# Qualitative Analysis of Origins and Evolution of an Elastomeric Respirator-based Hospital Respiratory Protection Program

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## ABSTRACT

Elastomeric respirators (elastomerics) may serve as one alternative to disposable N95 respirator use in healthcare. We explored factors which drove elastomeric adoption and continued use in a large academic medical center. We conducted semi-structured and focus group interviews in 2015 with a) 11 leadership key informants (KIs) with involvement in the respiratory protection program (RPP) when elastomerics were introduced and b) 11 healthcare workers (HCWs) recruited from hospital departments assigned to use elastomerics. Interview transcripts and responses were open-coded to capture emergent themes, which were collapsed into broader categories and iteratively refined. Factors identified by leadership KIs as influencing elastomeric adoption included: 1) N95 shortages during 2009's H1N1 influenza pandemic and 2) the presence of trained, certified safety professionals who were familiar with respiratory protection requirements. Factors identified as influencing ongoing use of elastomerics included: 1) cleaning/decontamination practices, 2) storage, 3) safety culture, 4) HCW respirator knowledge, and 5) risk perception. HCW users expressed dissatisfaction related to breathing, communication and cleaning of elastomerics. Other themes included convenience use of N95s rather than assigned elastomerics, despite perceptions that elastomerics are more protective. Through semi-structured and focus group interviews, we learned that 1) leadership introduced elastomerics due to necessity but now face challenges related to ongoing use, and 2) HCWs were not satisfied with elastomerics for routine care and preferentially used N95s because they were conveniently available at point of use. Although the impetus behind incorporation of elastomerics was clear, the most complex themes related to sustainability of this form of RPP. These themes were used to inform a broader questionnaire and will address the utility of elastomerics as a feasible and acceptable practical alternative to N95s in healthcare.

**Keywords: elastomeric respirator, N95 respirator; respiratory protection program; 2009 H1N1; pandemic; healthcare; reusable respirators; storage; decontamination; comfort; safety.**

# INTRODUCTION

Once considered a novel safety adjunct, respiratory protection for healthcare workers (HCWs) has evolved and is now a familiar fixture in the healthcare setting (CDC, 1999). Respiratory infectious disease pandemics trigger images of HCWs engaged in patient care wearing respiratory protective devices (RPDs). However, the care of patients being evaluated for more typical concerns, such as tuberculosis, also demands use of RPDs on a more routine basis. Especially during these day-to-day processes, gaps exist, such as marginal compliance with recommended hospital respiratory protection practices (Krah et al, 2016). Emergencies involving aerosol-transmissible infectious diseases add another layer of complexity on an already challenging situation

Respiratory protection planning for pandemic emergencies depends on existing knowledge and predictive modeling about how particular infectious agents are transmitted. The U.S. Department of Health and Human Services recommends that healthcare facilities stockpile a 6-8 week supply of disposable N95 filtering facepiece respirators (N95-FFRs) as part of pandemic preparedness (CDC, 2014). Previous pandemics (2002 SARS, 2009 H1N1 Influenza, and 2014 Ebola) have resulted in supply shortages in RPDs, leaving HCWs potentially exposed to airborne respiratory pathogens in the course of their work duties (Srinivasan et al, 2004; Mitchell et al., 2013; Beckman et al., 2013; National Academies of Science, Engineering, and Medicine, 2017). Future respiratory pandemics will surely occur; thus, solutions must be identified to address repeatedly experienced shortages of N95-FFRs (CDC, 2014; National Academies of Science, Engineering, and Medicine, 2017).

While one solution to preparing for respiratory pandemics includes stockpiling of N95-FFRs, barriers including storage space and possible N95-FFR expiration issues prevent this practice from easy implementation (CDC, 2014). Other solutions include extended use and limited reuse of N95-FFRs, but these techniques also have faced criticism due to concerns for contact transmission and lack of manufacturer recommendations and FDA clearance for reuse (CDC, 2014 (b)).

Another solution to averting N95-FFR supply shortages could be the inclusion of other respirator types, such as reusable half-face elastomeric respirators (ERs) as part of healthcare respiratory protection program (RPP) inventory. These ERs are commonly used outside of healthcare, such as in the manufacturing and construction sectors. In this scenario, each HCW is assigned his own respirator that can be cleaned after use and reused. Distributing respirators to individual workers could reduce the need for N95-FFR stockpiling, particularly if performed in advance of an emergency.

However, there are many unknowns regarding the use of ERs in healthcare, including availability at point of use, perceptions of interference with patient care activities, worker comfort, communication impairment, fear by patients, maintenance and decontamination, and storage (Ciconte & Danyluk, 2013, Shenal et al, 2012; Baracco et al, 2015, Bessessen et al, 2015, Subhash et al, 2015, Gosch et al, 2013, Radonovich et al, 2010, Baig et al, 2010). One large urban, US academic health system has used a combination of P100 filter-equipped ERs as part of its RPP since 2009 (Hines et al, 2016), along with disposable N95-FFRs and Powered Air-Purifying Respirators (PAPRs) in inpatient and ambulatory environments. The experiences of this site may thus, be extremely beneficial in informing many of the unknown questions about ER acceptance and use in healthcare.

As part of a larger study that aims to assess perceptions of and adherence to respiratory protection policies (including use of ERs) among HCWs and RPP leadership within a health system, we collected information using qualitative data acquisition approaches. Qualitative methods are particularly beneficial in understanding the motivation and beliefs of community members on a particular issue and in refining data collection efforts (Sherry & Marlow, 1999). The goal of this qualitative phase of the study was to understand the evolution of the organization's RPP, specifically how and why ERs became a standard part of the existing RPP. We also ascertained perceptions related to how the current RPP is

functioning and experiential data describing current actual use practices related to three types of available respirators currently in use. We performed Key Informant Interviews and a Focus Group interview to clarify response themes about respiratory protection perceptions, in order to create questionnaires to be used in a larger quantitative survey to understand whether ERs are a feasible and acceptable solution to N95-FFR shortages in healthcare settings.

# MATERIALS AND METHODS

We collected qualitative data in the spring of 2015 from Key Informants (KIs) and from HCW focus group participants from an urban, academic medical center where over 5600 employees are included in respiratory protection programs. From the KIs, we sought to understand a) the origins of the current RPP structure and b) decision logic regarding composition of respirator inventory. From both populations, we sought to obtain an assessment of stakeholders' opinions about the current functioning of the RPP. The study was approved by the university human research protections office institutional review board, and all participants provided written informed consent.

## Key Informant Interviews

KIs were selected based on known involvement with the organization's RPP during its evolution phase, when ERs were incorporated into use. The principal investigator (PI) contacted the KIs via email, informed them of the purpose of the study, and asked if they would participate in a face-to-face interview to be audio recorded and transcribed. Fifteen potential KIs were invited to participate; four individuals declined because of limited availability or limited involvement in the development of the RPP, and eleven participated in semi-structured interviews with the PI. Interviews were guided by a script and included questions about involvement in the RPP, how elastomeric respirators became incorporated into the program, and how KIs thought the RPP was working currently (see Appendix A "Key Informant Interview Script" for additional details). The KIs included leadership staff from departments of ambulatory and inpatient employee health, infection control, hospital epidemiology, occupational and environmental medicine, safety, human resources, quality and medical staff.

## Focus Group Interview

A separate focus group was formed and interviews conducted with eleven HCWs from areas of the hospital where workers are assigned to use ERs, including nurses, attending physicians, and respiratory therapists. These participants self-selected to participate by responding to flyers posted on nursing units, physician offices and in break rooms, emails disseminated by unit or division managers and/or announcements at shift-change or divisional meetings. The focus group occurred during the noon hour, and participants received lunch during the session. Participants were asked questions about the type of respirator assigned for their use, actual use practices, and how wearing their respirator integrates into their normal work practices (see Appendix B – Focus Group Script for additional details).

## Data Analysis

Thematic analysis of transcribed KI-interviews and the focus group interview was conducted using Excel and NVivo 10 qualitative software (Strauss, 1987; Charmaz, 2006; Bazeley & Jackson, 2013). Four researchers began by independently reading through transcripts and open coding responses to capture response themes emergent in the data. Identified themes were collapsed into broader categories during subsequent readings and iteratively refined through discussion with the larger research team until consensus was reached.

# RESULTS

A total of 11 KIs participated in the semi-structured interviews, and another 11 HCWs attended the focus group. Of the total 22 respondents, focus group participants and KIs were predominantly females (15 versus 7 males) and included 17 Caucasian, 3 African-American, and 2 Asian-American participants.

Major themes regarding the RPP emerged from KI responses and were derived through an iterative process progressing from identification of repeated factors mentioned in interviews, through refinement sorting where final common themes became apparent. These themes are displayed in Table I and are featured below.

**Table I. Qualitative Analysis of Response Themes from Key Informants and Focus Group Participants**

| Initial Codes* | Larger Categories[ǂ] | Final Themes [‡] | Description [§] |
|---|---|---|---|
| • **Impetus behind use of elastomeric respirators** | | Perceived origin of current respiratory protection program; Introduction of elastomeric respirators | Participants discuss how they believe the respiratory protection program came to exist, including how elastomeric respirators were introduced. |
| • **Introduction of program to staff** | | | |
| • **Key events surrounding program** | | | |
| • **Disposable respirator** | Knowledge and acceptance of respirators | Understanding the Respiratory Protection Program as it currently exists | Participants describe the respiratory protection program and policy as they understand it in its current form. |
| • **Elastomeric respirator** | | | |
| • **PAPR** | | | |
| • **Larger organizational structure** | Structure | | |
| • **Respiratory protection program structure** | | | |
| • **Cleaning and decontamination of respirators** | Respirator logistics | Perceived strengths of the program; Perceived barriers to the program | Participants discuss the strengths of the respiratory protection programs, as well as challenges to everyday implementation. |
| • **Economic and financial logistics** | | | |
| • **Storage of respirators** | | | |
| • **Use of respirators in emergency situations** | | | |
| • **Use of respirators in everyday situations** | | | |
| • **Problems of respiratory protection program** | Strengths and weaknesses | | |
| • **Proposed solutions to problems** | | | |
| • **Strengths of program** | | | |
| • **Risk assessment** | Safety discussions | Safety culture; Assessment of current state | Participants discuss what they consider to be important aspects of a safety culture, and if the current respiratory protection program contributes to such. |
| • **Safety compliance** | | | |
| • **Safety culture** | | | |
| • **Initial Staff training and fit testing** | Training | | |
| • **Re-training and re-fitting of respirators** | | | |

**Initial codes were identified from review of interview transcripts as factors repeatedly featured. [ǂ] Larger categories were created after analysis of the factors grouped as Initial Codes. [‡]Final themes emerged with collapse of the larger categories. [§]Describes the type of information derived from interview transcripts included in each final theme.*

## Perceived origin of the RPP and introduction of ERs

KIs linked the start of the RPP in its current form to key national events; for example, one person discussed the program emerging in response to the World Trade Center attacks of September 11, 2001 and subsequent anthrax attacks, while others mentioned the 2002-2003 SARS outbreak as the beginning of the present version of the RPP. However, most respondents were not yet employed at this site before 2008 (or not yet in their current RPP-affiliated role) and so were unable to comment further on the structure or content of the RPP during those times. The most frequently discussed event was the H1N1 pandemic of 2009 (Text box 1). Those who had knowledge of the RPP prior to 2009 mentioned that the pandemic caused it to be formalized and made more efficient.

Text box 1

*"Probably one of the biggest motivators toward cleaning up… or formalizing the program was the same one that brought us the elastomeric respirators in 2009-ish, the pandemic [H1N1]."-Key Informant*

KIs further discussed the H1N1 pandemic as the first time all staff felt susceptible and vulnerable, and this lead to efforts to provide hospital-wide protection. Guidelines from national authorities emerged, saying that respiratory protection was required for all staff caring for patients with suspected or confirmed H1N1 flu-like illness (CDC, 2009; OSHA, 2009; Institute of Medicine, 2009). A pandemic committee was convened to address respiratory protection at the medical center.

During the maturation of the RPP during the 2009 H1N1 outbreak, many different institutional stakeholders were involved in decision-making. This led to various different hospital-wide functional units being responsible for different aspects of the program. KIs stated that the number of committees involved created challenges in reaching consensus about the respiratory protection strategy (Text box 2), but the urgency of the situation forced resolution of differences. Responsibilities for the RPP were divided between functional units, but principally between the Employee Health program and the Safety program.

Text box 2

*"So I was asked to… be the facilitator of that group, to try and get us to consensus on things, which was challenging, … It was really difficult, because everyone came from different perspectives… It was this big, constant chess game." -Key Informant*

The idea of using ERs in a hospital setting was not completely foreign to this institution's respiratory protection leadership, as the medical center already possessed in 2009 a stock-pile of approximately 1200 ERs. The exact origin of these was unclear, but KIs recalled that they were ordered during or shortly after the 2003 SARS outbreak due to concerns about potential shortages. KIs agreed that in 2009, there was a shortage of disposable N9-FFRs due to the H1N1 outbreak. Attempts were made during the 2009 pandemic to procure N95-FFRs from multiple different vendors and from the Strategic National Stockpile, but availability was limited. Some participants mentioned that there was also a shortage of PAPRs during this time (Text box 3). In order to address these shortages, the pandemic committee decided to transition to the use of ERs, in addition to using available N95-FFRs and PAPRs. One KI integral to the evolution of the RPP was familiar with ERs from previous work experience outside of healthcare and saw them as reliable.

Text box 3

*"…with the [2009} pandemic…the perception was everybody's at risk, so we needed to provide these [elastomeric respirators] house-wide……We were happy to use any product we could get, within reason, that was protective of our staff." -Key Informant*

The committee deemed certain clinical units as being at or having higher risk than others, meaning that they were more likely to receive patients with suspected H1N1. These units were designated to use ERs, while lower risk units were assigned to either N95-FFRs or to PAPRs. Higher-risk units primarily included general medical and pediatric units, the medical intensive care and step-down units, and the emergency department. Decisions were also made to fit-test and provide ERs to workers in the ambulatory environments.

One concern raised among the KIs during pandemic committee proceedings was the need to fit-test the large number of workers considered potentially at risk due to national guidelines for respiratory protection during the 2009 pandemic. Prior to the pandemic, fit-testing was the responsibility of a single safety professional, and KIs reported that assuring compliance with regular fit-testing requirements was already challenging. To accommodate the increased number of HCWs requiring testing, the fit-testing strategy changed to unit-based fit-testing. Each clinical unit selected unit-based personnel to become fit-testers, who were trained by the Safety program to perform qualitative testing. Then, these fit-testers were deployed to their own units, performed testing and submitted reports back to the Safety program to assure compliance with expected respiratory protection practices.

## Understanding the Respiratory Protection Program Post-H1N1 Pandemic

Since the 2009 experience, many of the original procedures implemented have continued. For example, many of the same risk-unit-based respirator type assignments remain. Among staff assigned to units where ERs and N95-FFRs are in use, newly-hired employees now go through initial ambient aerosol quantitative fit-testing and respirator training through the Employee Health department. Subsequent required annual fit-testing still occurs through use of unit-based qualitative fit testers, trained by the Safety department, and HCWs also complete online respiratory protection training. Ambulatory workers go through initial and annual qualitative fit-testing and training through a separate Employee Health department.

Although all medical center staff who participate in the RPP are assigned to use a specific type of respirator, HCW focus group participants described use practices that did not always reflect these assignments. Three types of RPDs are available (N95-FFR, ER, and PAPR), and some staff seem to use them interchangeably, as is most convenient at point of use. For example, if N95-FFRs are stocked on a supply cart nearby a patient room, a HCW assigned to use an ER arriving to see a patient on airborne precautions may use an N95-FFR because it is readily available, instead of getting his own ER from a locker or storage cabinet. Staff members report knowing which device they were originally assigned (if they were assigned to an ER, for example), but sometimes use a different respirator than assigned. Generally, staff assigned to a fixed unit (i.e. nurses) reported adhering to wearing their assigned ERs; whereas, "mobile" staff, who work in a variety of areas around the hospital (i.e. respiratory therapists, physicians), reported using whatever RPD is readily available on a cart outside a patient room when they arrive to provide care for a patient where respiratory protection is required.

## Perceived Strengths of the Program

At least two KIs referred to ERs as being a more reliable form of protection than disposable N95-FFRs. Specifically, some KIs thought it to be easier to get a good and more dependable seal with an ER than with an N95. One KI stated that by issuing ERs, the organization's leadership exhibited concern for staff safety, and staff responded well to this. Specifically, issuing ERs to employees showed staff they were well taken care of (Text box 4). The key strength of the RPP noted by HCWs in the focus group was that they reported that during a pandemic, they would feel safer wearing ERs, as they were viewed as offering more protection (Text box 5).

Text box 4

*"It's a visible demonstration that the institution is concerned and takes seriously co-worker safety." -Key Informant*

Text box 5

*"I would use that one, the non-disposable one. Because I would suck it up because I would feel like it would probably do a better job." -Healthcare Worker*

## Perceived Barriers

### *Respiratory protection program, general*

The RPP was described by several KIs as under-resourced, which impacted several areas including the extent of fit testing and oversight and evaluation of the program. Instead of having a single department that is responsible for fit-testing all of the employees, clinical unit-based fit-testers take on the duty in addition to every-day responsibilities, potentially causing fit-testing to be a secondary concern. From a regulatory compliance standpoint, however, unit-based fit-testing assures that staff complete fit-testing annually, as required. One KI, for example, reported 100% compliance based on a recent audit with annual fit-testing in the majority of units.

One challenge is assuring compliance by physicians. Attending physicians are not employed by the medical center but by other on-campus entities, and do not have unit-based or division-based fit-testing. This makes assurance of appropriate respiratory protection training and fit-testing challenging to hospital departments in charge of fit-testing for everyone else. Most attending physicians, however, are assigned to use PAPRs, making fit-testing compliance not an issue from a reporting standpoint. Those who are assigned to ERs or N95-FFRs must repeat their fit-testing with their individual hospital re-credentialing procedures. Therefore, there is consistency in fit-testing and the accompanying training among the non-physician staff, but less certainty that respiratory protection training is assured among attending physicians.

### *Elastomeric respirator use*

Several barriers to use of ERs were mentioned and stood in contrast to the perceived convenience of disposable N95-FFRs (Text box 6). Staff mentioned that unlike disposable masks, ERs had to be tracked, cleaned and stored, which was difficult, especially for staff who are not unit-based (Text box 7). HCWs noted better user acceptability of N95-FFRs in terms of comfort, including facial

irritation. Some mentioned that they felt constrained by wearing the ER, reporting that it made it difficult to breathe and interact with patients. There was additional resistance to adopt ER use, because HCWs felt they were not given a choice, but simply told to use them when other respirators became scarce.

Text box 6

*"Everyone was concerned about things like communicating with this big (elastomeric) mask on, something that looked like a gas mask. And the impression it would have on patients. And the cumbersome nature of it. And the fact that people can't keep track of it and keep it on them. The lack of portability." -Key Informant*

Text box 7

*"In an emergent situation, we can't run to our locker. If I'm not assigned that patient and it's a code, we run and help each other. So we have to just throw on what's there because… patient first. So we just grab and we go, and we do what we have to do." -Healthcare Worker*

N95-FFRs were identified by KIs and HCWs as not needing decontamination, and were perceived as appropriate and accepted in the healthcare field, whereas some KIs assessed ERs as not "healthcare rated." KIs stated that they thought it unlikely that staff are compliant with recommended cleaning and storage procedures. There is little accountability for this, though HCW focus group participants recognized that improper cleaning and storage could lead to contamination issues.

## Assessment of Current State

KIs stated that the RPP had accomplished much in a short period of time. However, there was consensus that the program is more reactive than proactive. KIs described the program as existing at two levels: 1) routine everyday practice, during which the program is sufficient, and 2) during a pandemic, when as would be expected anywhere, resources are strained and protection is less assured (Text box 8).

Text box 8

*"I think we meet the basic legal requirements. I think we meet the practical requirements of protecting folks on a day-to-day basis. But… we can do better." Key Informant*

## Safety Culture

Respondents viewed creating and fostering a culture of safety as everyone's responsibility, and yet there was some concern from KIs that nursing units see themselves as separate from the organizational whole and therefore abide by different guidelines. An ideal safety culture was defined as one where safety of both patients and staff is seen as a priority. Currently, KIs perceived that staff underestimate risk to themselves during usual care and prioritize the safety of the patients (Text box 9). Some KIs described concerns of a lack of accountability among staff towards concepts like respiratory protection and their feeling of being inconvenienced by safety requirements. This culture may influence use practices that confound the optimal execution of an ER-based RPP.

Text box 9

*"I think people underestimate. They don't see the risk. And I think generally there isn't a lot of risk, but then when there is risk, we're not prepared for it." Key Informant*

# DISCUSSION

The focus group and KI interviews were performed in order to better understand the critical issues associated with ER use as part of a healthcare RPP. We gained insight from HCWs familiar with ER use and from leaders involved with carrying out the RPP through use of qualitative methods. These methods allowed us to: 1) make an initial assessment of this issue from informed community members; 2) understand their motivation and beliefs; 3) get their candid discussions of a potentially sensitive topic; 4) determine organizational strengths and challenges; and 5) refine data collection efforts for the next phase of our study (Sherry & Marlow, 1999).

We determined that ERs were incorporated into a hospital's RPP due to two primary factors: first, respiratory protection became a requirement during the 2009 H1N1 influenza pandemic, and supply shortages of N95-FFRs forced the organization to think creatively and implement an unconventional solution in being able to protect its workforce by incorporating ERs; second, there was safety expertise within the organization familiar with ERs from industry experience outside of healthcare who saw them as equally or perhaps even more reliable than N95-FFRs. As time since the 2009 H1N1 pandemic has evolved, the original institutional leadership has expressed concern regarding how well these devices are being cleaned, stored, and consistently used; but many feel strongly about the potential superior level of protection afforded by this RPD due to a more-reliable seal. Both devices carry the same assigned protection factor, thus theoretically providing equal protection (OSHA 2009). Assurance of that level of protection, however, depends on maintenance of a tight seal between the respirator and the user's face, for which several KIs expressed concern about the surety of the seal of an N95-FFR. HCWs report using respiratory protection, but not always the specific ER device they have been assigned and fit-tested to use. In general, there does not seem to be a universally-recognized adherence to *only* using the respirator for which one is fit-tested. Even when people think they are doing what they are supposed to be doing, they are not doing it right – i.e. using an *available* respirator when a patient is on airborne-precautions, but not a respirator that they have been fit-tested to use. A pattern of using respirators for which the users were not fit-tested risks employee exposure to infection. While both HCWs and KIs agree that safety culture is important, KIs feel that HCWs do not take respiratory protection as seriously as they should.

## Informing Respirator User Questionnaire Content

Following this study, our research team will deploy questionnaires to HCWs and RPP "decision makers" (DMs) to determine whether ERs represent a feasible and acceptable solution to address the problem of N95-FFR shortages in healthcare settings. The feedback provided by the present study's qualitative methods identified several critical topics to be addressed among the larger groups of HCWs and RPP DMs in their respective surveys.

First, absent an airborne threat from an organism of high public health and clinical impact, like H1N1 or Ebola, many HCWs may not have sufficient incentive to overcome barriers of comfort, cleanliness and perceived patient acceptance of wearing an RPD less familiar in healthcare settings. This reluctance to wearing ERs leads to violations of RPP guidelines, most importantly using disposable N95-FFRs for which HCWs have not been fit-tested. Our questionnaires should attempt to clarify how risk affects respirator preference and willingness to comply with recommended practices. For example, are

HCWs who perceive more risk from being exposed to a particular airborne hazard more accepting of ERs compared to those with lower perception of risk?

Second, the introduction of ERs into an RPP in a healthcare environment resolves respiratory protection problems created by N95-FFR shortages, but presents unique problems, like new and different storage, decontamination and availability issues. Questionnaires for our study's next phase will thus address current storage and decontamination practices and whether barriers here affect current optimal operations of an ER-based RPP.

Third, HCW knowledge about why respirators provide respiratory protection seems to be missing. Some HCWs appear to believe that respirators are a device, like gloves or gowns, which need only be worn to be effective. The importance of a good seal (and therefore fit-testing) seems to have been lost, demonstrating a lack of knowledge or appreciation for how a respirator must be worn to be effective. Our questionnaire should clarify the current knowledge-base of our users and determine whether this is impacting use practices and respirator preference.

Fourth, these observations suggest an underlying theme consistent with studies of patient safety, which suggest that safety culture is a critical element in implementing safety programs (Pousette et al, 2017; Scott et al, 2003). Some HCWs communicated that patient care "trumps" staff safety. Our questionnaires need to assess safety culture as a potential factor underlying how HCWs and DMs think about and use respiratory protection, particularly ERs.

Finally, building the consensus, capacity and habit of using ERs appears to erode over time, especially after the precipitating pandemic crisis (for example, H1N1) passes. Our questionnaires will incorporate features to attempt to explain why this happens, whether it is due to variations in frequency of use, safety culture, risk perception or other factors.

## Limitations

As is usual with qualitative research, limitations of this study include small sample size and self-selected participation, possibly resulting in a biased sample. Our selection of key informants was small by necessity, as we only sought input from those in positions of authority involved in decision-making about the respiratory protection program. Our focus group participants may have been motivated to participate based on a variety of experiences. They expressed a spectrum of views however, both complementary and critical of the respiratory protection program, minimizing a concern about a possible lack of balance in responses. Our findings may have limited generalizability, and caution should be used with extrapolating this limited qualitative data to different populations. For example, this focus group expressed some negative input regarding ERs. In contrast, when a recent effort to transition certain HCW groups at this institution from ERs to N95-FFRs occurred, at least 25% of users wished to remain in ERs, citing comfort and a greater feeling of safety (National Academies of Sciences, Engineering, and Medicine, 2017). Thus, a complete picture of the preferences of HCWs and ER users overall is more complex. Our system-wide survey, informed by these qualitative methods, of HCWs enrolled in RPPs will provide more generalizable insight than this small focus group interview. However, by using qualitative data methods, we were able to understand the history and evolution of a unique RPP from information that was not easily available otherwise.

# CONCLUSIONS

The Historical respirator shortages teach us that N95-FFR scarcities will recur with future respiratory pandemic emergencies. Using ERs as an alternative to N95-FFRs may provide one solution to respiratory protection emergency planning challenges. Learning from the experience of a program that has used ERs for more than 8 years may help to inform broader questions about feasibility and whether they are reasonable alternatives to use of N95-FFRs in healthcare more generally. While use of elastomeric respirators is not the national norm, our experiences may inform models to enlarge and sustain the respirator supply during anticipated future pandemics. By clarifying the perceptions and beliefs of users and respiratory protection program leadership, we have developed and refined surveys for HCWs and DMs that will help us determine the feasibility and acceptability of elastomeric respirators as an alternative to use of N95 respirators in healthcare settings.

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## Appendix A - Key Informant Interview Script

**Open-ended Questions and Prompts**

**Note: additional questions may be included based on responses provided by recipients to the prompts.**

**Part 1.**

*What is your current role within the institution? (For those no longer working at the institution, what was your most recent role within the institutional system?)*

*How long have you worked in your current (most recent institutional system) position? How long have you worked in your field?*

*In general, how are/were you involved in the policy decision making process?*

What is/was your role within the respiratory protection program at your institution**?** *In general, how are/were you involved in the respiratory protection program policy decision-making process?*

*Please tell me about the decision-making process leading to the current RPP structure. What was that process like? (What topics were raised?)*

What role did economic factors or financing of the RPP play in the decision making? Who was most (concerned/interested in/focused on) the economics? What were their roles?

How do you think the experience with the 2009 H1N1 influenced the decision making?

*What about other infectious disease outbreaks?*

*What was your involvement in the decision-making processes leading to the current RPP? Who else was involved?*

*Overall, looking across all of the factors involved, why do you think the decisions were made the way they were?*

**Part 2.**

*How did you personally receive education related to respiratory protection in healthcare?*

*How are workers at your institution trained about respiratory protection?*

*How are employees educated about decontamination or reuse of respirators?*

*Could you describe how your Respiratory Protection Program addresses emergencies, like a respiratory pandemic?*

*Overall, how do you think the respiratory protection program is working?*

*Do you have episodic program evaluations? If so, what is included? Who is involved? What happens after the evaluation?*

*What are the strengths of your RPP?*

*What things would you like to see changed about your RPP?*

*What changes have you noticed with use of elastomeric respirators or PAPRs compared to disposable respirators?*

**Part 3**

*What comes to mind when you hear the term "safety culture?"*

*How would you describe the Safety Culture in your institution?*

*What are some of the major components of the safety culture here?*

*How important to having a safety culture is the RPP?*

**Thanks – you have been very helpful! Is there anything else you would like to add – anything I haven't covered?**

## Appendix B - Focus Group Script

You are all here because you are assigned to wear a respirator during certain types of patient care. Many of you have been assigned to wear a reusable "elastomeric" style respirator, while some of you wear disposable masks. (Show examples: Elastomeric Respirator; Disposable N95).

We are currently involved in a research project sponsored by the CDC's National Institute for Occupational Safety and Health to understand factors that lead to a successful respiratory protection program in healthcare. In particular, we are trying to understand what kind of a role the elastomeric respirators play. Our institution is unique in using this type of a respirator, and we are seeking input as to how healthcare workers, like yourselves, view these types of respirators. The answers you provide here today will help us shape the content of an electronic questionnaire that we will be sending out to healthcare workers here and at some of our partner institutions to get more quantitative responses as to respirator use and preferences.

The answers you provide here today are meant to be confidential. We will not share your individual responses with your manager or Supervisor. Only the study staff needs to know your responses. However, you are here as part of a group, and we ask that each of you respect that aspect of confidentiality as well. We cannot guarantee that other members of the focus group will maintain that confidentiality, but have asked participants not to be a part of the focus group if they cannot keep the information shared here confidential.

I will be asking you several scripted questions that are meant to prompt discussion. There may be additional unscripted questions based on the answers you all provide, which is a characteristic of this type of qualitative research.

*Are there any questions before we move forward with the questions?*

Questions:

- How many of you are assigned to wear an elastomeric respirator?
    - How do you remember that process occurring?
    - Were you offered an option of respirator styles to choose from?
    - Were you fit-tested?
    - If you had a choice, why did you end up in the respirator that you did?

- Who here uses a disposable respirator?
    - Have you been fit-tested here to wear the respirator that you normally wear?

- Who wears a respirator that is different from what you think you have been assigned to use or that you have been fit-tested to use?
    - Why don't you wear the respirator that you have been assigned or fit-tested to use?

- What do you like about your respirator?

- What don't you like about your respirator?

- What is it like to communicate while wearing your respirator?

- How do patients or their family members interact with you differently when you are wearing your respirator?
    - What problems arise, if any, in interacting with patients while wearing your respirator?

- What do you do with your respirator when you are done wearing it?

- How do you receive training about using your respirator?
    - How often do you get fit-tested, and who fit tests you?

- Do you work in an environment where different workers are using different types of respirators, when caring for the same patient?
    - If so, what questions, if any, does that bring up for you?

- Which respirator do you think you would prefer to have, and why?

- How does wearing your respirator affect you physically or psychologically?
    - For example, do you feel short of breath? Do you feel hot? Do you feel anxious? Has this ever become an issue that affected how you did your job?

- Do you think your responses to the things we have talked about today would be different if we were talking about wearing your respirator during a pandemic – such as with the 2009 H1N1 swine flu, as compared to normal usage?

- What is the longest amount of continuous use that you have needed to wear a respirator while engaged in patient care?

- Have you ever had to wear a respirator while involved in a sterile procedure, such as a surgery or putting in a central line? What was that process like?

Is there anything else you think is important related to wearing your respirator that you think we should know about?