipment and specific application.

Before using any of the 3M products or information detailed herein, you must evaluate it and determine if it is suitable for your intended use. You assume all risks and liability associated with such use. 3M makes no warranties relating to the efficacy of any of the 3M products detailed herein in preventing the spread and/or contraction of the Influenza A (H1N1) virus. 3M will not be liable for any loss or damage arising from the 3M product or any information contained herein, whether direct, indirect, special, incidental or consequential, regardless of the legal theory asserted, including warranty, contract, negligence or strict liability.

Frequently Asked Questions (FAQs)

How can I clean, sanitize and/or disinfect reusable respirators and PAPRs?
The Canadian Standards Association (CSA) Standard Z94.4-02 on Selection, Use, and Care of Respirators mandates cleaning and sanitizing as part of the care and maintenance program. The CSA requires the user to follow the respirator manufacturer's instruction, or procedures authorized by the program administrator in consultation with the manufacturer, or CSA recommended procedures for cleaning and sanitizing, Appendix F.

The CSA recommends the following chemical agents for sanitizing:

Hypochlorite Solution	50 ppm/vol of chlorine made by adding approx. 1 mL of laundry bleach to 1L of water at 43° C (110° F)
Aqueous solution of Iodine	50 ppm/vol of iodine made by adding approx. 0.8 mL of tincture of iodine to 1L of water at 43° C (110° F)

Refer to the User Instructions for your specific elastomeric facepiece or Powered Air Purifying Respirator (PAPR) unit and headgear to identify the components that can be cleaned. For example: filters cannot be cleaned or disinfected and should be properly disposed of; and

breathing tubes with noise dampening materials cannot be immersed in any water or cleaning fluids.

3M Canada offers a variety of low and intermediate-level Health Canada D.I.N. (drug identification number) disinfectant cleaners that are hospital grade quaternary ammonium based. Some of these 3M disinfectant cleaners are sold as a concentrate which is then further diluted using the 3M™ Twist 'n Fill™ System to yield ready-to-use solutions and one which is sold as a ready-to-use product (no further dilution required). Please refer to the material safety data sheets (MSDS) for details on these products.

	Disinfectant Type	Packaged Format	Approximate Average Yield
Twist 'n Fill™ Neutral Disinfectant Cleaner No. 23	Low-level	2L concentrate	227 L ready-to-use
Twist 'n Fill™ Quat Disinfectant Cleaner No.5	Low-level	2L concentrate	240 L ready-to-use
TB Quat Disinfectant Ready-to-Use Cleaner	Intermediate-level	1L ready-to-use	1L ready-to-use

These disinfectant cleaners are effective against a broad range of bacteria, viruses and fungi on hard non-porous surfaces. In Canada, the TB Quat Disinfectant Ready-to-Use Cleaner is the only 3M disinfectant cleaner product with claims against tuberculosis. In Canada, the 3M Neutral Disinfectant Cleaner No. 23 and 3M Quat Disinfectant Cleaner No. 5 have claims against Influenza Type A virus. Please review the specific claims for each product prior to selecting a cleaner.

With any disinfecting agent, follow the User Instructions in regards to usability, application and contact time, and ensure all components are thoroughly rinsed with fresh, warm water and thoroughly dried before use or storage. It is important to follow the User Instruction inspection procedures supplied with each elastomeric facepiece or PAPR unit and headgear to identify any damage or deterioration of components and replace them as necessary.

Note: Components of elastomeric respirators or PAPR respiratory systems may become damaged over time with prolonged or extended use of disinfecting products.

Are the 3M disinfectant cleaner products Health Canada D.I.N. registered?
Yes.

	Health Canada D.I.N.
Twist 'n Fill™ Neutral Disinfectant Cleaner No. 23	02268620
Twist 'n Fill™ Quat Disinfectant Cleaner No.5	02091852
TB Quat Disinfectant Ready-to-Use Cleaner	02292653

If I do not have a 3M disinfectant cleaner product can I use another disinfectant cleaner?
Consider an equivalent hospital grade quaternary ammonium disinfectant cleaner or another Health Canada DIN registered disinfectant cleaner that has been tested for efficacy against the targeted organisms or family of organisms.

Will the 3M quat disinfectant products damage my respirators?
Components of elastomeric respirators or PAPR respiratory systems may become damaged over time with prolonged or extended use of disinfecting products. Systems should be inspected by the end user following each disinfecting cycle and prior to re-use.

3M conducted limited testing with the Twist 'n Fill™ Cleaner No. 5 and No. 23 on 3M half and full facepiece elastomeric respirators and some components of PAPRs. After visual inspection, no physical damage was noted, however, a slight odor remained in some cases.

Can I use other disinfectants registered by Health Canada specifically against the Influenza Type A virus to clean my respirator?
Health Canada lists many disinfectant products registered with a D.I.N. specifically against the Influenza Type A virus. However, 3M has not evaluated if these alternative disinfectant products will damage the cleanable elements of the respirators. If you choose to use one of these cleaners to sanitize and/or disinfect your respirator and its components, please be aware that it has not been evaluated by 3M with regards to compatibility with the respirator system and proceed accordingly.

Can disposable respirators, reusable facepieces and Powered Air Purifying Respirators (PAPRs) be sterilized prior to reuse?
No, sterilization processes such as ethylene oxide, radiation and steam sterilization will damage the components and should not be used.

How do I clean, sanitize and/or disinfect my respirator?
For all types of respirators follow the hygiene and infection control practices established by your employer for the targeted organisms or for Influenza A (H1N1)

Then follow the recommendations below for your specific type of respirator. Cleaning is recommended after each use. Nitrile or vinyl gloves should be worn during cleaning and other personal protective equipment (PPE) as indicated. It is important to follow all steps.

Reusable 6000, 7500 and 7800 series respirators

1. Remove cartridges and/or filters
2. Clean facepiece (excluding filters and cartridges), with 3M™ Respirator Wipes 504 or by immersing in a warm, mild pH neutral (pH 6-8) detergent cleaning solution. The water temperature should not to exceed 49°C (120°F). Scrub with a soft brush until clean. Do not use detergents that contain lanolin or other oils, gasoline (petrol), chlorinated degreasing fluids (such as trichloroethylene), organic solvents or abrasive cleaning agents. Equipment machine cleaning may be utilized provided facepieces are held in a stationary position and temperatures do not exceed 49°C (120°F).

3. Soak the facepiece in a ready-to-use solution of a hospital grade hard surface, non-porous disinfectant cleaner such as one of the 3M quat disinfectant cleaners listed above. Follow the user instructions for the product selected, including contact time required.
4. Rinse in fresh, warm water and air dry in a non-contaminated atmosphere.
5. The cleaned respirator should be stored away from contaminated areas when not in use.

3M™ GVP Powered Air Purifying Respirator (PAPR)

1. Disconnect breathing tube from any attached headgear.
2. Disconnect other end of breathing tube from GVP-100 PAPR assembly.
3. Remove the battery and blower assembly from the waist belt.
4. Tight fitting facepieces can be cleaned as noted above. For all other headgear, clean all parts of the headgear assembly with a clean soft cloth dampened with warm 49°C (120°F) water containing a mild pH neutral (pH 6-8) detergent. Do not use detergents that contain lanolin or other oils, gasoline (petrol), chlorinated degreasing fluids (such as trichloroethylene), organic solvents or abrasive cleaning agents. Refer to the headgear specific User Instructions for cleaning details. Do not soak hoods during cleaning.
5. Headgear components should be wiped with a clean soft cloth dampened with a ready-to-use solution of a hospital grade hard surface disinfectant cleaner such as one of the 3M disinfectant cleaners listed above. Follow the user instructions for the product selected. Efficacy specifically against Influenza A (H1N1) virus has not been demonstrated with the 3M quat disinfectant cleaners listed above. Do not soak hoods in disinfecting products.
6. Wipe all components with a clean soft cloth dampened with clean warm 49°C (120°F) water.

Clean the remaining parts of the system as follows. You should not use solvents to clean the motor/blower unit or battery case as they may chemically weaken the plastics. Do not use detergents that contain lanolin or other oils , gasoline (petrol), chlorinated degreasing fluids (such as trichloroethylene), organic solvents or abrasive cleaning agents.

7. Remove the filter/cartridge from the blower assembly. Properly dispose of the used filter/cartridge according to local regulations. Do not attempt to clean the filter/cartridge.
8. Wipe the battery pack with mild cleaning solution. Do not immerse the battery pack.
9. Clean the breathing tube by wiping down with a soft cloth dampened with a warm water and mild detergent solution then wipe with a cloth dampened with clean water. Air dry in uncontaminated atmosphere, temperature not to exceed 49°C (120°F). Alternatively, the breathing tube can be immersed in the cleaning solution. If this is done, the breathing tube must be rinsed in clean water, hung vertically and allowed to completely air dry prior to reuse or storage. The breathing tube can also be connected to the motor blower and air forced through the breathing tube until dry.
10. Screw the blower plug and filter plug (GVP-115 consists of both plugs) into the motor blower unit.

11. With the plugs in place the unit can be rinsed with a mild cleaning solution or it can be placed in an equipment washer. Do not expose to cleaning or drying temperatures greater than 49°C (120°F).
12. Wipe the components with a clean soft cloth dampened with a ready-to-use solution of a hospital grade hard surface disinfectant cleaner such as one of the 3M quat disinfectant cleaners listed above. Follow the user instructions for the product selected. Efficacy specifically against Influenza A (H1N1) virus has not been demonstrated with the 3M quat disinfectant cleaners listed above.
13. Wipe all components with a clean soft cloth dampened with clean warm 49°C (120°F) water.
14. Reassemble unit as described in the GVP User Instructions.
15. After cleaning, the PAPR unit and headgear should be inspected following the inspection procedures in the User Instructions for that item.

3M™ Breathe Easy™ Turbo Blower/Filtration Unit

1. Disconnect breathing tube from any attached headgear.
2. Disconnect other end of breathing tube from PAPR assembly.
3. Remove the battery and blower assembly from the waist belt.
4. Tight fitting facepieces can be cleaned as noted above. For all other headgear, clean all parts of the headgear assembly with a clean soft cloth dampened with warm 49°C (120°F) water containing a mild pH neutral (pH 6-8) detergent. Do not use detergents that contain lanolin or other oils, gasoline (petrol), chlorinated degreasing fluids (such as trichloroethylene), organic solvents or abrasive cleaning agents. Refer to the headgear specific User Instructions for cleaning details. Do not soak hoods during cleaning.
5. Wipe headgear components with a clean cloth dampened with a ready-to-use solution of a hospital grade hard surface disinfectant cleaner such as one of the 3M quat disinfectant cleaners listed above. Follow the user instructions for the product selected. Efficacy specifically against Influenza A (H1N1) virus has not been demonstrated with the 3M quat disinfectant cleaners listed above. Do not soak hoods in sanitizer.
6. Wipe all components cleaned with a clean soft cloth dampened with clean warm 49°C (120°F) water.

Clean the remaining parts of the system as follows. You should not use solvents to clean the motor/blower unit or battery case as they may chemically weaken the plastics. Do not use detergents that contain lanolin or other oils, gasoline (petrol), chlorinated degreasing fluids (such as trichloroethylene), organic solvents or abrasive cleaning agents.

7. Remove the filter cartridges from the Turbo PAPR blower assembly. Properly dispose of the used filter/cartridge according to local regulations. Do not attempt to clean the filter/cartridge.
8. Wipe the battery pack with a mild cleaning solution. Do not immerse the battery pack.
9. Clean the breathing tube by wiping down with a clean soft cloth dampened with a warm water and mild detergent solution then wipe with a cloth dampened with clean water. Air dry in uncontaminated atmosphere, temperature not to exceed 49°C (120°F). Alternatively, the breathing tube can be immersed in the cleaning solution. If this is done, the breathing tube must be rinsed in clean water, hung vertically and allowed to

completely air dry prior to reuse or storage. The breathing tube can also be connected to the motor blower and air forced through the breathing tube until dry.

10. Clean the Turbo blower unit by wiping down with a soft cloth dampened with a warm water and mild detergent solution then wipe with a cloth dampened with clean water. Do not immerse the Turbo PAPR blower unit. Be careful not to let any of the cleaning solution enter into the Turbo PAPR blower unit. Air dry in uncontaminated atmosphere, temperature not to exceed 49°C (120°F).
11. Wipe components with a clean soft cloth dampened with a ready-to-use solution of a hospital grade hard surface disinfectant cleaner such as one of the 3M disinfectant cleaners listed above. Follow the user instructions for the product selected.
12. Wipe all components cleaned with a clean soft cloth dampened with clean warm 49°C (120°F) water.
13. Reassemble unit as described in the user instructions. Efficacy specifically against Influenza A (H1N1) virus has not been demonstrated with the 3M quat disinfectant cleaners listed above.
14. After cleaning the PAPR unit and headgear should be inspected following the inspection procedures in the User Instructions for that item.

3M™ Air-Mate™ Powered Air Blower/Filtration Unit

1. Disassemble the breathing tube from the headgear. From the inside of the headgear push the breathing tube connector out of the head gear receiver. Twist the end of the breathing tube (that is attached to the unit) counterclockwise to separate the breathing tube from the unit.
2. Remove blower assembly from the waist belt.
3. Clean all parts of the headgear assembly with a clean soft cloth dampened with warm 49°C (120°F) water containing a mild pH neutral (pH 6-8) detergent. Do not use detergents that contain lanolin or other oils, gasoline (petrol), chlorinated degreasing fluids (such as trichloroethylene), organic solvents or abrasive cleaning agents. Refer to the headgear specific User Instructions for cleaning details. Do not soak the headgear during cleaning.
4. Wipe the headgear with a clean soft cloth dampened with a ready-to-use solution of a hospital grade hard surface disinfectant cleaner such as one of the 3M quat disinfectant cleaners listed above, ensuring contact time as outlined on quat disinfectant cleaner label. Follow the user instructions for the product selected. Do not soak the headgear. Efficacy specifically against Influenza A (H1N1) virus has not been demonstrated with the 3M quat disinfectant cleaners listed above.
5. Wipe all components with a clean soft cloth dampened with clean warm 49°C (120°F) water.

Clean the remaining parts of the system as follows. You should not use solvents to clean the motor/blower unit or battery case as they may chemically weaken the plastics. Do not use detergents that contain lanolin or other oils, gasoline (petrol), chlorinated degreasing fluids (such as trichloroethylene), organic solvents or abrasive cleaning agents.

Clean the breathing tube by wiping down with a soft cloth dampened with a warm water and mild detergent solution then wipe with a cloth dampened with clean water. Air dry in uncontaminated atmosphere, temperature not to exceed 49°C (120°F). Alternatively, the breathing tube can be immersed in the cleaning solution. If this is done, the breathing tube must be rinsed in clean water, hung vertically and allowed to completely air dry prior to reuse or storage. The breathing tube can also be connected to the motor blower and air forced through the breathing tube until dry.

6. Clean the Air-Mate PAPR blower unit by wiping down with a soft cloth dampened with a warm water and mild pH neutral detergent solution then wipe with a cloth dampened with clean water. Do not immerse the Air-Mate PAPR blower unit. Be careful not to let any of the cleaning solution enter into the Air-Mate PAPR blower unit. Air dry in uncontaminated atmosphere, temperature not to exceed 49°C (120°F).
7. Wipe components with a clean soft cloth dampened with a ready-to-use solution of a hospital grade hard surface disinfectant cleaner such as one of the 3M quat disinfectant cleaners listed above. Follow the user instructions for the product selected. Efficacy specifically against Influenza A (H1N1) virus has not been demonstrated with the 3M quat disinfectant cleaners listed above.
8. Wipe components with a clean soft cloth dampened with clean warm 49°C (120°F) water.
9. If necessary, open the Air-Mate blower unit and remove the filter from the blower assembly. Properly dispose of the used filter according to local regulations. Do not attempt to clean the filter.
10. Wipe the battery pack with mild cleaning solution, if necessary (battery is enclosed in the unit and protected by the filter). Do not immerse the battery pack. Then wipe with a clean soft cloth dampened with clean warm 49°C (120°F) water.
11. Reassemble unit as described in the Air-Mate User Instructions.
12. After cleaning, the PAPR unit and headgear should be inspected following the inspection procedures in the User Instructions for that item.

Note: Technical information provided by 3M is based on experience and/or test data believed to be reliable but the results may not be relevant to every user's application. For this reason 3M does not accept any responsibility or liability, direct or consequential, arising from reliance upon any information provided. The user should determine the suitability of any disinfectant product for compatibility for use with 3M OH&ES products.

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Glossary of Terms:

Cleaning: Removal of all soil (organic and inorganic) and foreign material from objects and surfaces. This is typically accomplished with water and mechanical action. Detergents may be used to assist the process.

Note: Failure to remove foreign material (soil, lubricants, etc.) from an object can make the disinfecting process ineffective.

Disinfecting: A process of inhibiting or destroying disease-producing microorganisms, but may not kill bacterial spores. It usually involves the use of chemicals, heat and/or ultraviolet light and is divided into three categories: high, intermediate and low level disinfection.

Sanitizing: A process to reduce the number of microorganisms on an inanimate object to "safe" levels, but may not destroy disease-producing organisms, e.g., dishes and eating utensils are normally sanitized.

Sterilizing: A validated process to render a product free of all forms of viable microorganisms including bacteria, viruses, spores and fungi.

Note: Items must be thoroughly cleaned before effective sterilization can occur.

References for Terms
Rutala, WA. American Journal of Infection Control. APIC Guideline for Selection and Use of Disinfectants. Vol. 24, No. 4, pp. 313-342, August 1996.
Rutala, WA. CDC. Guideline for Disinfection and Sterilization in Healthcare Facilities. 2008.

Appendix N

Procedures for Cleaning and Disinfection of Reusable Respirators at ARH, RCH and SMH

fraserhealth Better health. Best in health care.	Site: ARH Reference Number: VII-I-301k	
ITEM #	Page 1 of 2	
DEPARTMENT: STERILE PROCESSING	DATE: FEB 13-12	REVISED:
DISTRIBUTION: ICU, DECONTAM II /STERI-PEEL	DEVELOPED BY: M. HANDLEY	
	VERIFIED BY: T. HERD	

REUSABLE RESPIRATOR

PREVIOUS NAME:

PURPOSE: **Cleaning and Disinfection of reusable respirators**

DECONTAM: THERE IS A BIN UNDER THE SINK FILLED WITH SUPPLIES NECESSAY FOR THE CLEANING OF THE RESPERATOR MASKS

1. Cleaning - Fill lukewarm water in the sink near the ultrasonic designated for the cleaning of the Respirators up to the bottom of the green line. This is approximately 21 litres of water
   - Add 105 ml of *Neutrawash* (based on 5ml per litre of water)
   - Immerse the respirators in the neutral detergent solution for 2 mins.
   - Flip respirators onto the other side and immerse for another 2 mins.
   - Scrub crevices under water with brushes, swabs, or pipe cleaners for 30 seconds or until visible soil is removed (whichever is longer)
   - Rinse in warm running tap water
   - Remove excess water prior to disinfection

REUSABLE RESPIRATOR

2. Disinfection – Fill lukewarm water in the designated sink, up to the bottom of the green in mark. This is approximately 21 litres of water
   - Add 21 ml of bleach to water in sink (based on 1ml per litre of water)
   - Immerse the respirators in the bleach solution for 10 mins.
   - Flip respirators onto the other side and immerse for another 10 mins.
   - Scrub respirator crevices, openings and holes under water with brushes, swabs, or pipe cleaners for 1 minute
   - Rinse in warm running tap water
   - When Respirator has been rinsed thoroughly place it in the clean marked bin kept under the sink. Line the bin with a clean huck towel. Pass the bin to the clean side to dry
   - **AIR DRY ONLY. DO NOT PLACE IN DRYER**
3. When the Respirator is dry place it in a plastic bag marked clean and return it to ICU for storage

EQUIPMENT: Reusable Respirator

LOCATION: Return to ICU for storage

INVENTORY: Varies

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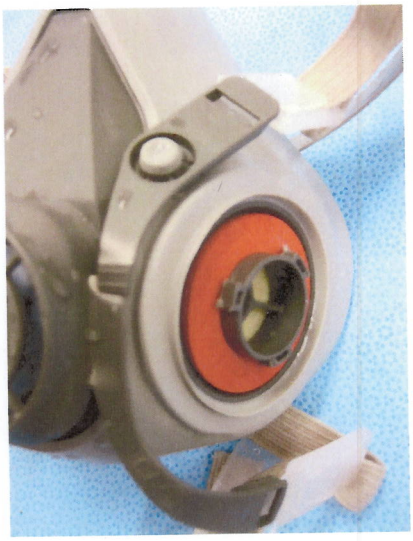
ITEM #	Page 1 of 2
DEPARTMENT: STERILE PROCESSING	DATE: JAN 20, 2012 REVISED:
DISTRIBUTION: DECONTAM/ASSEMBLY	DEVELOPED BY: SONA JASSAL
	VERIFIED BY: SITE COORDINATOR/EHS

REUSABLE RESPIRATOR



PREVIOUS NAME:

PURPOSE: **Cleaning and Disinfection of reusable respirators**

DECONTAM:

1. Cleaning - Fill lukewarm water in 'Sink 3' of 'Bay 1', up to the bottom of the red line/mark. This is approximately 43 litres of water
   - Add 215 ml of *Neutrawash* (based on 5ml per litre of water)
   - Immerse the respirators in the neutral detergent solution for 2 mins.
   - Flip respirators onto the other side and immerse for another 2 mins.
   - Scrub crevices under water with brushes, swabs, or pipe cleaners for 30 seconds or until visible soil is removed (whichever is longer)
   - Rinse in warm running tap water
   - Remove excess water prior to disinfection

REUSABLE RESPIRATOR

2. Disinfection – Fill lukewarm water in the Rubbermaid container, up to the built in mark. This is approximately 13 litres of water
   - Add 13 ml of bleach solution (based on 1ml per litre of water)
   - Immerse the respirators in the neutral detergent solution for 10 mins.
   - Flip respirators onto the other side and immerse for another 10 mins.
   - Scrub respirator crevices, openings and holes under water with brushes, swabs, or pipe cleaners for 1 minute
   - Rinse in warm running tap water
   - Air dry respirators with gun and then hang above sink, on clean side, overnight (***Please Note: Respirators can't go in the dryer***)

3. Call ICU for pick-up of clean respirators (local 52-4576)

EQUIPMENT: Reusable Respirator

ASSEMBLE: Air dry respirators with air gun on the clean side, and then hang them above the sink overnight.

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ITEM #	Page 1 of 2	
DEPARTMENT: STERILE PROCESSING	DATE: JAN 20, 2012	REVISED: January 31, 2012 YC
DISTRIBUTION: SPD MANUAL/DECONTAM	DEVELOPED BY: B.LIEW	
	VERIFIED BY: SITE COORDINATOR/EHS	

3M FACE MASK

PREVIOUS NAME:

PURPOSE: **Cleaning and Disinfection of reusable respirators**

DECONTAM:

Cleaning - Fill lukewarm water in Rubbermaid container (labelled **Neutrawash**), up to the built in curve or line. This is approximately 13 litres of water
Add 65 ml of Neutrawash (based on 5ml per litre of water)
Immerse the respirators in the neutral detergent solution for 2 mins
Flip respirators onto the other side and immerse for another 2 mins
Scrub crevices under water with brush (labelled **3M**) for 30 seconds or until visible soil is removed (whichever is longer)
Rinse in warm running tap water
Remove excess water prior to disinfection

3M FACE MASK

Disinfection – Fill lukewarm water in the Rubbermaid container (labelled **Bleach**), up to the built in curve or line. This is approximately 13 litres of water
Add 13 ml of bleach solution (based on 1ml per litre of water)
Immerse the respirators in the bleach/water solution for 10 mins
Flip respirators onto the other side and immerse for another 10 mins
Rinse in warm running tap water
Air dry respirators with gun and then place in Rubbermaid container (labelled **Dry**)

DO NOT PUT RESPIRATORS IN DRYER OR HANG TO DRY

Dispatch – Deliver to ICU

END OF DAY:

All bins are to be processed thru cartwasher and then returned to 3M Trolley in Decontam
Brush(s) are to be processed thru instrument washers and returned to 3M Trolley in Decontam

BRUSHES ARE NOT TO BE USED IN ANY OTHER AREA OF DECONTAM