Informing the use of N95 respirators by the general public to reduce wildfire smoke exposure

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Abstract

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Climate change is increasing the frequency, intensity, and duration of wildfires. To reduce personal exposure to wildfire smoke and resulting adverse health effects, N95 respirators are increasingly used by the general public to filter out fine particles ($PM_{2.5}$) present in smoke. When mandated in an occupational setting, the use of N95 masks requires medical clearance, proper training, and fit testing. This rigorous attention to training and proper respirator fit is generally, neither required or practiced by, the lay public. A literature resource summary was conducted to understand the current state-of-knowledge around the use of N95 respirators and training in occupational and other settings to inform novel use for the general public during wildfire smoke events. The goal of this study pilot was to assess the efficacy of training materials by quantifying the transference of knowledge from selected interventions into N95 respirator fit in a convenience sample of untrained, lay public. This is the first study to assess efficacy of N95 respirator training materials for the general public during wildfire smoke events. To this end, we administered a Knowledge, Attitude and Practices (KAP) survey to identify baseline knowledge and training retention; conducted a quantitative respirator fit test prior to, and after, each participant received their randomly assigned training material; and observed and analyzed the

actions taken by participants during the donning process that affect fit. This study found that without prior knowledge, the selected trainings significantly improved fit, but fit factors equivalent with occupational use were not observed. Pre-training fit testing found that most individuals achieved a fit factor of 2, a 50% decrease in particulate exposure. Post-training fit testing found most individuals reached a fit factor of at least 10, an expected 90% reduction in exposure. In comparing participants pre-intervention KAP survey results with initial fit factors, participants tended to overestimate their knowledge on proper fit. We found that the selected factsheet and manufacturer training significantly improved the fit factor of participants, though the improvement did not achieve the passing fit factor of 100 for required use in an occupational setting. In the absence of fit testing, effective training and risk communication is necessary for the use of N95 respirators by the general public. With training, N95 respirators can provide protection for the general public during wildfire smoke events, but without proper use, N95 respirators may not reduce $PM_{2.5}$ exposure to levels considered safe for public health. The results of this study will provide evidence on the efficacy of N95 respirators and training for proper fit as a personal intervention to reduce exposure to wildfire smoke.

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Abbreviations and Acronyms

AQI: Air Quality Index

CDC: Center for Disease Control

CFR: Code of Federal Regulations

COVID-19: disease progression from exposure to SARS-Cov2

CNC: ambient aerosol condensation nuclei counter

UW DEOHS: University of Washington Department of Environmental and Occupational Health Sciences

DOH: Washington State Department of Health

FDA: Food and Drug Administration

FFP: Filtering Face Piece

HDX: Home Depot Brand

IRB: Institution Review Board

KAP: Knowledge, Attitudes, and Practice

N95: Filter material not resistant to oil with 95% filtration efficiency

NIOSH: National Institute for Occupational Safety and Health

NPPTL: National Personal Protective Technology Laboratory

OSHA: Occupational Safety and Health Association

PEL: Permissible Exposure Limit

PPE: Personal Protective Equipment

PM: Particulate matter

$PM_{2.5}$: Particulate matter less than 2.5 microns in diameter

PNASH: Pacific Northwest Agricultural Safety and Health Center

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Training materials evaluated in the project were developed by colleagues across Washington state. Vida Ting at University of Washington in partnership with King County Public Health developed the “Smoke from Fires: N95 Respirator Masks” video, alongside original content by the Ashland Chamber of Commerce; and Washington State Department of Health (WA DOH) developed the “Wildfire Smoke and Face Masks” factsheet. It was a pleasure to work with your materials.

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Study Aims

Wildfires are becoming an increasingly important public health issue across the Western United States as human populations in the wildland-urban interface continue to grow (Radeloff et al., 2005). This is further exacerbated by climate change which extends regional fire seasons and increases the frequency, duration and intensity of wildland fires (Liu et al., 2016). The number of houses in the wildland-urban interface grew from 30.8 to 43.4 million (41%) in the United States between 1990 and 2010 (Radeloff et al., 2018). Population health is negatively affected by exposure to wildfire smoke, with the growing body of literature demonstrating an increase in all-cause mortality (Doubleday et al., 2020; Zu et al., 2016; Kollanus et al., 2016) and respiratory morbidity (Liu et al., 2017a; Lui et al., 2017b; Tinling et al., 2016; Reid et al., 2016b; Parthum et al., 2017; Le et al., 2014). To reduce personal exposure to wildfire smoke, N95 respirators are increasingly used by the general public as a means to filter out particulate matter (PM) present in smoke. In Washington state, the distribution of N95 respirators during wildfire smoke events increased between the years 2018 and 2019 (J. Fox, personal communication, 2019). When the use of N95 respirators is mandatory in a workplace setting, medical clearance, proper training, and fit testing are required in order to ensure employees are properly fitted and that the respirator provides expected exposure reduction. However, in the general public, training around medical appropriateness and fit are absent from use. With respirator use by the general public increasing as wildfire smoke events increase, there is a need to better understand the efficacy of PPE interventions and risk communication strategies employed to protect population health (Pendergrast et al., 2019).

The goal of this study was to assess the efficacy of training materials by quantifying the transference of knowledge from selected interventions into N95 respirator fit in a convenience sample of untrained, lay public and to inform recommendations for the use of N95 respirators as a public health intervention for reducing wildfire smoke exposure.

Aim 1: Summarize the current state-of-knowledge around and the use of N95 respirators as a public health intervention for wildfire smoke exposure reduction and the trainings used to achieve proper fit.

1.1 Using review methodology, identify and summarize the N95 respirator intervention and training literature.

Aim 2: Evaluate the impact training has on N95 respirator fit in a convenience sample of untrained, lay-public.

2.1 Assess knowledge, attitudes, and commitment to N95 respirator use in sample population

2.2 Characterize the impact training has on respirator fit and describe differential impact on respiratory fit by training mode

2.3 Identify pertinent user-behaviors important to N95 respirator fit

Aim 3: Translate findings to practice partners and public health stakeholders.

3.1 Present findings to the public health practice community

3.2 Provide recommendations for new training materials on N95 respirator mask fit/use for the general public

3.3 Draft research findings for publication in scientific journals

The results from this study will be helpful to public health practice and research partners as they consider the appropriateness of a N95 respirators as a recommendation to reduce personal exposure to wildfire smoke.

Aim 1: Summarize the current state-of-knowledge around and the use of N95 respirators as a public health intervention for wildfire smoke exposure reduction and the trainings used to achieve proper fit.

Background

Exposure to wildfire smoke negatively impacts population health, especially across the Western United States. With the wildfire season expected to be three weeks longer and twice as smoky, there is an increased risk of exposure and negative health impacts (Yue et al., 2013). There are several personal interventions available to the general public to reduce exposure, including the use of N95 respirators. Although the use of N95 respirators by the general public is increasing, there are limited studies on (1) the use of N95 respirators for wildfire smoke exposure reduction, in general, and (2) their use outside of traditional workplace setting, including training interventions. Given the emergency response nature of wildfire smoke events, public health practitioners have been placed in a precarious position of needing to make recommendations for general public use, despite the lack of efficacy research in this population. In order to make evidenced-based public health decisions aimed at protecting population health, public health practitioners should draw from and apply important information learned from occupational health and safety-related research. The goal of this literature resource summary was to summarize the current state-of-knowledge around N95 respirator efficacy as an intervention and corresponding training.

Methods

To determine the current state-of-knowledge on the efficacy of N95 respirator use and associated training, across multiple settings, we identified peer-reviewed literature by searching key terms on the Pubmed, Embase, and the Cochrane library databases through July of 2020

(Appendix F); as well as conducting a bibliographic search. We scanned abstracts for relevance, and selected studies based on the following inclusion and exclusion criteria.

Inclusion Criteria:

- Conducted after 1995
- In English
- Full research article
- Discussed N95 respirators and air pollution or wildfires; training and education on proper N95 respirator use; communicating proper N95 respirator use; fit of N95 respirators; health impacts; policy and regulations for use; N95 respirator ethics; attitudes and perceptions of N95 respirator use; information on the wearer of N95 respirators

Exclusion:

- Occupational fit testing protocols
- Re-use of N95 respirators for occupational use
- Specific to only other types of respiratory protection
- Surgical masks donned over N95 respirators
- Infection control for occupational settings
- Filtration efficiency for biological hazards or nanoparticles
- Workplace protection factors
- Compared effectiveness between respirators
- Decontamination of the mask

Studies were tracked and stored using Zotero (Zotero: Corporation for Digital Scholarship, Vienna, VA, USA). There are several limitations with these methods to consider: (1) while elements of a systematic review were included, all relevant articles may not have been identified, (2) subjectivity in identification of articles, as only one coder was used, and (3) is that N95 respirators have multiple labels they are referred to as (e.g. N95's, N95 mask, dust mask, half mask, particulate respirator, filtering face piece, etc.)

To summarize the current state-of-knowledge and apply important information to the novel use of N95 respirators for wildfire smoke exposure, we analyzed the content of the selected studies, identified key findings, and used deductive coding methods to classify literature by the following qualitative themes: (1) occupational use pertinent for non-traditional application, (2) policies and regulations, (3) use for ambient air pollution, (4) use for disasters, (5) training and risk communication, and (6) ethics, behavior theory, and attitudes and perceptions. Qualitative themes and code definitions were developed to classify literature *a priori* (Table 1); and studies were coded by the primary author.

Information collected will be used to inform the introduction of Aim #2 of this project.

Table 1. Definitions of inclusion criteria for identified themes important to use for informing N95 respirators use for the lay public

Theme	Definition of Inclusion Criteria
Occupational use pertinent for non-traditional application	Article contained information on N95 respirator use in occupational settings that is pertinent for non-traditional application (e.g. use by the lay public). Sub-codes include: filter efficiency, fit (i.e. mask leakage or fit factor), healthcare use, and proper use
Physiological Impacts	Article contained information on the physiological impacts of wearing an N95 respirator that is important to consider for recommending public use. Sub-codes include: general public, occupational settings, and sensitive sub-populations.
Policies and regulations	Article contained information on N95 respirator regulations or policies. Sub-codes include: occupational settings and non-occupational settings.
Use for ambient air pollution	Article contained information about the non-occupational use of N95 respirators, or other masks, for ambient air pollution. Sub-codes include: health benefits, exposure reduction, and filter efficiency of ambient air pollutants.
Use for disasters	Article contained information about occupational and non-occupational use of N95 respirators, or other respiratory protection, for disasters. Sub-codes include: physical (i.e. wildfires) and biological hazards (i.e. mold)

Training and risk communication	Article contained information on respirator training and risk communication surrounding use of N95 respirators. Sub-codes include occupational settings and non-occupational settings; training mode; training type.
Ethics, behavior theory, attitudes and perceptions	Article contained information on ethics, behavior theory, attitudes and perceptions surrounding N95 respirator use. Sub-codes include: occupational and non-occupational settings.

Results

A summary of the selected studies, including theme, intended research focus, outcome measure, and key conclusions is illustrated in Table 2. A total of 98 articles was identified by search terms and included for review; an additional 9 articles were found by scanning bibliographies. Twenty-seven articles were coded as use in occupational settings important for lay public; 19 as physiological impacts; 1 as policies and regulations; 28 as use for ambient air pollution; 12 as use for disasters; 16 as training and risk communication; and 4 as ethics, behavior theory, and attitudes and perceptions. Twenty-five articles were found where the general public was the intended research focus; 18 for occupational settings; 9 for sensitive sub-populations (i.e. children, adults over the age of 65, or those with pre-existing health conditions); 19 for healthcare settings; and 37 articles for general use (i.e. neither specifically occupational or general public). Health outcomes were the outcome measure for 15 articles; fit for 22 ; filtration efficiency for 10; socio-cognitive perceptions for 10; proper use for 16; physiological impacts for 16; 10 for risk reduction behaviors; and policy recommendations for 12.

Table 2. Summary of studies examining issues important to consider in the use of N95 respirators by the general public, sorted by theme.

Study	Year	Theme	Research Focus	Outcome Measure	Key Findings
Ruchirawat et al.[1]	2002	Ambient Air Pollution	Occupational	Health Outcome	• Police offers that wore masks had lower biomarkers for PAH exposure, indicating that masks can reduce exposure to particle-associated PAHs
Janssen and Bidwell* [2]	2006	Ambient Air Pollution	Occupational	Filter Efficiency	• N95 filter material should not be used for diesel particulates • R95 and P95 filters provide acceptable filtration for diesel particulates
Langrish et al. [3]	2009	Ambient Air Pollution	General Public	Health Outcome	• Wearing a face mask can have positive health benefits on short-term cardiovascular outcomes such as blood pressure and heartrate variability
Langrish et al. [4]	2012	Ambient Air Pollution	Sensitive sub-populations	Health Outcome	• Using an FFP for ambient particulate matter pollution reduced cardiovascular symptoms and health issues among those with coronary heart disease
Wertheim et al.[5]	2012	Ambient Air Pollution	General Use	Health Outcomes	• No effect was seen on biomarkers PAH's by wearing a R95 respirator • This may be due to the inability of particulate respirators to filter out gases
Penconek et a.*[6]	2013	Ambient Air Pollution	Occupational	Filter Efficiency	• Using an FFP may not ensure provide suitable protection against diesel exhaust
Ho et al.[7]	2014	Ambient Air Pollution; Ethics, Behavior Theory, Attitudes and Perceptions	General Public	Socio-Cognitive Perceptions	• Haze air pollution event in South Asia increased purchase • During the 2013 haze event, 1 million free N95 respirators were distributed • Usefulness and accessibility where not associated with psychological stressed due to adequate supply led to purchasing stock up of N95 respirators
Guha et al.[8]	2015	Ambient Air Pollution	Sensitive Sub-Populations	Filtration Efficiency	• In selected masks designed for pediatric use, there was high penetration of particles in the submicron range

Qian et al.[9]	2016	Ambient Air Pollution	General Public	Risk Reduction Behaviors	• Almost half of participants have worn a face mask outside during poor air quality; of that the most common were cotton and gauze face masks
Shakya et al.[10]	2016	Ambient Air Pollution	Occupational	Health Outcomes	• Among traffic police, use of an N95 respirator had health benefits related to lung function when worn during work during a short-period
Zhang et al.[11]	2016	Ambient Air Pollution	Sensitive Sub-Populations	Policy Recommendations	• Wearing of masks for extended periods of time among elderly individuals and those with cardiovascular diseases may cause feelings of breathlessness
Huang et al.*[12]	2017	Ambient Air Pollution	General Public	Socio-Cognitive Perceptions	• Respondents reported a willingness to wear mask during hazy days to reduce exposure • Women were more likely to wear a mask on a hazy day
Shakya et al.[13]	2017	Ambient Air Pollution	General Public	Filtration Efficiency	• The use of cloth masks for reducing exposure to particles <2.5 microns in size is only marginally beneficial
Shi et al.[14]	2017	Ambient Air Pollution	General Public	Health Outcome	• Wearing a face mask can have positive health benefits on short-term cardiovascular outcomes such as blood pressure and autonomic nervous function
Cherrie et al.[15]	2018	Ambient Air Pollution	General Public	Filter Efficiency; Fit	• First study to connect respiratory filter efficiency and fit performance when donned on individuals. • Some commercial face masks marked for $PM_{2.5}$ in China may not provide adequate filtration efficiency for diesel particles due to poor fit • Recommends including exposure reduction measurements when studying the health impacts of face masks • Masks marketed for air pollution in China did not always achieve expected protection when worn and the masks that were effective, did not provide consistent protection across activities done by study participants
Guan et al.[16]	2018	Ambient Air Pollution	General Public	Health Outcome	• Among young, healthy adults in China, the use of N95 respirators partially reduced acute respiratory inflammation associated with particulate exposure, but oxidative stress and endothelial disfunction did not improve • Mixed findings

Rajper et al.[17]	2018	Ambient Air Pollution	General Use	Risk Reduction Behaviors	• Almost all participants used face masks • Females were more likely to take preventative measures, including face masks
Xiong et al. [18]	2018	Ambient Air Pollution	Sensitive Sub-Populations	Risk Reduction Behaviors	• Wearing a mask was not the most common personal intervention to reduce ambient $PM_{2.5}$ • Most participants that did report wearing a mask used disposable, cotton, or gauze masks • For ambient air pollution, women and younger participants (18-44) more likely to wear a face mask
Yang et a.[19]	2018	Ambient Air Pollution	General Public	Health Outcome	• Short term use of a respirator for air pollution in subway can have cardiovascular benefits by improving heart rate variability
Goh et al.[20]	2019	Ambient Air Pollution	Sensitive Sub-Populations	Health Outcome; Fit	• A pediatric designed N95 mask was found to be safe, well fitting, and comfortable for children use during rest or mild exertion
Huang and Morawska[21]	2019	Ambient Air Pollution	General Public	Policy Recommendations	• Face coverings may provide a false sense of security against ambient air pollution • Until evidence is available, recommend only wearing tight fitting masks for biological hazards, not air pollution
Khayan et al.[22]	2019	Ambient Air Pollution	General Use	Mask Design	• Respirators with activated carbon, spunbond, and meltdown are more effective at filtering toxic gases in ambient air pollution (i.e. COx, NOx, and SOx) that respirators with only spunbond and meltblown
Morishita et al.[23]	2019	Ambient Air Pollution	General Public	Health Outcome	• First study on health benefits of N95 respirators for air pollution in North America • Aortic hemodynamics appeared to better with N95 respirator use near roadway, but did not mitigate adverse effects of particulate matter • Mixed findings
Pacitto et al.[24]	2019	Ambient Air Pollution	General Use	Filtration Efficiency	• Median for reducing $PM_{2.5}$ was 48% • Higher effectiveness for $PM_{2.5}$ than other traffic air pollutants • Large variability in performance between face masks

Faridi et al.[25]	2020	Ambient Air Pollution	General Public	Filtration Efficiency	• Effectiveness for reducing ambient particle number concentrations, PM_{10}, $PM_{2.5}$, and PM_1 varied by respirator manufacturer • Consumers should consider design-related factors of respirators
Kyung and Jeong[26]	2020	Ambient Air Pollution	General Public	Policy Recommendations	• Review recommends face masks as a common and simple way to reduce exposure to high concentrations of PM • Individuals with decreased lung function should be cautious when using N95 respirators
Kyung et al.[27]	2020	Ambient Air Pollution	Sensitive Sub-Populations	Health Outcomes	• Individuals with COPD may be able to safely wear N95 respirators for outdoor PM exposure • Those with very severe COPD should be cautious • Patients should be warned to remove N95 respirators if have headaches, dizziness, or dyspnea
Tang et al.[28]	2020	Ambient Air Pollution	General Public	Risk Reduction Behaviors	• The use of face masks was more common among commuters and pedestrians during rush hour, rather than people working outside along the street for extended periods of time
Künzli et al.[29]	2006	Disaster	Sensitive Sub-Populations	Risk Reduction Behaviors; Health Outcomes	• Children with asthma were more likely to take preventative measures like wearing a mask to reduce WFS smoke exposure • Suggests benefits of wearing mask for children
Cummings et al.[30]	2007	Disaster	General Public	Proper Use	• Few individuals using N95 respirators for cleaning up mold after a hurricane demonstrated proper donning of an N95 respirator • The most common error was not molding the nosepiece, straps in incorrect position, and upside down
Harber et al.[31]	2009	Disaster	General Public	Socio-Cognitive Perceptions	• Among subjects with mild respiratory impairments, most tolerated use of respirator • Assessment of the impact of N95 respirator use should include physiological impacts and subjective response • Use of respirator may be feasible outsides of a traditional occupational setting
Johanning et al.[32]	2014	Disaster	Occupational	Policy Recommendations	• Recommends use of N95 respirators for cleaning up mold after natural disasters; but if it's for a large-scale project, they should have medical clearance and understand proper use

Galea et al.[33]	2018	Disaster	General Public	Socio-Cognitive Perceptions	• Of selected respiratory protection, the N95 respirator were perceived by participants to be the best for use with volcanic ash (i.e. fit and effectiveness) • Participants had concerns about comfort and breathability
Mueller et al.[34]	2018	Disaster	General Public	Filter efficiency	• N95 respirators, or particulate respirators can provide protection for volcanic ash in air • Other types of cloth face coverings will provide limited protection • Wetting a face covering did not improve filtration
Steinle et al.[35]	2018	Disaster	General Public	Fit	• Best performing out of selected respiratory protection type was an N95 respirator, but also subjects perceived it to be the most uncomfortable and difficult to breathe through
Laumbach[36]	2019	Disaster	General Public	Policy Recommendations	• The following should be considered for the use of an N95 respirator for reducing wildfire smoke exposure: (1) only used when cannot avoid outdoor activity, (2) ability to protect depends on fit, (3) there may be some physiological stress, and (4) those vulnerable to wildfire smoke are also sensitive to effects of wearing an N95 respirator
Pantelic et al.[37]	2019	Disaster	General Public	Risk Reduction Behaviors	• A large proportion of building occupants in the study wore face masks indoors, even after $PM_{2.5}$ concentration returned to normal after the Chico Camp fire
Parker et al.[38]	2019	Disaster	General Use	Policy Recommendations	• Recommends the use of N95 respirators to reduce inhalation exposure of harmful air quality, include wildfires, especially with climate change
Long et al.[39]	2020	Disaster	General Public	Policy Recommendations	• Review found that N95 respirators did not associated with lower risk of influenza compared to influenza • N95 respirators should not be recommended for the general public
Riden et al. [40]	2020	Disaster	Occupational	Risk Reduction Behaviors	• Employers did not mention masks or respirators as a safety practice for works to reduce wildfire smoke exposure • Farm workers discussed use of masks to prevent exposure and health effects for wildfire smoke
Honarbakhsh et al.[41]	2017	Ethics, Behavior Theory, Attitudes and Perceptions	Healthcare	Socio-Cognitive Perceptions	• The most important obstacles in using an N95 respirator among healthcare workers: (1) difficulty breathing, (2) heat around face, (3)

					pressure on nose, (4) difficulty communicating, (5) inaccessibility, (6) lack of use
Hansstein and Echegaray[42]	2018	Ethics, Behavior Theory, Attitudes and Perceptions	General Use	Socio-Cognitive Perceptions	• Using a mask for air pollution can be a simple and effective action • Young, well-educated cohorts experienced resistance to wearing a mask, but recommended highlighting social desirability and using less defensive language to overcome this
McDonald et al.*[43]	2020	Ethics, Behavior Theory, Attitudes and Perceptions; Air Pollution	General Public	Policy Recommendations	• Using the developed ethical decision-making framework, can increase clarity and thus trust and agreement about the recommendation for the use of facemasks for air pollution
Smart et al.[44]	2020	Ethics, Behavior Theory, Attitudes and Perceptions	Sensitive Sub-Populations	Socio-Cognitive Perceptions	• Children's perceptions of using facemasks were influenced by design, breathability, and hotness • Making masks more appealing, breathable, cooler, and improved fit for children's faces will make their use more appealing
Burgess and Mashingaidze [45]	1999	Occupational Use	Healthcare	Fit	• 69% failure for proper fit • Results were not associated with frequency of use or experiencing wearing one • Few participants performed a seal check, and of those more passed the fit test
Coffey et al.*[46]	2004	Occupational use	Occupational	Fit	• Fitting characteristics can vary among respirators • Fit testing improved the level of protection of poor-fitting respirators • Best protection was with respirators with good fitting and passing at fit test
Derrick et al.[47]	2005	Occupational Use	General Use	Proper Use	• Seal check should not be a surrogate of fit testing for indicating proper fit
Oestenstad et al.[48]	2007	Occupational Use	General Use	Fit	• No significant difference between genders (i.e. respirator brand interaction and respirator fit)
Grinshpun et al. [49]	2009	Occupational use	General Use	Filtration Efficiency; Fit	• In testing the two pathways particles can enter a respirator, more particles entered through face seal leakage than through penetrating the filter material

					• Priority in respirator development should shift to designing better fit to reduce face seal leakage
Winter et al.[50]	2010	Occupational Use	Healthcare	Fit	• Among healthcare workers, a large proportion failed a fit test with the selected masks • Training improved fit
Danyluk et al.[51]	2011	Occupational Use	General Use	Proper Use	• Performing a seal check is not a surrogate for fit testing and adequate seal
Lam et al.[52]	2011	Occupational Use	General Use	Proper Use	• Seal check is not a reliable replacement for fit testing for indicating proper fit
Mitchell et al.[53]	2012	Occupational Use	General Use	Fit Testing Procedures	• Homemade fit testing solutions may be a suitable alternative to quantitative fit testing when it is too expensive or not readily available
Or et al.[54]	2012	Occupational Use	Healthcare	Proper use	• Training in how to perform a seal check, improved the like hood of proper fit • Concludes proper donning cannot be achieved without performing a seal check
Roberge[55]	2012	Occupational Use	Occupational	Policy Recommendations	• Exhalation valves on N95 respirators can improve comfort, tolerance, and physiological demand. This could impact compliance and thus protection, but additional research is needed
Viscusi et al.[56]	2012	Occupational Use	General Use	Proper Use	• There may be some benefit for performing a seal check vs. not performing during the donning process • Additional research is needed with more subjects and respirator/model types
Nichol et al.[57]	2013	Occupational Use	Healthcare	Proper use	• 44% competence of proper N95 respirator use rate among nurses • Knowledge was a significant predictor of competency
Niezgoda et al.[58]	2013	Occupational Use	General use	Fit	• Seal pressure differed between subjects donned in a standard size flat fold N95 respirator and a cup-shaped one; there was no difference in face seal or fit factors; but more subjects passed fit testing while donned in the flat fold design

					• The ability of flat fold N95 respirators to achieve the same protection as the cup shaped allows for increased comfort without losing protection
Roberge et al.[59]	2014	Occupational Use	General Use	Fit	• Placement of the top strap of an N95 respirator below the ear, rather than high above the ears, did not significantly impact fit
Sasaki and Kotake[60]	2014	Occupational Use	Healthcare	Proper Use	• Inadequate use among Japanese nurses, including lack of fit testing and performing a seal check
Brouwer et al.[61]	2015	Occupational Use	Healthcare	Proper Use	• Only 36% of healthcare workers in the study knew how to properly use an N95
Gao et al.[62]	2015	Occupational Use	General Use	Filtration Efficiency	• Penetration of combustion particles has higher than model NaCl particles • Concern about applicability of N95 filter performance based challenged with NaCl aerosol for combustion particles
Brosseau et al.[63]	2015	Occupational Use	Healthcare	Proper Use	• Most written respiratory protection programs of hospitals did not have adequate information on fit-testing and training • Most healthcare workers were able to position the respirator correctly on their face and mold the nosepiece • During the donning process, health care workers frequently missed placing the straps correctly and performing a seal check
Johnson et al.*[64]	2016	Occupational Use	General Use	Policy Recommendations	• When considering the protectiveness of respirators, there are many considerations to their performance, including the respirator itself and the wearer; all of this needs to be considered • Training improves ability to wear a respirator, but does not eliminate the physiological or psychological barriers to wearing one
Lam et al.[65]	2016	Occupational Use	General Use	Proper Use	• Results did not support seal checks as an indicator of leakage in donning an N95 respirator
Cramer et al.[66]	2017	Occupational Use	Occupational	Socio-Cognitive Perceptions	• Among Midwestern farmers, respondents did not think respirators were effective in dusty conditions • Most did not know masks/respirators be fitted or N95 approved; and many of the younger respondents thought they were not necessary

Lee et al.[67]	2017	Occupational Use	Healthcare	Fit	• Variation in the characteristics of respirators (i.e. fold vs. valve vs. cup types) may influence their performance and expected protection for healthcare (e.g. fit)
Brown et al. [68]	2018	Occupational Use	Healthcare	Risk Reduction Behaviors	• Many of the healthcare workers in the study improperly donned and doffed the N95 respirators
Seng et al.[69]	2018	Occupational Use	Occupational	Mask Design	• The presence of an exhalation valve may make them more comfortable to wear and thus increased compliance with use
Cherry et al.[70]	2020	Occupational Use	Occupational	Health Outcome	• Wearing masks may reduce absorption of PAHs among wildland fire and thus provide respiratory benefits
Petsonk and Harber[71]	2020	Occupational Use	Healthcare	Policy Recommendations	• Deviations from standard respiratory standards and programs (e.g. training and fit testing) due to impacts of COVID-19 should not normalized as they put healthcare workers at risk
Foo et al.[72]	2006	Physiological Impacts	Healthcare	Physiological Impacts	• Adverse skin reactions associated with use of PPE, including N95 respirators
Lim et al.[73]	2006	Physiological Impacts	Healthcare	Physiological Impacts	• The use of an N95 respirator among health care workers may lead to headaches
Bansal et al.[74]	2009	Physiological Impacts	General Use; Sensitive Sub-Populations	Physiological Impacts	• Most individuals, even with mild respiratory dysfunction, will tolerate physiological effects of wearing an N95 respirator during low to moderate exertion
Harber et al.[75]	2010	Physiological Impacts	General Use	Physiological Impacts	• Physiological impacts of wearing a respirator will vary by health status of user • Pre-existing health conditions may reduce ability to physiologically adapt to using respirator • Type of respirator is important for physiological impact (e.g. elastomeric dual cartridge half mask versus N95 respirator)
Wu et al.* [76]	2011	Physiological Impacts	General Use	Physiological Impacts	• Wearing an N95 respirator had no impact on anxiety, unlike an elastomeric half-face mask with dual-cartridges • In selecting a respiratory, impacts on anxiety should be considered

Roberge et al.[77]	2012	Physiological Impacts	General Use	Physiological Impacts	• Wearing an N95 respirator for 2 hours during a low-moderate work rate did not significantly impact thermal burden (i.e. core temperature or uncovered face skin temperature) • Perceptions of increase thermal burden, may relate to temperature of face skin underneath the respirator and air inside respirator
Kim et al.[78]	2013	Physiological Impacts	General Use	Physiological Impacts	• Healthy individuals had small pulmonary and heart rate responses to wearing a N95 respirator during a low-moderate work rate for 1 hour, indicating they can be well tolerated
Rebmann et al.[79]	2013	Physiological Impacts	Occupational	Physiological Impacts	• Among long-term use of respirators by healthcare workers, there was no clinically significant physiological burden • Subjective symptoms were reported (i.e. shortness of air, lightheadedness, difficulty communicating, headaches) • Compliance was high
He et al.[80]	2014	Physiological Impacts	General Use	Fit	• Breathing frequency may impact the performance of N95 respiratory, with higher frequencies increasing total inward leakage
Roberge et al.[81]	2014	Physiological Impacts	General Use	Health Outcomes	• Short term N95 respirator use among healthy pregnant women did not have any significant differences on physiological response than nonpregnant women
Kim et al.[82]	2015	Physiological Impacts	General Use	Physiological Impacts	• The external airflow resistive load of face coverings did not have any significant differences on physiologic response between pregnant and non-pregnant woman
Tong et al.[83]	2015	Physiological Impacts	Healthcare	Physiological Impacts	• Wearing an N95 respirator can add burden on gas exchange the metabolism among pregnant healthcare workers
Luximon et al. [84]	2016	Physiological Impacts	General Use	Physiological Impacts	• N95 respirators can result in higher face temperature and thus perceived comfort
Fikenzer et al.[85]	2020	Physiological Impacts	General Use	Physiological Impacts	• N95 respirators impaired ventilation, cardiopulmonary exercise capacity, and comfort • Important for recommendations for use at work or during exercise

Hu et al.[86]	2020	Physiological Impacts	Healthcare	Physiological Impacts	• Skin reactions can be experienced with prolonged use of N95 respirators among health care workers
Hua et al.[87]	2020	Physiological Impacts	General Use	Physiological Impacts	• Skin reactions are associated with mask use, especially N95 respirators
Ong et al.[88]	2020	Physiological Impacts	Healthcare	Physiological Impacts	• Using PPE, such as N95 respirators, among healthcare workers can lead to headaches or exacerbation of pre-existing headaches
Roeckner et al.[89]	2020	Physiological Impacts	General Use	Health Outcomes	• Limited use of N95 respirators is unlikely to have adverse effects on pregnant women and the fetus
Zuo et al.[90]	2020	Physiological Impacts	Healthcare	Physiological Impacts	• Skin reactions related to mask use were common, especially N95 respirators
Lofgren[91]	2018	Policies and Regulations	General Public	Policy Recommendations	• Fit capability is not part of the critical performance requirement certification of FFP's by NIOSH • Without this, individuals may be buying respirator models that fit only a small percentage of users
Takemura et al.[92]	2008	Training and Risk Communication	Occupational	Fit	• Among workers exposed to dust, education significantly decreased mask leakage; education was easy and took a short amount of time
Brosseau[93]	2010	Training and Risk Communication	General Use	Fit	• Almost all subjects were able to properly place the respirator on their face and mold the nosepiece; straps were improperly place most of the time • Almost all had reviewed instructions (73%) and performed a seal check (80%) • A majority were able to achieve a fit factor of 10; mean fit factors ranged from 19-28
Sugerman et al.[94]	2012	Training and Risk Communication	General Public	Risk Reduction Behaviors	• Decreased recall and compliance to more technical public health messages during wildfires (i.e. N95 respirators)
Harber et al.*[95]	2013	Training and Risk Communication	General Use	Fit	• Of three training interventions (e.g. brochure, video, and computer-based), the video training was significantly better than the other two types of training

Harber et al.[96]	2013	Training and Risk Communication	General Use	Proper Use	• Knowledge tests after training participants indicated adequate learning, but performance measures were poor • Inspection, strap tension, and conducting seal check were identified as steps in the donning process as problematic; mask position was done well • Recommends the approval of respirators consider the users' ability to learn how to don and doff one
Jones et al.[97]	2013	Training and Risk Communication	General Use	Fit	• Among three types of training modalities (i.e. video presentation, small group demonstration, and slide show) there was no difference on ease or success of N95 respirator fit
Haber et al.[98]	2014	Training and Risk Communication	General Use	Fit; Proper use	• For those who use respirators intermittently, they should periodically be retrained and evaluated
Yu et al.[99]	2014	Training and Risk Communication	General Use	Fit	• Fit factor significantly improved with training compared to no training
Luong et al.[100]	2016	Training and Risk Communication	Occupational	Proper Use, Fit	• Review of training and education on PPE use among workers • Conclude that there is 'very low' quality evidence behavior interventions (i.e. education and training) for the effect on correctness and frequency of respiratory protection equipment
Rembialkowski et al.[101]	2017	Training and Risk Communication	General Use	Fit	• It would be beneficial for respirators users to re-train every time they use a respirator and receive assisted training
Kim et al.[102]	2019	Training and Risk Communication	Occupational	Fit	• Training on how to wear an N95 respirator improved the expected protection among healthcare workers • Three types of training: lecture, real-time feedback, and fit check
Beam et al.[103]	2020	Training and Risk Communication	Healthcare	Risk Reduction Behaviors	• Reflective practice training improved target safety behaviors more than the video training • Participants perceived their donning and doffing performance to be better than scored on their safety behaviors
Díaz-Guio et al.[104]	2020	Training and Risk Communication	Healthcare	Socio-Cognitive Perceptions	• Educational intervention improved perceived difficulties with donning an N95 respirator

Robertsen et al.*[105]	2020	Training and Risk Communication	Occupational	Socio-Cognitive Perceptions; Fit	• The intervention (training and/or fit testing) improved the individual's knowledge and attitudes surrounding respiratory protection equipment • Practical issues with respiratory protection equipment are sources of non-compliance with use
Tan et al.[106]	2020	Training and Risk Communication	Occupational	Proper use	• In a training program for healthcare workers, N95 respirators needed the most training
Verbeek et al.[107]	2020	Training and Risk Communication	Occupational	Proper Use	• In person training, computer simulation, and video lecture may be lead to better donning and doffing • Quality of evidence is low for different types of training for donning and doffing procedures for respirators

*Indicates it was found by looking through bibliography of another article

Summary

The most evidence available of identified themes on N95 respirators use was is in occupational settings (n=27), specifically in healthcare (n=19), and ambient air pollution (n=28). We only identified one article analyzing related policy and regulations—grey literature was not included in this summary. While the evidence is growing for the recommendation to use face masks for air pollution, an ethical framework can support public health decision-making.

Our literature summarization found that research on the use of respirators for ambient air pollution, including filter efficiency, exposure reduction, and health benefits has increased in the last few years. Wearing an N95 respirator for ambient particulate exposure may have short term cardiovascular benefits (i.e. heart rate variability and blood pressure). The findings are still mixed if N95 respirators effectively reduce exposure to ambient pollution—in regard to both filter efficiency of the material for the compounds and whether proper fit can be achieved by the general public. However, it should be noted that the composition and concentration of wildfire smoke can be drastically different than ambient air pollution (Black et al., 2017). Research specific to wildfire smoke, reported an increase in use or risk reduction behavior, but did not elaborate on the associations between use and exposure reduction and/or health benefits.

Women, children, and those with pre-existing conditions, may be more likely to wear a mask to reduce exposure to air pollution and wildfires. Common errors in the donning process among the general public and in occupational settings include molding the nosepiece, straps in the incorrect position, or having upside down—important considerations for developing training materials.

The protection an N95 respirator can provide is dependent on the filter material and fit. Fitting characteristics will vary by N95 respirator type (e.g. cup or folding) and by manufacturer and model. This is a challenge for general public use as there are a lot of N95 respirators available on market, and individuals outside of required use in occupational settings do not necessarily have access to fit testing to confirm fit. N95 respirators with exhalation valves may improve comfort and tolerance and reduce thermal burden, and thus compliance. This is important as wildfire smoke often comes with high outdoor temperatures.

Most studies looking at the physiological impacts of wearing an N95 respirator were conducted among healthcare workers. Although there is a lot to learn from this setting, their use (i.e. frequency and duration) is different than for the general public's use for air pollution or wildfires. Overall, a healthy individual can wear an N95 respirator for short periods of time for a low to moderate work rate without experiencing a physiological burden (e.g. walking to the store from your car during bad wildfire smoke). However, N95 respirators are often perceived as uncomfortable and reduce breathability, potentially inhibiting compliance.

Training improved proper N95 respirator use in occupational settings, but even healthcare workers struggled with properly donning and doffing an N95 respirator, suggesting that the general population, where there is less occupational knowledge and familiarly of use, may struggle as well. Educational based trainings can improve knowledge, but this does not necessarily correlate to action and fit, and the act of seal-check should not be used as indictor of good fit. Video and interactive training is likely to improve proper use more than other training modalities; and training should be repeated over time of with each donning, if possible.

Further research is needed on the filtration efficiency of N95 respirators for wildfire smoke, as Gao et al. (2015) found higher penetration of combustion particles than model NaCl particles across N95 filter material, supporting. Epidemiological research is needed to understand the health benefits associated with exposure reduction during wildfire smoke events. And more information is needed on the efficacy of training interventions designed for the general public, as well as a better understanding of the public's knowledge, attitudes, and commitment to practice for using N95 respirators to reduce wildfire smoke exposure.

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Aim 2: Evaluate the impact training has on N95 respirator fit in a convenience sample of untrained, lay-public.

The effect of training on N95 respirator fit in a convenience sample of untrained, lay-public: implications for non-traditional use during wildfire smoke events

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Abstract

Climate change is increasing the frequency, intensity, and duration of wildfires. To reduce personal exposure to wildfire smoke and resulting adverse health effects, N95 respirators are increasingly used by the general public to filter out fine particles ($PM_{2.5}$) present in smoke. When mandated in an occupational setting, the use of N95 masks requires medical clearance, proper training, and fit testing. This rigorous attention to training and proper respirator fit is generally, neither required or practiced by, the lay public. Here, we assessed the impact training has on N95 respirator fit in a convenience sample of forty individuals with no formal respirator training. To this end, we administered a Knowledge, Attitude and Practices (KAP) survey to identify baseline knowledge and training retention; conducted a quantitative respirator fit test prior to, and after, each participant received their randomly assigned training material; and observed and analyzed the actions taken by participants during the donning process that affect fit. We found that the selected factsheet and manufacturer training improved the fit factor of participants best, though the improvement did not achieve the passing fit factor of 100 for required use in an occupational setting. Pre-training fit testing found that most individuals achieved a fit factor of 2, a 50% decrease in particulate exposure. Post-training fit testing found most individuals reached a fit factor of at least 10, an expected 90% reduction in exposure. In comparing participants pre-intervention KAP survey results with initial fit factors, participants tended to overestimate their

knowledge on proper fit. In the absence of fit testing, effective training and risk communication is necessary for the use of N95 respirators by the general public. With training, N95 respirators can provide protection for the general public during wildfire smoke events, but without proper use, N95 respirators may not reduce $PM_{2.5}$ exposure to levels considered safe for public health. The results of this study will provide evidence on the efficacy of N95 respirators and training for proper fit as a personal intervention to reduce exposure to wildfire smoke

Key Words: N95 respirators, wildfire smoke, personal intervention, training

1.0 Introduction

1.1 Wildfires

Wildfires are becoming an increasingly important public health issue across the Western United States as human populations in the wildland-urban interface continue to expand (Radeloff et al., 2005). The number of houses in the wildland-urban interface (WUI) grew from 30.8 million to 43.4 million (41%) in the United States between 1990 and 2010 (Radeloff et al., 2018). This is further exacerbated by climate change which has extended regional fire seasons and increased the frequency, duration and intensity of wildfires (Liu et al., 2016). By 2050, it is predicted that the duration of the wildfire season will be extended by three weeks and that the fires will be twice as smoky (Yue et al., 2013). Wildfire smoke contains a variety of compounds, including fine and coarse particulate matter ($PM_{2.5}$ and PM_{10}), carbon dioxide, hydrocarbons, carbon monoxide, and other hazardous compounds. Approximately 90% of total particle mass emitted from wildfires consists of fine particulate matter (Vincente et al., 2013). Wildfire smoke events can have extremely high $PM_{2.5}$ concentrations that can last for hours, days, or weeks.

1.*2 Health Effects of Wildfire Smoke Exposure*

Population health is negatively affected by exposure to wildfire smoke, with $PM_{2.5}$ as the primary air pollutant of concern for public health. The particular risk of $PM_{2.5}$ exposure is that fine particles can be inhaled deep into your lungs causing irritation and inflammation. Further, due to their small size, these particles can enter systematic circulation. Short term exposure to particulate matter can result in health effects ranging from eye, nose, and throat irritation to headaches, wheezing, coughing, and shortness of breath. Wildfire smoke exposure is associated with all-cause mortality (Doubleday et al., 2020; Zu et al., 2016; Kollanus et al., 2016), respiratory morbidity in the general population (Liu et al., 2017a; Lui et al., 2017b; Tinling et al., 2016; Reid et al., 2016b; Parthum et al., 2017; Le et al., 2014), and exacerbation of symptoms for individuals with asthma, chronic obstructive pulmonary disease, bronchitis, or pneumonia (Youssouf et al., 2014; Liu et al., 2015; Reid et al., 2016a).

Fan et al. (2018) modeled an estimate that 5,200 to 8,500 of hospital admissions related to respiratory issues between 2008 and 2019 were due to wildfires. A recent study in Washington State found an increased risk of all-cause mortality during the days following exposure to wildfire smoke (Doubleday et al., 2020). Johnston et al. (2012) estimated the annual global mortality from wildfire smoke to be 339,000 deaths. Epidemiological data for cardiovascular related mortality and morbidity due to wildfire smoke is inconclusive and no studies have found an association between exposures to wildfire smoke and respiratory related mortality (Cascio, 2018). Children, adults over the age of 65, individuals with pre-existing respiratory and cardiovascular conditions, and those who spend large amounts of time outdoors are at highest risk of exposure and the associated health impacts. Collectively, these subpopulations account for a very large number of individuals in the United States (Cascio, 2018). Understanding the relationships between wildfire smoke and human health is complex due to aspects such as exposure assessment, cumulative exposures, and toxicological data, and the research continues to evolve (Black et al., 2017).

1.3 Risk Reduction Through Exposure Reduction

With the increasing risk of wildfires due to climate change and expansion of the WUI, there is increased attention on the use of personal interventions to reduce risk from wildfire smoke. These include reduction of outdoor physical activity, remaining indoors with a clean air room or improved air filtration, utilization of clean air shelters, and evacuation of the affected area (Laumbach, 2019). No large-scale studies have been conducted on the effectiveness of these interventions to reduce exposure to wildfire smoke (Laumbach, 2019). Additional efficacy research is needed to support these recommendations as evidence-based public health actions.

1.4 Increasing use and need of N95 Respirators in Washington State

The use of N95 respirators as a personal exposure reduction intervention has increased over the last several years. In 2017 and 2018, the Washington State Department of Health (WA DOH) distributed statewide a total 72,460 and 249,040 N95 respirators, respectively. (J. Fox, personal communication, 2019). Noting the implications of wide-spread public use, a 2018 Wildfire Smoke Risk Communication Stakeholder Synthesis Symposium, held in Seattle, Washington, called for evidence-based intervention strategies. N95 mask efficacy research and risk communication strategies were identified as specific needs to protect population health during prolonged and extreme smoke events (Pendergrast et al., 2019).

1.5 What are N95 respirators?

Commonly referred to as N95 masks or dust masks by the general public, N95 respirators are a form of personal protective equipment (PPE) known as disposable filtering facepieces (FFP), which are certified by the National Institute for Occupational Safety and Health (NIOSH) for use in an occupational setting to reduce exposure to particulates or biohazards (Respiratory Protective Devices, 1995). Respirators or masks sold to the general public are not required to be certified by NIOSH. N95 respirators work by using electrostatic attraction (i.e. Van der Waal forces) and physical forces (i.e. gravitational settling, inertia, interception, and diffusion) to capture particulates in fibrous filter material (Hinds 1999). NIOSH certification requires a minimum filtration of 95% of the most penetrating particles of 0.3 microns in size. Particles both smaller and larger in size are presumably filtered more efficiently due to aerosol properties during movement of air through the filter material (Respiratory Protective Devices, 1995; Hinds, 1999). N95 respirators do not provide protection against gasses and vapors. The mandatory use of N95 respirators in an occupational setting requires medical clearance, proper training, and individual fit testing (Respiratory Protection, 1998). The effectiveness of an N95 respirator to reduce exposure to particulate matter depends on the filter material and fit, which is an evaluation of the seal between the mask and the wearer's face. Without fit testing, an N95 respirator may not be effective because the individual fit cannot be guaranteed. This is especially important as no single N95 respirator model and size will properly fit every individual (Rembialkowski et al., 2017). While fit testing is not a challenging task, it can be time-consuming and may not be feasible on a large scale or in settings where their use is not mandatory (Jones et al., 2013). There are currently no national regulations for the use of respirators at work during wildfire smoke events with unsafe levels of particulate matter (PM) Rather, there is only a permissible exposure limit (PEL) for general PM originated in the workplace (Air Contaminants, 2016). The lay public is not subject to standard occupational requirements around the use of N95 respirators (i.e. medical clearance and fit testing) and aspects of occupational use that are important to proper use and fit could be hard to communicate to the lay public, especially when there is no policy or no equivalent regulatory body equivalent to OSHA.

1.6 Use of N95 respirators by the general public during other disasters

The use of N95 respirators by the general public during disasters, such as wildfires, is not novel. They have been used for cleaning-up mold after flooding and as a non-pharmaceutical intervention for public health emergencies, such as pandemics (CDC, 2018). Few peer reviewed studies focus on their use among the general public or a similar untrained non-occupational group. After Hurricane Katrina, public health authorities recommended public use of N95 respirators when cleaning mold; however, it was found that a majority participants improperly donned them (Cummings et al., 2007). The Food and Drug Administration (FDA) has developed guidance for classifying the use of filtering facepiece respirators, including N95 respirators, for the general public during a public health emergency (FDA, 2020). This rule is to ensure safety and effectiveness of classified devices by identifying issues (i.e. filtration and breathability; proper fit; skin reactions; and proper use) and requiring corresponding mitigation measures (i.e. NIOSH certification; fit assessment; biocompatibility testing; and labeling). To our knowledge, this is the only known non-occupational regulatory policy for the use of N95 respirators. During the 2020 COVID-19 pandemic, the use of face coverings, including N95 respirators, has become the standard among the general public (Matusiak et al., 2020). However, non-NIOSH approved face masks, such as surgical masks, dust masks, and cloth face coverings will not provide the filtration efficiency as a N95 or another NIOSH approved respirator (Rengasamy et al., 2008; Rengasamy et al., 2009; Rengasamy et el, 2010).

1.7 Use of N95 respirators for ambient air quality and non-emergency purposes

The use of N95 respirators or other face masks is also becoming more prevalent to reduce exposure to ambient urban air pollution and other sources of particulate matter. Studies primarily done in China have examined the association between mask wearing for ambient particulate matter air pollution and short-term cardiovascular benefits, including lower blood pressure and increased heart rate variability (Shi et al. 2017, and Langrish et al., 2009). Langrish et al. (2012) found that among patients with coronary heart disease, using a filtering face piece respirator for ambient particulate matter pollution reduced cardiovascular symptoms and health measures.

These results identify filtering face piece respirators as a potential personal intervention for sensitive sub-populations to reduce particulate matter exposure. However, these studies did not include associated exposure reduction estimates (Cherrie et al., 2018). Guan et al. (2018) found mixed results for health benefits associated with use of face masks. Among young, healthy adults in China, the use of N95 respirators partially reduced acute respiratory inflammation associated with particulate exposure, but oxidative stress and endothelial dysfunction did not improve (Guan et al., 2018). Additional research is needed on respirator use by sensitive sub-populations (e.g. children, older adults, or those with pre-existing respiratory and cardiovascular conditions), as they experience the health burdens of air pollution exposure disproportionately. Morishita et al. (2019) conducted the first study in North America (in a less severely polluted environment) on the cardiovascular benefits of wearing an N95 respirator for traffic-related air pollution and found mixed findings—highlighting the importance of further studies, especially for combustion-derived nanoparticles.

Two studies have specifically looked at the efficiency performance of mask filters of diesel exhaust particulates; both of which did not recommend commercially available dust masks or using N95 filters (not resistant to oil) for diesel exhaust particulates, as it may not provide sufficient protection (Penconek et al., 2013; and Janssen and Bidwell, 2006). Janseen and Bidwell (2006) noted that R95 (resistant to oil) and P95 filters (oil proof) would be acceptable for diesel particulate exposure in the workplace. Though these studies looked at the filter efficiency performance for this type of particulate and not the fit on an individual and expected exposure reduction, they are important to consider as diesel exhaust is a component of urban ambient air pollution. Cherrie et al. (2018) is the first study to connect respiratory filter efficiency and fit performance when donned on individuals for air pollution. They found that some commercial face masks marked for $PM_{2.5}$ in China may not provide adequate filtration efficiency for diesel particles due to poor fit and recommend including exposure reduction measurements when studying the health impacts of face masks. The study also found that masks marketed for air pollution in China did not always achieve expected protection when worn and the masks that were effective, did not provide consistent protection across activities done by study participants. It is important to consider that the results of all discussed studies may not be generalizable to the use of other types and models of face masks, as they all use different respirators for their study protocols and the fitting characteristics of respirators vary by manufacturer (CDC, 1998; Coffey et al., 2004).

Ethics is also an important consideration in public health decision making surrounding the recommendation of facemasks as an intervention for air pollution (McDonald et al., 2020). McDonald et al. (2020) developed an ethical decision-making framework that can increase clarity and thus trust and agreement about the recommended use of facemasks.

Equivalent research is needed for the filter efficiency, expected exposure reduction, and health benefits of respirator use for wildfire smoke pollution due to a different mix and size distribution of chemicals than present in ambient air pollution (Black et al., 2017).

1.8 N95 Respirator Training

The proper use and potential health benefits start with effective training to ensure correct donning and fit. Respiratory protection programs in the workplace require training when their use is mandatory (Respiratory Protection, 1998). If their use is voluntary, employers are required to supply the employee with Appendix D of the OSHA Respiratory protection Standard 1910.134, which recommends that the employee read the instruction manual that comes with the purchase of a respirator. The content of the instruction manual will vary by manufacturer. Previous studies in occupational settings have found training to be effective in improving use (Diaz-Guio et al., 2020; Pompeii et al., 2020; Verbeek et al., 2020; Donham et al., 2010).

However, the public does not have access to training typically available in occupational settings (e.g. employer provided one-on-one or assisted training) which has been found to improve use and fit of N95 respirators (Harber et al., 2013b). If the occupational training programs assess confirmation of learning, it is usually done so using a knowledge-based test immediately following training. Harber et al. (2013b) assessed respirator user training using both knowledge and performance outcomes. Just-in-time training is a type of training designed to teach individuals when the information is needed, rather than ahead of time, and is increasingly used for staff in disaster settings, including respiratory protection. Jones et al. (2013) assessed the effectiveness of three modalities of just-in-time trainings for N95 respirator fit. Harber et al. (2013a) also compared three respirator training methods (i.e. print, video, and computer-based training). Proper respirator training is unlikely used outside of traditional occupational settings (Harber et al., 2013b). To our knowledge, no studies have assessed N95 respirator training designed for public disaster preparedness. Without training, the proper use of N95 respirators is unlikely (Jones et al., 2013).

1.9 Risk Communication of N95 Respirators

There is a need for increased information about N95 respirator use for the general public and effectiveness as a personal intervention to reduce wildfire smoke exposure. Achieving filtration efficiency requires proper use and fit—the nuances associated with this can be hard to communicate to the general public. This is especially difficult in public health, when the practice of plain talk is common and there is less compliance to more technical public health messages during wildfires (e.g. technical language such as “N95 respirators,” compared to “stay indoors”) (Sugerman et al., 2012). Public health officials must weigh the benefit of providing an option that is better than nothing against the danger of potentially providing a false sense of security (Huang and Morawska, 2019). Without regulations, established science, and access to fit testing, effective training is key for proper use and thus reduced risk to wildfire smoke by the general public. Here, we evaluated the impact of training has on N95 respirator fit in a convenience sample of untrained, lay-public. This study will add to the limited body of knowledge on the efficacy and effectiveness of personal interventions for the public to reduce exposure to wildfire smoke and provide recommendations for training and communication to the lay public around the use of N95 respirators.

2.0 Materials and Methods

Our goal was to evaluate the transference of knowledge from different training materials into proper N95 respirator use in a convenience sample of untrained individuals. We employed a pre/post experimental study and evaluated the change in fit, before and after receiving one of four randomly selected training materials, by estimating fit factors as determined by occupational fit testing.

This project was approved by the University of Washington Institutional Review Board (IRB) and all participants went through an informed consent process prior to data collection (Appendices G, I). All participants were assigned a unique subject ID to protect personal information. The unique subject ID and study records could not be linked to identifying information. Additional details are available in Appendix A.

2.1 Study Population

This study recruited 40 participants from a convenience sample of University of Washington students, faculty, and staff. A variety of recruitment materials were used to promote the study, including in-person conversations during university classes, social media messaging in academic groups, and flyers posted throughout campus (Appendix H). Participants were then selected for the study based on pre-established inclusion and exclusion criteria via email to conduct a screening of eligibility (Appendix I). Inclusion criteria included participants over the age of 18. No exclusions were made on the basis of gender, race, ethnicity, sex, or religion. Those who had a pre-existing respiratory or cardiovascular disease; were unwilling to refrain from smoking 60 minutes prior to and during the study; did not read in English (training materials were limited to English); had received previous training on how to wear an N95 respirator; had received a previous fit testing for a respirator; or had motor impairments that prevented them from being able to put on the mask themselves; or hear verbal training to watch the video were excluded.

2.2 Materials

Three training materials commonly available to the general public and frequently used with N95 respirators during wildfire smoke events were selected: (1) the Washington State Department of Health's (DOH) factsheet, "Wildfire Smoke and Face Masks" (WA DOH, 2019); (2) the "Smoke from Fires: N95 Respirator Masks" video, done in collaboration between the University of Washington Department of Environmental Occupational Health Sciences (DEOHS) and Seattle and King County Public Health Department (KCPHD), with partial original content from a video produced by the Ashland Chamber of Commerce (2018), (Ting, 2018); and (3) the manufacturer's instructions enclosed with the purchased N95 respirator. We utilized a control group where participants received no training to assess a potential learning effect and natural variability with increased donning's of an N95 respirator.

The OSHA classification of FFP signifies N95 respirators as a negative pressure respirator, so that during inhalation, the air pressure inside the respirator is negative compared to the air pressure outside the respiration, pulling particles through the N95 filter medium. Three sizes of HDX N95 respirators were selected for this study: H950S (small); H950 (medium/large); and H950V (one size fits all). The brand of respirator was chosen for this study based on its availability and accessibility to the general public, as well as the availability of sizes to fit a range of face dimensions. If the respirator fit poorly on an individual due to incompatibility with their face size, it would negate the impact of training between fit tests. Thus, we chose to don participants in the correct sized N95 respirator for the first two fit tests to account for differences in face size as an effect modifier on the fit. We used the anthropometric measurement guidelines developed by NIOSH and NPPTL to take participants' facial measurements (Zhuang et al., 2007). Mento-sellion length (face length) was taken using a sliding caliper, and bizygomatic breadth (face width) using a spreading caliper; both of which are traditional anthropometric instruments. These measurements were then applied to the NIOSH-NPPTL bivariate respirator fit panel to determine correct size. One measurement of mento-sellion length and bizygomatic breadth was taken. If the measurements were on the border of the size panel's limits, a second measurement was taken and then averaged with the first. Participants that were measured to be a medium or large received the H950 (medium/large) model, as there was no manufacturer brand widely available to the general public that included all three individual sizes and a one size fits all.

2.3 Fit Testing Methodology

The primary author completed respiratory protection training and conducted the fit testing and data collection at the University of Washington DEOHS Roosevelt Building. To measure fit, we selected the ambient aerosol condensation nuclei counter (CNC) quantitative fit testing protocol outlined in OSHA standard 29 CFR 1910.134. The premise of a fit test is that all the particles detected inside the mask during the test did not pass through the N95 material, but rather passed through gaps in the seal such as between the chin or around the nose. This is different than the filtration efficiency of the N95 material, which is assessed by another process. Both proper fit on the individual and the filter material are important in achieving protection. Quantitative fit testing assesses the adequacy of respirator fit by numerically measuring the amount of aerosol leakage into the respirator measured by a fit factor, the ratio of the concentration in the ambient air to the concentration inside the respirator when donned. To do so, we used a factory calibrated TSI PortaCount Pro + 8038 (serial #8039154313, Shoreview, MN), in the N95 companion mode. The N95 companion mode measures negatively charged 40-60nm sized particles, as this size and charge is best captured by the N95 filter material and therefore detection of these particles indicates a seal leak. The HDX N95 respirators were probed following TSI protocols. The TSI PortaCount Pro + 8038 calculates an overall fit factor using fit factors produced by eight separate exercises (excluding Grimace). These exercises are completed by the individual while wearing the respirator and standing for 60 seconds/exercise. The eight exercises in order of completion are: (1) Normal Breathing (2) Deep Breathing (3) Head side-to-side (4) Head up-and-down (5) Talking out loud (6) Grimace (7) Bending (8) Normal Breathing. The equation to calculate a fit factor is presented as equation 1:

Equation 1[a]:

$$Fit\ Factor = C_B + C_A / 2C_R$$

[a] (C_B = particle concentration in the ambient sample before the respirator sample; C_A = particle concentration in the ambient sample after the respirator sample; and C_R = particle concentration in the respirator sample).

There is a new modified version of the ambient aerosol condensation nuclei counter quantitative fit test protocol that is more streamlined with fewer exercises and duration (Respiratory Protection, 1998). However, this modified protocol was issued and finalized after this study had started and thus, we continued to follow the original protocol. During the fit test, the administrator prompted the subject on how to perform the exercises but did not provide indication on how to properly don an N95 respirator. The standard programming of the TSI PortaCount Pro + 8038 will automatically stop the fit test if the individual fails to achieve the occupational regulatory minimum accepted FF of 100. To be able to collect data on FF's below 100, we programed the TSI PortaCount Pro + 8038 to have a passing FF of 1. A TSI defined Daily Check was conducted each day prior to fit testing. Ambient air particle levels were high enough for reliable tests for all participants. Participants were not informed of their fit factors during the study in case knowing whether they had a high or low fit factor impacted their sense of security and affected how they received the training and donned the N95 respirator.

2.4 KAP Survey Methodology

A Knowledge, Attitude, and Practice (KAP) Survey was administered pre and post interventions and fit testing. The survey gathered data on knowledge gained from training (or study process in the case of the controls), attitudes regarding respirator use, and commitment to use of N95 respirators during future wildfire smoke events. The survey included twenty-one questions assessed on a 5-point Likert scale (Appendices P, Q).

2.5 Observation Methodology

This study also sought to describe observations of physical actions taken by study participants that influence proper fit. Participants were video recorded in single plane during the donning process and key actions important to fit were later analyzed (Figure 8, Table B7). Actions analyzed were selected *a prioi* based on key concepts in training materials, expert knowledge of the research team, and methods developed in Harber et al. (2013b). Two members of the research team reviewed 20% of the videos together and adjudicated differences in interpreting the actions taken, prior to the primary coder completing the remainder.

2.6 Study Protocols

Measurements taken to determine the appropriately sized N95 respirator for the participant, including the length and width of the participant's face, were taken while the participant was standing and then compared to the NIOSH and National Personal Protective

Technology Laboratory (NPPTL) Bivariate Test Panel (Appendix M, Zhuang et al., 2007). After completing the pre-intervention KAP survey (Appendix Q), participants were given their correct sized respirator and asked to don it. Once donned, participants completed their pre-intervention quantitative fit test. Participants were then randomized into one of the four intervention arms: control, video, factsheet, or manufacturer's instructions (Appendix L). Participants were allotted as much time as they needed to feel they adequately learned the training material. After completing the intervention, subjects donned a new N95 respirator of the same size and completed a second quantitative fit test. If the participants were in the control group, they were given the option to have a break. Participants then completed a third quantitative fit test after donning a one-size fits all N95 respirator with the option to take a break or review the training material. After the fit testing portion of the protocols, participants completed the post-intervention KAP survey (Appendix R) and completed a demographic questionnaire (Appendix S). On completion of study protocols, participants received a $25 gift card in appreciation for their efforts.

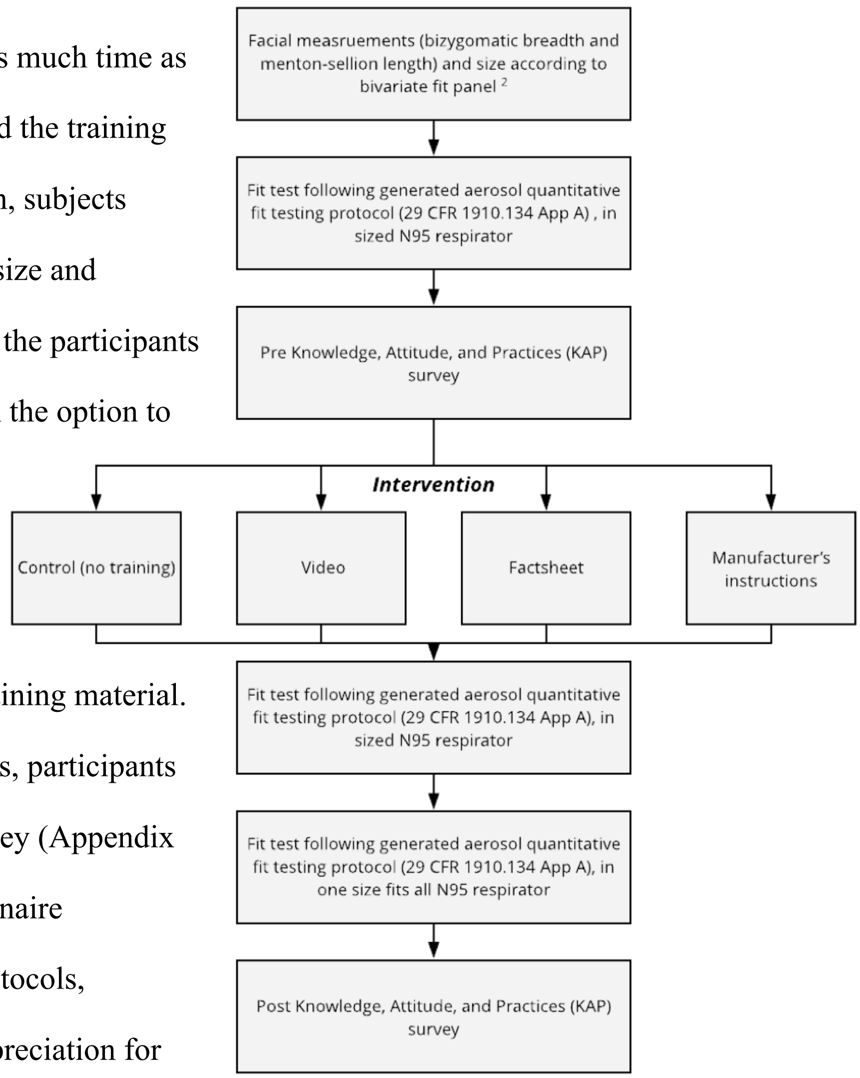


Figure 1. **Flow diagram of study protocols**
Diagram of study protocols and data collected from participants including: facial measurements, pre- and post-KAP surveys, three fit tests, and training intervention

2.7 Data Analysis

All participant data was imported into an Excel spread-sheet (Excel, 2016, Microsoft, Inc., Redmond, WA), then into R studio 1.1.456, for data analysis (RStudio, Inc., 2018). Figures were developed using the '*ggplot2*' package (v3.3.2; Wickham, 2016). Participant characteristics, KAP survey data, and video observation data were analyzed and described using the *'summarytools'* package in Rstudio (v0.9.6; Comtois, 2020).

We used multivariate linear regression to compare the impact of training modality on N95 respirator fit between all fit tests by intervention group (α=.05). The model is shown as equation 2.

Equation 2[b]:

$$Y_{post} = \beta_0 + \beta_V I\{V\} + \beta_M I\{M\} + \beta_F I\{F\} + \beta_{pre} Y_{pre}$$

[b] (*I{V}, I{M}, I{F}* are the indicators for membership in each intervention group, such that *I{intervention} = { 1, if the participant is in intervention group and 0 otherwise* ; $\beta_V, \beta_M, \beta_F$ are the coefficients associated with the group membership variables; and β_{pre} is the coefficient associated with the adjusting variable Y_{pre}. The reference group is our control group.)

To compare the difference in N95 respirator fit between the correct size respirator and a one size fits all respirator, a separate multivariate linear regression model was built, and used the Y_{one} size as the outcome with adjustment for the Y_{post} (α=.05). The model is shown as equation 3 with the indicators and coefficients are the same as the model above.

Equation 3[b]:

$$Y_{one} = \beta_0 + \beta_V I\{V\} + \beta_M I\{M\} + \beta_F I\{F\} + \beta_{post} Y_{post}$$

In addition to investigating how training materials influence fit, we also investigated the expected level of protection after such change in fit. Fit factor thresholds of (>2, >5, >10, >50, >100) were selected (FDA, 2007) and the proportion of participants achieving those fit factors compared. We built a linear regression model of post-training fit test results based on whether the participants were in the treatment group, adjusting for the pre-training fit test results (α=.05).

The example of the model for a fit factor of >2 is shown as Equation 4.

Equation 4[c]:

$$I\{Y_{post} > 2\} = \beta_0 + \beta_t I\{treatment\} + \beta_{pre} I\{Y_{pre} > 2\}$$

[c] Where the outcome is defined as $I\{Y_{post} > 2\} = \{1, \text{ if } Y_{post} > 2 \text{ and } 0, \text{if } Y_{post} \leq 2$; the main effect is defined as *I{treatment} = { 1, if the participant is in treatment and 0, if the participant is in control group;* and the adjustment variable is defined as $I\{Y_{pre} > 2\} = \{1, \text{ if } Y_{pre} > 2 \text{ and } 0, \text{ if } Y_{pre} \leq 2$.

The change in KAP survey responses pre and post intervention was assessed using a paired sample t-test allowing for unequal variance (α=.05).

For the selected actions related to fit, participant results were coded as 'yes' or 'no' based on whether they completed the action and results summarized as percentage of participants completing each action. Code for all data analysis can be found in Appendix T.

3.0 Results

In describing the results below, the terms "pre", "post", and "one size" refer to which fit test each participant completed. "Pre" refers to the first fit test before receiving an intervention, where the participant was sized to an N95 respirator using the NIOSH- NPPTL Bivariate Test Panel. "Post" refers to the second fit test after receiving an intervention and the participant donned the sized N95 respirator. "One size" refers to the third fit test after receiving an intervention, but where the participant donned a one size fits all N95 respirator.

3.1 Study Population

A total of 40 individuals participated in the study between October and December of 2019. Data were collected from all participants for every portion of the study: three quantitative fit tests, a pre- and post- KAP survey, and recording of video observations. There were 10 unique participants in each intervention group and 10 in the control group. Table 3 describes demographic characteristics of the entire study population by intervention group and by N95 respirator size. Overall, a majority of the participants were female (72.5%, n=29), between the ages of 18-24 (55%, n = 22), white (60%, n=24) or Asian (42.5%, n=17), and did not identify as Hispanic or Latino (95%, n = 38). Most of the participants were college graduates (57.5%, n = 23) with only six having prior occasional use of a respirator (<5 times a year).

Table 3. Demographics of participants

	All		Control		Factsheet		Manufacturer's Instructions		Video	
Characteristic	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Sex										
Male	11	27.5	3	30.0	3	30.0	3	30.0	2	20.0
Female	29	72.5	7	70.0	7	70.0	7	70.0	8	80.0
Age										
18-24	22	55.0	8	80.0	5	50.0	4	40.0	5	50.0
25-30	5	12.5	1	10.0	1	10.0	1	10.0	2	20.0
31-35	2	5.0	1	10.0	1	10.0	0	0.0	0	0.0
36-44	3	7.5	0	0.0	1	10.0	0	0.0	2	20.0
45-64	4	10.0	0	0.0	1	10.0	3	30.0	0	0.0
65+	1	2.5	0	0.0	1	10.0	0	0.0	0	0.0
Race										
Asian	17	42.5	7	70.0	4	40.0	3	30.0	3	30.0
American Indian/Alaska Native	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Native Hawaiian/Pacific Islander	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
White	24	60.0	4	40.0	7	70.0	7	70.0	6	60.0
Black or African American	2	5.0	0	0.0	0	0.0	0	0.0	2	20.0
Other	1	2.5	0	0.0	0	0.0	1	10.0	0	0.0
Ethnicity										
Hispanic or Latino	2	5.0	1	10.0	1	10.0	0	0.0	0	0.0
Not Hispanic or Latino	38	95.0	9	90.0	9	90.0	10	100.0	10	100.0
Education										
High School or less	1	2.5	0	0.0	0	0.0	0	0.0	1	10.0
Some College/technical training	16	40.0	4	40.0	3	30.0	4	40.0	5	50.0
College Graduate	23	57.5	6	60.0	7	70.0	6	60.0	4	40.0
UW Status										
Student	26	65.0	7	70.0	7	70.0	5	50.0	7	70.0
Staff	14	35.0	3	30.0	3	30.0	5	50.0	3	30.0
Respirator Use										
Yes, occasional	6	15.0	0	0.0	3	30.0	2	20.0	1	10.0
Yes, often	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
No	34	85.0	10	100.0	7	70.0	8	80.0	9	90.0

Facial characteristics of study participants are described in Table 4. A majority of participants were size small (65%, n = 26), but were equally distributed across intervention groups (n = 6, 7, 7, 6). Table B1 in Appendix B further breaks down the distribution of participant size by the NIOSH-NPPTL bivariate respirator fit panel. We were unable to recruit any participants for the large sized panel numbers of 8, 9, and 10.

Table 4. Facial characteristics of participants

	All		Control		Factsheet		Manufacturer's Instructions		Video	
Characteristic	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Face Size										
Small	26	65	6	60	6	60	7	70	7	70
Medium/Large	14	35	4	40	4	40	3	30	3	30
Facial Hair										
Yes	3	7.5	0	0	2	20	1	10	0	0
No	37	92.5	10	100	8	80	9	90	10	100
Facial Scar										
Yes	0	0	0	0	0	0	0	0	0	0
No	40	100	10	100	10	100	10	100	10	100
Glasses										
Yes, worn during fit test	13	32.5	4	40	2	20	5	50	2	20
Yes, not worn during fit test	5	12.5	2	20	1	10	2	20	0	0
No	27	67.5	6	60	8	80	5	50	8	80
Head Covering										
Yes	0	0	0	0	0	0	0	0	0	0
No	40	100	10	100	10	100	10	100	10	100

3.2 Fit Factors

We used fit factor, the ratio of particulate concentration in the ambient air to the concentration inside the respirator when donned, as the measurement of N95 respirator fit for participants in this study. Figure 2 displays boxplots of fit factor distributions for each fit test by intervention group. Fit factors increased when subjects received training while donned in a properly sized respirator. However, FF's decreased after subjects subsequently donned a one size fits all respirator.

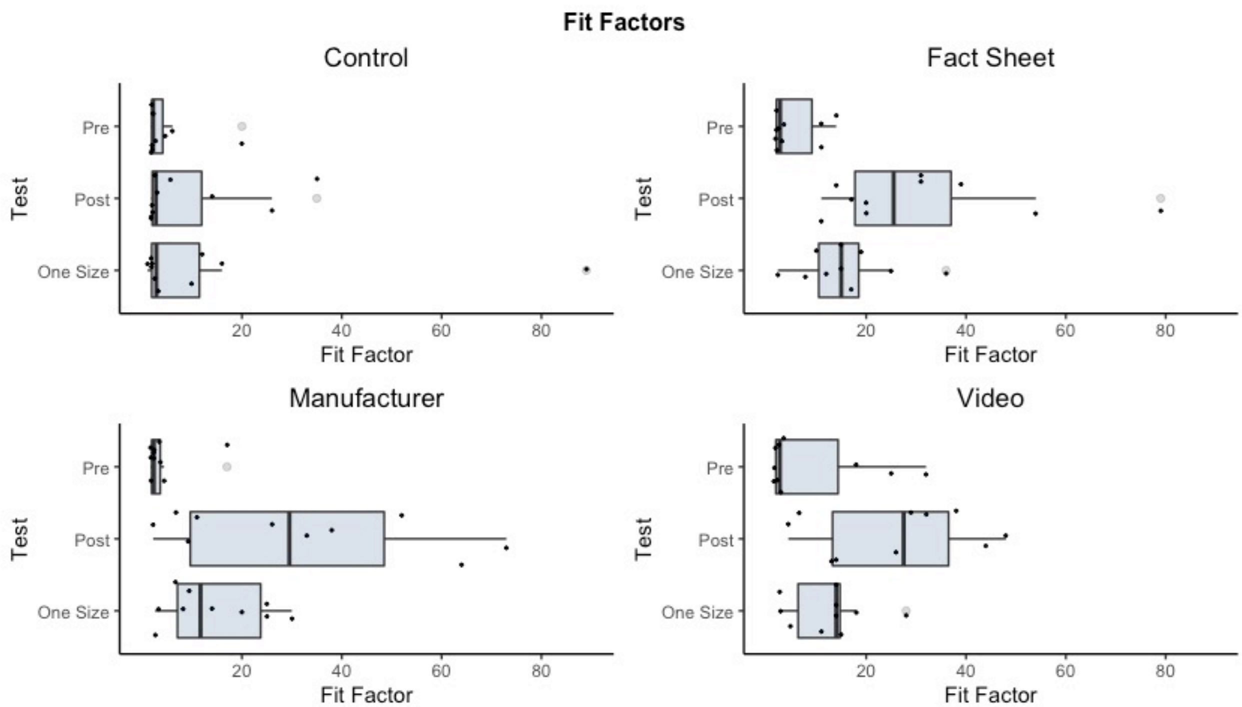


Figure 2. Boxplots of participant's fit factors by intervention
Boxplots display participant's fit factors by intervention and fit test. The box spans the interquartile range of participant's fit factors; the median fit factor is marked by the vertical line inside the box, and the whiskers outside the box extend to the highest and lowest fit factors observed.

The changes in individual participant fit factors before and after training in the correct size mask are displayed through line graphs in Figure 3.The change in the correct size to a "one size" after training is displayed in Figure 4. Training demonstrates an increase in fit compared to the control group. After donning the one size fits all respirator, we observed a decrease in fit as measured by fit factor. In both figures, the change is greater in the training groups compared the control group.

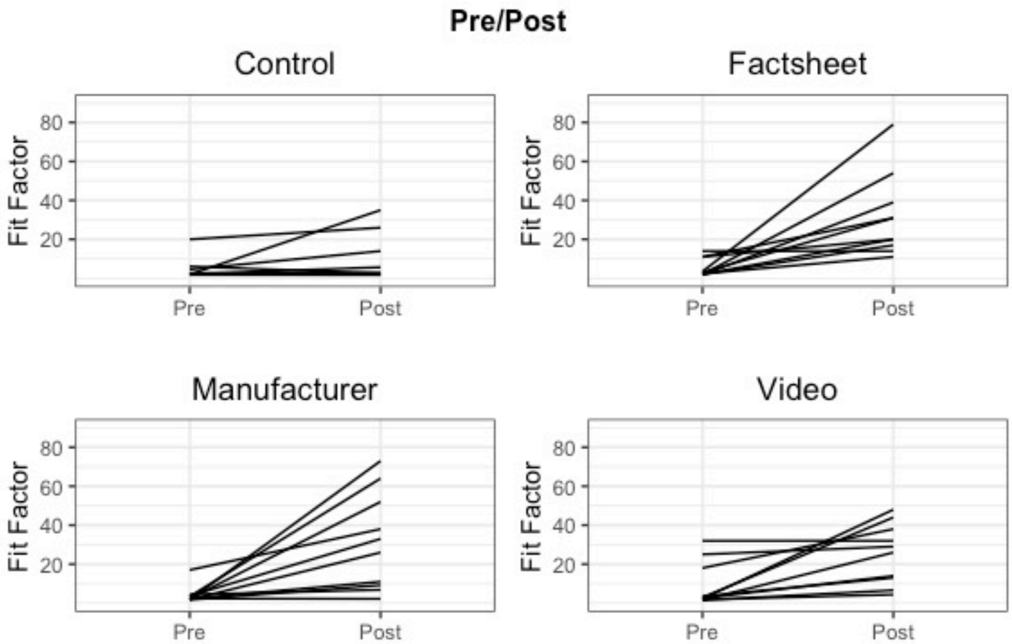


Figure 3. Pre-Post fit factors by intervention
Change in individual participant fit factor before to after training while donned in the correct sized N95 respirator by intervention, as measured by quantitative fit testing.

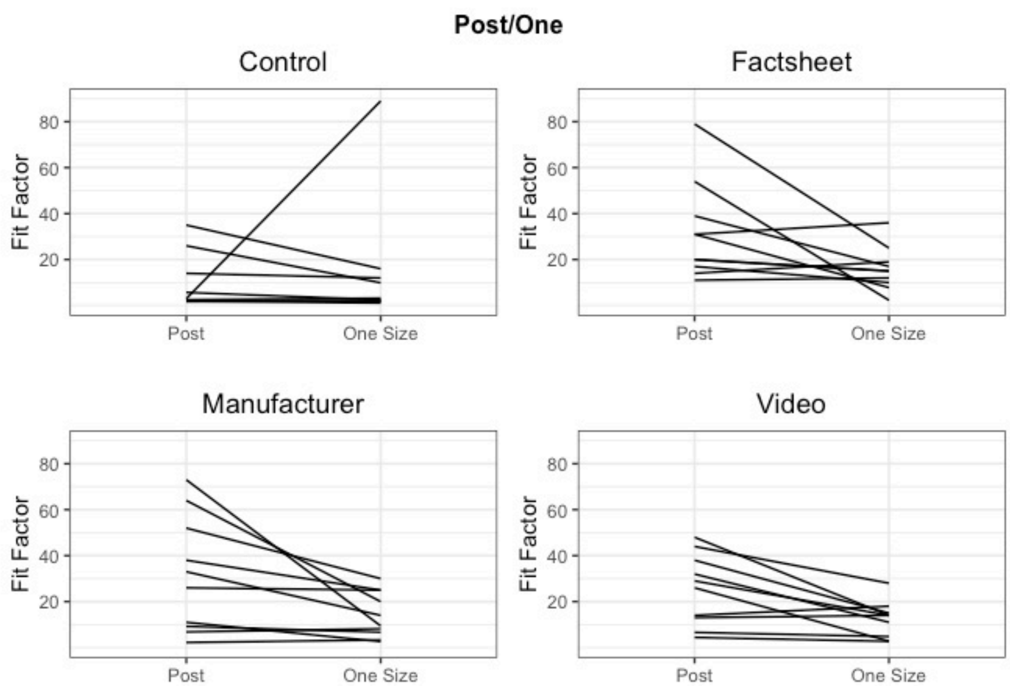


Figure 4. Post-One size fit factors by intervention
Change in individual participant fit factor from donned in the correct sized N95 respirator to donned in a one size respirator after training by intervention, as measured by quantitative fit testing.

The results of our multivariate linear regression model estimating the change in fit factor between the pre and post fit tests are described below in Table 5 as model 1. Results of our analysis to estimate the change in fit factor between the post and one size fit tests are described in Table 5 as model 3. These models compare participants' fit factors in the training groups to the fit factors of the participants in the control group. Compared to those who did not receive training, participants wearing the correct sized respirator and who received the manufacturer's training increased their fit factor by an average of 22.28 points (CI: 4.82, 39.74, p =0.014). Participants receiving the factsheet training showed an average increase in fit factor of 21.98 points (CI: 4.52, 39.45, p =0.015), while participants receiving the video training showed an average increase in fit factor of 14.71 points (CI: -3.22, 32.65, p = 0.105).

Results of model 2 indicate that there was no change in fit factor between the pre-training fit test in an appropriately sized mask and the one size fits all fit test, which occurred after receiving training (Factsheet—CI:-12.40, 12.28; Manufacturer—CI: -13.84, 14.83; Video—CI: -16.41, 13.04). Similarly, results from model 3 indicate no difference in fit between the post-test in an appropriately sized mask and the one size fits all fit test; both of which occurred after the training intervention (Factsheet—CI:-16.84, 13.84; Manufacturer—CI: -18.30, 12,35; Video—CI:-18.78, 10.72).

Table 5. Change in sized mask fit factors prior to and after the intervention and in a one size fits all respirator

	Factsheet			Manufacturer's Instructions			Video		
	Coefficient (SE)	**(95% CI)**	***p***	**Coefficient (SE)**	**(95% CI)**	***p***	**Coefficient (SE)**	**(95% CI)**	***p***
Model 1 (pre/post)	21.983 (8.603)	(4.518, 39.448)	0.015*	22.277 (8.599)	(4.820, 39.735)	0.014*	14.714 (8.832)	(-3.216, 32.645)	0.105
Model 2 (pre/one size)	1.942 (7.065)	(-12.400, 16.284)	0.785	0.498 (7.062)	(-13.838, 14.834)	0.944	-1.683 (7.253)	(-16.408, 13.041)	0.818
Model 3 (post/one size)	-1.500 (7.554)	(-16.835, 13.835)	0.844	-2.978 (7.549)	(-18.304, 12.348)	0.696	-4.027 (7.265)	(-18.776, 10.721)	0.583

The change in the proportion of participants achieving different fit factors thresholds are described in Table B4 in Appendix B and Figure 5 below. Training (all modalities) while donned in the correct size respirator improved the proportion of participants achieving fit factor thresholds of 2, 5, and 10 by 23%, 75%, and 72% cumulatively. During the first fit test in the correct size without training, most participants were able to achieve a fit factor of at least 2 (n=31, 77.5%), but a much smaller proportion achieve a fit factor threshold higher than 2 (for FF>5, n=9 or 22.5%; for FF>10, n =7, or 17.5%). Training increased the number of participants that achieved a fit factor of at least 5 and 10 during the second fit test in the appropriately sized respirator. In the factsheet intervention group, there was an additional seven participants who achieved a FF of 5 and seven who achieved a FF of 10; for the manufacturer training there was an additional eight and six participants, respectively; and for the video training, six and five additional participants, respectively.

Participants who achieved fit factors of 5 and 10 decreased across all training modalities when donned in a one size fits all respirator compared to the post training fit test in a properly sized respirator. The proportion of participants achieving a fit factor of at least 5 and 10 after any training in the one size is higher (80%, 67%) than those without training in the correct size (23%, 23%). All participants that received training achieved at least a fit factor of 2, despite the size of the respirator. No participant achieved a fit factor of 100, the occupational standard. The five participants that achieved a fit factor of 50 only did so after training in the correctly sized respirator.

Table 6 describes the results of the linear regression model to determine the efficacy of training materials in achieving different fit factor thresholds. Model 1 refers to the change in proportion of participants achieving this threshold before and after training in the correct size; model 2 refers to the change before training in the correct size to after training in the one size; and model 3 refers to the change in the correct size to a one size respirator after training. The models compare the proportion achieving fit factor thresholds in training groups to the control group. The proportion of participants achieving a FF of 2, while donned in the appropriately sized respirator will improve by 13.6% (CI: -3.9%-31.1%, p=0.12) on average with the factsheet training when compared to no training; 24.3% (CI: 2.4%-46.3%, p=0.032) with the manufacturer's instructions; and 24.3% (CI: 2.4%-46.3%, p=0.032) with the video training. All trainings improved the proportion achieving a fit factor of 5 in the correctly sized respirator when compared to the control group. The proportion of factsheet trained participants in the correct size respirator who achieve a fit factor over 5 is 59.5% (95% CI of 11.7%– 46.5%) higher than those receiving no training; with the manufacturer's instructions, 51.2% (CI:9.4%-93.0%, p=0.019) higher; and with the video training, 48.7% (CI:7.2%-90.1%, p=0.024) higher. The factsheet was the best modality to improve the proportion achieving a FF of 10 with an expected increase of 65.3% (CI:32.4%-98.2%, p=<.001) on average when compared to no training. The factsheet was also the best intervention to improve the proportion of individuals achieving fit factors of 5 (48.7%) and 10 (54.7%) before training in the correct size to after when donned in the one size respirator (CI:7.2%-90.1%, p=0.024; CI: 10.2%-99.1%, p=0.019) in comparison to the control group. There was no strong change in the proportion of participants achieving the fit factor thresholds between training in the correct size to the one size respirator.

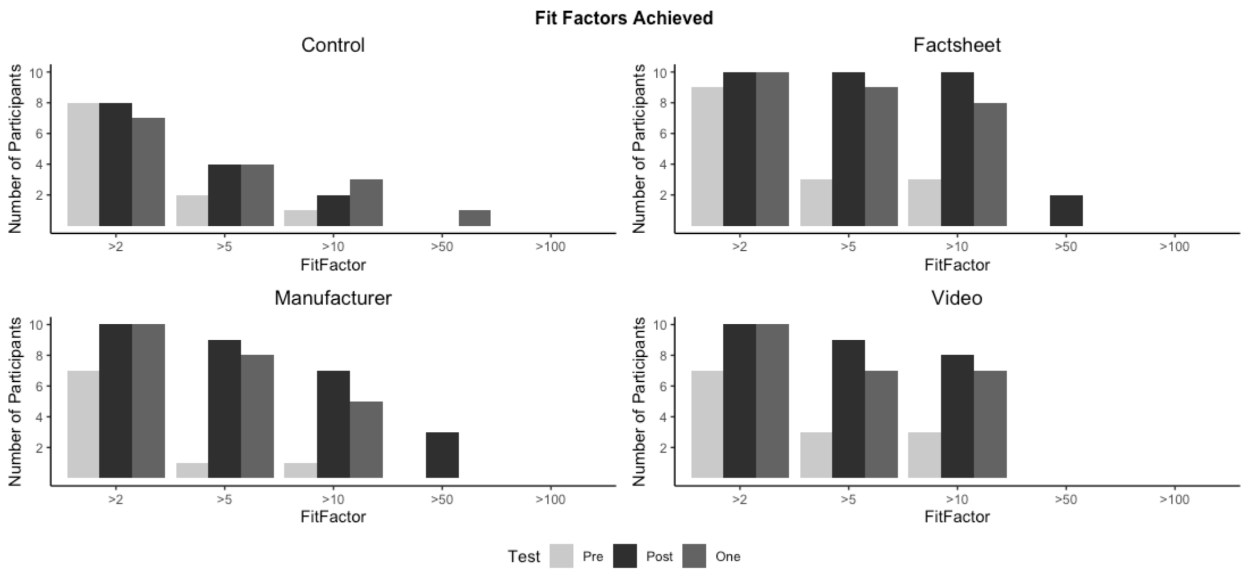


Figure 5. Bar graphs of the proportion of participants achieving fit factors of 2, 5, 10, 50, 100 by intervention

Change in the proportion of participants achieving fit factor thresholds of 2, 5, 10, 50, and 100, as measured by quantitative fit testing by intervention and fit test.

Table 6. Results of the analysis on the change of the proportion of participants achieving fit factors of 2, 5, 10, 50, 100

	Factsheet			Manufacturer's Instructions			Video		
Model 1. Pre/Post	**Coefficient (SE)**	**(95% CI)**	**p**	**Coefficient (SE)**	**(95% CI)**	**p**	**Coefficient (SE)**	**(95% CI)**	**p**
Fit Factor > 2	0.136 (0.083)	(-0.039, 0.311)	0.12	0.243 (0.104)	(0.024, 0.463)	0.032*	0.243 (0.104)	(0.024 0.463)	0.032*
Fit Factor > 5	0.595 (0.169)	(0.238, 0.951)	0.003*	0.512 (0.198)	(0.094, 0.930)	0.019*	0.487 (0.196)	(0.072, 0.901)	0.024*
Fit Factor > 10	0.653 (0.156)	(0.324, 0.982)	<.001*	0.400 (0.207)	(-0.037, 0.837)	0.070	0.413 (0.198)	(-0.005, 0.832)	0.053
Fit Factor > 50	0.200 (0.133)	(-0.080, 0.480)	0.151	.300 (0.153)	(-0.021, 0.621)	0.065	N/A	N/A	N/A
Fit Factor > 100	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Factsheet			**Manufacturer's Instructions**			**Video**		
Model 2. Pre/One Size	**Coefficient (SE)**	**(95% CI)**	**p**	**Coefficient (SE)**	**(95% CI)**	**p**	**Coefficient (SE)**	**(95% CI)**	**p**
Fit Factor > 2	0.284 (0.156)	(0.037, 0.745)	0.087	(0.311, 0.157)	(-0.020, 0.641)	0.064	0.311 (0.157)	(-0.020, 0.641)	0.064
Fit Factor > 5	0.487 (0.196)	(0.072, 0.901)	0.024*	0.416 (0.217)	(-0.043, 0.875)	0.073	0.270 (0.223)	(-0.200, 0.741)	0.242
Fit Factor > 10	0.547 (0.211)	(0.102, 0.991)	0.019*	0.200 (0.232)	(-0.290, 0.690)	0.401	0.360 (0.226)	(-0.117, 0.837)	0.13
Fit Factor > 50	-0.100 (0.100)	(-0.310, 0.110)	0.331	-0.100 (0.100)	(-0.310 0.110)	0.331	N/A	N/A	N/A
Fit Factor > 100	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	Factsheet			**Manufacturer's Instructions**			**Video**		
Model 3. Post/One Size	**Coefficient (SE)**	**(95% CI)**	**p**	**Coefficient (SE)**	**(95% CI)**	**p**	**Coefficient (SE)**	**(95% CI)**	**p**
Fit Factor > 2	0.250 (.163)	(-0.093, 0.593)	0.143	0.250 (0.163)	(-0.093, 0.593)	0.143	0.250 (0.163)	(-0.093, 0.593)	0.143
Fit Factor > 5	0.150 (0.226)	(-0.327, 0.627)	0.516	0.067 (0.203)	(-0.361, 0.494)	0.746	-0.018 (0.227)	-0.496 (0.460)	0.937
Fit Factor > 10	0.133 (0.282)	(-0.462, 0.729)	0.643	-0.048 (0.205)	(-0.479, 0.384)	0.819	0.062 (0.199)	-0.357 (0.482)	0.758
Fit Factor > 50	-0.100 (0.109)	(-0.330, 0.130)	0.372	-0.100 (.113)	(-0.339, 0.139)	0.390	N/A	N/A	N/A
Fit Factor > 100	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

3.3 KAP Survey

Descriptive results of participants' answers to the KAP survey are shown in Table B3 and B4 in Appendix B. Results of the paired sample t-test allowing for unequal variance between pre and post KAP survey results are shown in Table 7. Those receiving the video training answered

"I don't know" to survey questions the least after the video training (n=2), followed by the factsheet (n=4), then manufacturer's instructions (n=68). There was no change in survey answers in the control group between the pre- and post- fit test. Training changed participants' responses to most questions if they received the factsheet (n=11, 52.4%), less if they received the video (n=8, 38%), and almost none (n=2, 9.5%) if they received the manufacturer's instructions. After training, 100% of the participants in the active intervention groups agreed or strongly agreed they knew how to properly wear an N95 respiratory (KAP Ques K1), 96.7% agreed or strongly agreed they were easy to use (KAP Ques A2), and 55% agreed or strongly agreed they were an effective way to reduce exposure (KAP Ques A20).

Table 7. KAP pre-post survey results by intervention

	Control			Factsheet			Manufacturer's Instructions			Video		
	Pre	Post	Test	Pre	Post	Test	Pre	Post	Test	Pre	Post	Test
Question	Avg.	Avg.	P-value	Avg.	Avg.	P-value	Avg.	Avg.	P-value	Avg.	Avg.	P-value
K1	2.3	2.4	0.74	2.7	4.6	<0.01*	1.7	4.5	<0.01*	2.4	4.6	<0.01*
A2	3.8	3.7	1.00	4.0	4.5	0.05*	3.6	4.2	0.05*	3.7	4.4	<0.01*
K3	2.9	3.0	N/A	4.0	4.5	<0.01*	1.1	2.0	0.18	3.0	4.1	0.03*
K4	N/A	N/A	N/A	4.0	4.3	0.50	N/A	N/A	N/A	2.0	4.9	0.20
K5	2.7	2.8	N/A	2.4	4.9	<0.01*	4.3	5.0	0.50	3.5	4.9	0.06
K6	2.3	2.4	N/A	4.0	1.5	0.50	N/A	N/A	N/A	2.5	1.3	0.06
K7	4.1	4.4	N/A	4.0	5.0	0.01*	4.5	5.0	N/A	4.8	5.0	0.17
K8	4.3	4.3	N/A	4.0	4.9	N/A	4.3	4.6	0.36	3.8	4.9	<0.01*
K9	1.3	1.3	N/A	1.6	1.1	0.07	1.8	1.3	0.10	1.4	1.1	0.19
K10	4.4	4.7	0.17	4.0	4.8	0.03*	4.3	4.8	0.08	4.4	5.0	0.01*
K11	4.4	4.9	0.10	3.4	4.8	0.02*	4.6	4.7	1.00	4.3	5.0	0.05*
K12	5.0	4.8	0.35	4.2	5.0	0.05*	4.6	4.8	0.60	4.7	4.7	1.00
K13	4.2	4.0	0.36	4.2	4.9	0.02*	4.5	4.3	0.39	4.0	4.8	0.23
K14	3.7	3.3	0.42	2.5	1.0	0.06	N/A	N/A	N/A	1.7	1.1	0.18
K15	1.7	1.7	0.36	1.9	2.7	0.09	1.3	2.1	0.36	1.5	2.6	<0.01*
K16	3.9	3.8	0.60	3.9	4.4	<0.01*	4.8	4.9	0.39	4.0	4.4	0.07
A17	4.1	4.1	0.46	4.0	4.4	0.08	4.0	4.4	0.50	3.8	4.3	0.17
A18	3.9	3.6	0.20	3.8	4.5	0.05*	3.4	4.1	0.10	3.1	3.7	.05*
P19	4.7	4.5	0.44	4.2	4.5	0.35	4.3	4.7	0.60	3.8	4.0	0.45
A20	4.3	4.3	1.00	3.8	4.5	0.07	3.8	4.0	1.00	3.4	4.6	0.11
P21	3.7	3.9	0.17	3.9	3.7	0.08	3.4	4.0	0.30	3.1	3.7	N/A

1. * indicates p-value > .05

3.4 Observations

Actions and inactions during the donning process associated with proper fit are described by fit test in Figure 6 and Table B7 in Appendix B. Action codes and descriptions are provided in Table B6 in Appendix B. Without training, most participants in the active intervention groups were able to properly center the respirator on their face (n=29, 96.7%); with the nosepiece up (n=27, 90%); and straps in the right position (n=15, 50%); and on straight, not twisted or crossed (n=21, 70%). After training, this improved to 100%, 100%, 90%, and 100%, respectively. Training (all modalities) improved the number of participants molding the nosepiece by 77%.

Figure 7 shows a plot of fit factors by selected key actions considered important for fit. This graph highlights which actions (e.g. molding the nosepiece) more positively impact the fit factor and thus improved fit more than others (e.g. seal check).

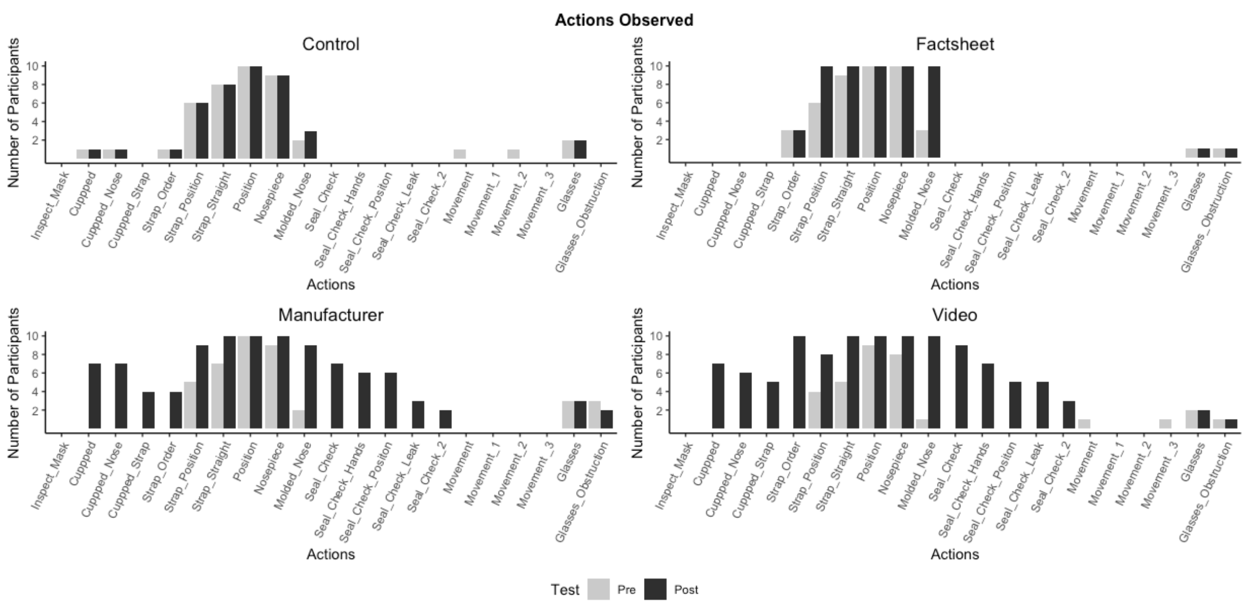


Figure 6. Actions taken during the donning process by intervention
Change in the number of participants completing actions important to the donning processes by intervention and fit test.

Figure 7. Key actions in the donning process vs. participants' fit factors
Distribution of fit factors by selected key actions important to the donning process by completion

4. Discussion

The effectiveness of an N95 respirator to filter particulate matter and protect health not only depends on the filter efficiency, but also on proper use and fit. In an occupational setting, training on proper use of respiratory protection is required, and most of the available research and data on N95 respirators focuses on such settings. With the increasing use of N95 respirators by the general public, especially during wildfire smoke events, additional information is needed for public health practitioners to make evidenced based public health recommendations.

This is the first study to assess the efficacy of training materials designed for the general public about proper N95 respirator use, specifically during wildfires. Previous studies have found that training improves respirator use and compliance in occupational settings (Diaz-Guio et al., 2020; Pompeii et al., 2020; Verbeek et al., 2020; Donham et al., 2010). Types of training previously studied include: video, slideshow, lecture, brochure, and computer-based training (Harber et al., 2013a; Harber et al. 2013a; Jones et al., 2013). Jones et al. (2013) specifically researched the communication medium through which the training occurred (i.e. paper, video, and interactive training) and found that no differences on ease or success of N95 respirator fit between modalities. Harber et al. (2013a) also compared training modalities (i.e. brochure, video, computer-based training) using quantitative fit testing and found that video training improved fit significantly better than brochure or computer-based training. Kim et al. (2019) also conducted quantitative fit testing and estimated fit factors as a measure of successful training and found an improvement in respirator performance among healthcare workers. Some have used other completed actions as an indicator of successful training (e.g. change in knowledge or completing a seal check or other actions) (Harber et al. 2013b; Jones et al., 2013; Cummings et al., 2006; Tan et al., 2020). Since assessing knowledge alone may not be successful indicator of fit, Harber et al. (2013b) also measured performance outcomes and found that knowledge tests showed adequate learning of donning and doffing respirators, although success in performance measures was poor.

Of the few studies regarding respiratory protection training, many focus on "just in time" training, which is a specific type of emergency rapid training used for individuals (Jones et al. 2013). Public health messaging primarily focuses on preparing the general public in advance of wildfire smoke (EPA, 2019). With wide scale access to fit testing unlikely for the general public, effective and quality training is necessary to ensure correct use (Harber et al., 2013b); and occupational health professionals may not always be there to ensure proper use and fit (Harber et al., 2013a). However, previous research has found that knowledge gained from training is lost over time (Harber et al., 2014).

4.1 Fit Factors

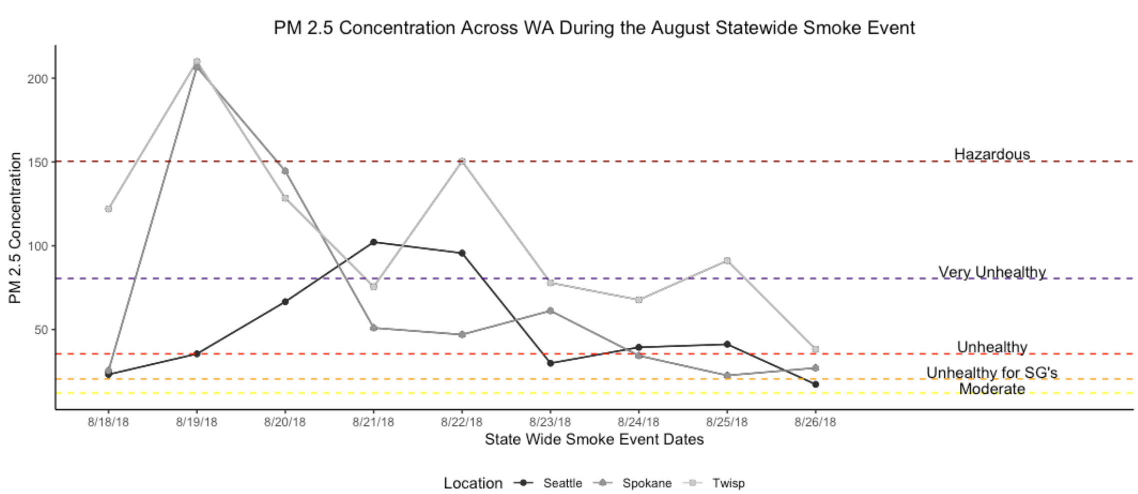
This study aimed to quantify the impact training has on N95 respirator fit among the general public. We found that both the factsheet and manufacturer's instructions improved fit factor by an average of 22 points compared to the control group when donned in the correct size respirator (Table 5). It is important to note that in an occupational setting a fit factor of 100 is considering passing for respirator use when required in the workplace; filtering face pieces voluntarily worn in the workplace do not require fit testing. On average, all training modalities improved the proportion of study participants achieving a fit factor of at least 5 when donned in the correct size respirator compared to the control group (Table 6). Jones et al. (2013) did not find significant differences in success of fit between types of teaching modalities (i.e. video, slideshow, and lecture), while Harber et al. (2013a) found video training to be significantly better than brochure or computer-based training . Another done by Harber et al. (2013a) assessed respirator use training, but they did not provide an analysis on fit before and after training between the three modalities they evaluated.

When considering both the analyses on the change individual fit factors and the proportion achieving thresholds, the factsheet overall improved fit the most when donned in a correct size N95 respirator. The factsheet training was the only group to noticeably improve the number of participants achieving at fit factor of at least 10. While the factsheet did not improve the number of participants achieving a FF of at least 2, unlike the manufacturer's instructions and video training, this is likely due to already having nine out of ten participants achieve a FF of at least 2 prior to training, compared to seven participants in each the video and manufacturer's training. The first analysis showed that the improvement on fit from receiving the video training was not substantial (Table 5). However, the video training was found to improve the proportion of individuals achieving fit factors of at least 2 and 5 when donned in the correct sized respirator (Table 6). When looking at Figure 3, there were three participants in the video group who started off with high fit factors. None of the participants reported having used a respirator before and only one had molded the nose piece on the pre fit test. For the remaining seven participants, a large increase was seen, leading us to believe there is still utility in the video training.

Although our analysis did not show a difference in fit factors post training between the correct size N95 respirator and the one size fits all respirator, we observed a negative change in directionality of individual fit factors in Figure 4 in comparison to fit factors between the pre and post training fit test. One participant saw a steep increase in fit factor between post training in the correct size respirator and a one size fits all respirator, likely due to the model of respirator inherently fitting their face shape better. This outlier may have biased the results of the model. There were no differences in observed donning actions between those two fit tests. For best protection, we recommend that the general public, if choosing to wear a N95 respirator for wildfire smoke, don a correct size (S, M, L) rather than a one size fits all. With no difference in fit between trained in the correct size and trained in a one size fits all N95 respirator, training is likely the most impactful intervention. Most participants did achieve fit factors of at least 2, 5, and 10 while donned in a one size fits all respirator, indicating a need for further research. Using the NIOSH-NPPTL bivariate fit panel to determine size may be possible for the general public considering it only requires two, relatively simple face measurements. Accessibility of sized respirators may be challenging, as the most common N95 respirators on the marketplace (e.g. online or in hardware stores) are one size fits all, with no discernment in size. The impact between sized and one size fits all respirators is an area for future research.

Despite participants not achieving fit factors at or above the occupational standard of 100, these results indicate that the general public is still able to achieve some protection to protect health. Achieving fit factors of 2, 5, and 10 can reduce exposure by 50%, 80%, and 90%, respectively. Achieving these protection values while donned in a correct size respirator could bring exposure down from a hazardous or very unhealthy category of the Air Quality Index (AQI) to unhealthy for sensitive groups or moderate air quality. During the Washington State 2018 smoke events, the peak $PM_{2.5}$ concentration in Spokane, WA was 206.7 $\mu g/m^3$. A fit factor of 5 would have brought down $PM_{2.5}$ concentration inside the respirator to 41.34 $\mu g/m^3$ (AQI index of unhealthy for sensitive groups), while a fit factor of 10 would have brought the respirator $PM_{2.5}$ concentration down to 20.67 $\mu g/m^3$ (AQI Index of moderate). However, during wildfire smoke events the $PM_{2.5}$ concentrations will vary and estimated exposure could change—highlighting the importance of monitoring air quality. The general public may be able to use the equation, *ambient concentration/fit factor = concentration inside the respirator*, to estimate exposure using our most commonly expected fit factors of 5 and 10 after selected trainings. Proximity to a wildfire event is also important to consider, as individuals may be experiencing exposure to higher concentrations of $PM_{2.5}$ than estimated by federal air quality monitors. It is important that other personal interventions to reduce wildfire exposure beside respiratory protection are taken first (e.g. reduce outdoor physical, stay indoors with a clean air room or improved air filtration, seek clean air shelters, or evacuate the area). This is especially important with the lack of public access to fit testing to confirm whether an individual N95 respirator model fits on an individual's face. Thus, quality and efficacious training is needed for the general public in order to ensure that N95 respirators are worn properly.

Figure 8. $PM_{2.5}$ concentrations across WA State during the August statewide smoke event



4.2 KAP Survey

All training materials improved participants' knowledge on how to properly wear a respirator; however, this may be a subject's perception rather than actual performance, when compared with fit factors and observed actions. Most participants thought that N95 respirators are an effective way to reduce exposure and thought their ability to wear one improved after training. Similar results were found in Harber et al. (2013b). The improvement in KAP depended on the content of the training (e.g. identified donning actions and health risk messaging). Materials with more hazard and health risk messaging with explanations for why to wear an N95 respirator improved KAP (i.e. the factsheet in comparison to the manufacturer's instructions). However, improvement in KAP did not always mean improvement of fit and fit factors and vice versa. The video improved KAP but results did not show an improvement in fit factors (CI: -3.22, 32.65, p = 0.105). The manufacturer's instructions improved fit (CI: 4.82, 39.74, p =0.014) but did not change KAP responses. We expect this may be due to the lack of health risk messaging in the manufacturer's instructions related to the use of N95 respirators for wildfire smoke exposure. After receiving training, 90% agreed or strongly agreed N95 respirators are a convenient way to reduce personal exposure to wildfire smoke and 86.7% would wear one when air quality is poor due to wildfires (KAP Ques A17, P19). Additionally, more than half of participants (56.7%) agreed or strongly agreed they would wear an N95 respirator before taking other actions to reduce personal exposure to wildfire smoke (KAP Ques P21)—all of this adding to the importance of effective, quality training for the general public.

4.3 Observations

In our observation analysis of actions important to fit, training had the most positive impact on improving strap position and molding the nose (Figure 6). Without training, it is unlikely that a member of the general public will mold the nosepiece, an important action in improving fit. This finding is consistent with Harber et al. (2013b). While both the factsheet and manufacturer's instructions improved fit, the factsheet did not have instructions to conduct a seal check. Figure 7 shows that conducting a seal check may improve fit factor, but less data is available compared to other actions. Harber et al. (2013b) found that conducting a seal check was not indicative of fit. While analyzing the video recordings, observations showed that participants who did seal checks often struggled and did not always do it properly. Our results indicate that conducting a seal check should not exclusively be used as an indicator of improved fit from training. Seal checks are an important action in the donning process, but there is a need for improved training to the general public on how to conduct one. Having thorough instructions of donning actions in training materials for the general public is important to achieving proper fit.

4.4 Limitations and Future Research

This study is limited by challenges with the study population, including sample size (10 in each intervention group); subject population selection (i.e. UW faculty, students, and staff), although while previously untrained, is not generalizable to the lay public (the disproportionate distribution in gender, race, ethnicity, and age, is not reflective of the general public); and convenience sampling techniques may have led to under-representation or over-representation of specific demographics. The face sizes of recruited participants did not match the full distribution of the NIOSH-NPPTL Bivariate Test Panel; however, an equal number of smalls and medium/larges were represented across intervention groups. Although occupational health and safety guidance has established that facial hair impacts the ability to achieve a seal, we did not exclude them from the study because we anticipate members of the general public will continue to wear them with facial hair, and therefore, should be represented. Providing recommendations for those with facial hair is beyond the scope of this study, although this is an area for continued research. Three of our participants had facial hair, but their individual fit factors improved with training and followed the same trends as those without facial hair.; this trend could be confounding with the generally poor fit and seal achieved by participants and the low fit factors achieved with training. We hypothesize that we would see a larger difference between participants with and without facial hair if the N95 respirators fit better overall. Several participants took key steps to improve fit (e.g. molding the nose piece) during the donning process without training; we would also expect this to occur among members of the general public. The Hawthorne effect, where participants alter their behavior because they are being observed, is also a limitation with participant research.

This study is also limited by challenges with N95 respirators. The design and quality of N95 respirators varies by manufacturer and model and thus the fit may vary by face shape (CDC, 1998; Coffey et al., 2004). This is why fit testing is required in an occupational setting to ensure proper fit for each individual. Due to the nature of a pilot study, we only used one manufacturer (HDX) and selected models (H950S, H950, H950V). The same manufacturer was used throughout the study to eliminate potential bias from different manufacturers and to ensure results were due to training. Plans to conduct a secondary analysis with a different model of N95 respirators were put on hold due a limited supply chain and increased need by healthcare workers during the 2020 COVID-19 pandemic.

There were additional limitations due to nuances related to fit. An individual's fit factor can change with each donning (i.e. changes in process), which was adjusted for with the control group without training (Vuma et al., 2019). Fit factors give an estimate of expected protection at the time of fit testing. With each additional donning, before or after training, there may be an improvement in fit due to increased practice of use. We controlled for this by utilizing an intervention group that completed study protocols without training. Additionally, the NIOSH-

NPPTL bivariate fit panel protocol was used to take measurements of participants' faces for determining proper mask size. This protocol was developed by NIOSH based on the US working population and may not be representative of the general public. Selected training materials are not generalizable to other training of similar medium, such that all manufacturer's instructions are all slightly different, though the fundamental steps are the same.

Finally, there were limitations with the study protocols. Video recordings of the participants were taken in a single plane, and thus we were not able to assess whether there was a gap in seal of the respirator around the chin and nose. Control group participants could have learned donning information by completing the KAP survey. Although analysis did not show a significant change in responses between the pre and post survey.

Repeating study protocols with a larger study population that meets the distribution of the face sizes in the NIOSH-NPPTL bivariate fit panel along with a variety of N95 respirator make and models will improve upon the generalizability of these results.

5.0 Conclusion

This study is the first to assess the impact of training has on respirator fit and describe differential impact on respiratory fit by training mode for a non-occupational sample population. Previous studies have looked at the effectiveness of respiratory training, although not within the scope of the general public nor for use during wildfires. Our research design analyzed how three publicly available training materials translated into proper fit using quantitative fit testing to estimate participant fit factors before and after training. With or without training and despite selected respirator type, the likely expected fit factor is 2 or a baseline 50% reduction in exposure. Trained study participants, on average, will achieve a fit factor of at least 5 or 10, an expected 80% and 90% exposure reduction, when donned in the correct size respirator. While this does not meet occupational standards, it may be enough to provide some protection for the general public and reduce the level of risk to a healthier category of the Air Quality Index. Our results indicate that fit and knowledge on proper use is important for expected protection and in the determining the effectiveness of an N95 respirator for protecting health. In the absence of wide scale access to fit testing, effective and quality training is necessary to ensure proper use of N95 respirators by the general public during wildfires. Public health training and messaging with hazard and health risk messaging on the use of N95 respirators for wildfire smoke may help improve fit more than standard manufacturer's instructions. The results of this work will support evidence-based public health decision making in regard to N95 respirators as an intervention to reduce wildfire smoke exposure. Risk communication surrounding N95 respirator use is, and will continue to be, challenging for public health practice. Public health officials must make a decision that balances recommending an intervention that can provide some protection for individuals (i.e. better than nothing) versus individuals feeling safer and expecting more protection than they are receiving and do not consider other actions to reduce exposure (i.e. false sense of security). This is especially challenging when there is not access to fit testing to guarantee proper fit. Additional research is needed to test the impact of training on a variety of N95 respirator models, understand the impact of correct sizing and manufacturer quality of N95 respirators, assess compliance and real time use during wildfire smoke events, connect health benefits to public use during wildfire smoke events, and determine what information from N95 respirator use in an occupational setting is beneficial and transferable to use among the general public.

6.0 Implications for Practice

The following are practice recommendations for public health officials in communicating the use of N95 respirators for protection during wildfire smoke:

- Communicate that protection depends on more than the efficiency of the filter material, but on proper use and fit, which is dependent on many factors
- Clarify in messaging that every make and model of N95 respirators will fit an individual face differently and protection cannot be guaranteed without fit testing
- Communicate that a correctly sized respirator will improve protection and include information on sizing in messaging
- Include link to NIOSH approved respirators; as without NIOSH certification, filtration effectiveness cannot be guaranteed
- Disclaim that even with training, individuals may not achieve full protection from wildfire smoke and without training the expected protection decreases
- Recommend reviewing instructions on proper use before every donning
- Incorporate wildfire hazard and health risk information when communicating N95 respirator training and use and include basic information on N95 respirators to provide additional context to proper donning
- Emphasize that other actions to reduce exposure to wildfire smoke should be taken prior to using an N95 respirator (i.e. reduce outdoor physical, stay indoors with a clean air room or improved air filtration, seek clean air shelters, or evacuate the area) and they should only be used for a limited duration of exposure and when there are no other options (i.e. while walking from one's car to the store)
- Train public health officials and physicians on their proper use, as they are often the first point of contact for information

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Aim 3: Translate findings for communication to practice partners and public health stakeholders.

Findings from this research study will be presented to practice partners, including the Washington State Department of Health (DOH), local health agencies (LHJ's), and academic and other community partners through various mediums, such as professional conferences and association meetings. The goal of these presentations is to disseminate the results of my research to the public health community to improve the risk communication and training of N95 respirators for use by the general public during wildfire smoke events.

Preliminary findings were presented at the 3rd International Smoke Symposium in April of 2020. The audience of this professional conference included public health officials, air quality regulators and forecasters, land managers, fire practitioners, and researchers. The goal of this presentation was to inform attendees of the research we were conducting and increase awareness of the nuances of N95 respirator use by the general public for reducing wildfire smoke exposure. Preliminary findings were also presented to the Northwest Air Quality Communicators Group in April of 2020. The audience of this meeting included air quality communications from a variety of agencies in the Pacific Northwest. The goal of this presentation was to inform members of the research we were conducting and discuss risk communication of N95 respirators for the 2020 wildfire season, especially as it related to the 2020 COVID-19 pandemic.

Results and recommendations are being used to inform the risk communication of proper N95 respirator use by WA DOH, including key messages for their website and communication materials. Findings will be used to develop a new training factsheet for the general public in partnership with DOH and a communication piece for outdoor workers in collaboration with the University of Washington's Pacific Northwest Agricultural Safety and Health Center (PNASH).

Conclusion

The goal of this project is to assess the impact of training has on respirator fit and describe differential impact on respiratory fit by training mode for a non-occupational sample population to inform the use of N95 respirators and respective training materials as an intervention for reducing wildfire smoke exposure. The results of this study:

I. Summarized the current state-of-knowledge around the use of N95 respirators as an intervention, and identified gaps in knowledge in proper use of N95 respirators

II. Identified challenges and gaps in proper use of N95 respirators, including pertinent user-behaviors

III. Assessed how knowledge, attitudes, and commitment to N95 respirator use

IV. Characterized the impact training has on respirator fit and describe differential impact on respiratory fit by training mode

Results will assist public health practice and research partners as they consider the appropriateness of N95 respirators as a public health intervention to reduce personal exposure to wildfire smoke and make evidence-based decisions. Results will assist in the development and improvement of materials to train the general public on proper N95 respirator use for wildfire smoke events.

Future direction and research needs include:

1. Impact of training on a variety of N95 respirator models
2. The effect of the correct size on respirator fit for the general public
3. Compliance and real time use during wildfire smoke events
4. Epidemiological research to understand the health benefits associated with exposure reduction during wildfire smoke events
5. Consistent and efficacious messaging and training among public health partners

Appendix A. Materials and Methods

Aim #1

Literature Resource Summary

To summarize the current state-of-knowledge around N95 respirator efficacy as an intervention and corresponding training, we conducted a literature resource summary. Although elements of a narrative/systematic review were included, a full systematic review was outside the scope of this thesis. We identified peer-reviewed literature by searching key terms on the Pubmed, Embase, and the Cochrane library databases through July of 2020 (Appendix F); as well as conducting a bibliographic search. We scanned abstracts for relevance, and selected studies based on the following inclusion and exclusion criteria.

Inclusion Criteria:

- Conducted after 1995
- In English
- Full research article
- Discussed N95 respirators and air pollution or wildfires; training and education on proper N95 respirator use; communicating proper N95 respirator use; fit of N95 respirators; health impacts; policy and regulations for use; N95 respirator ethics; attitudes and perceptions of N95 respirator use; information on the wearer of N95 respirators

Exclusion:

- Occupational fit testing protocols
- Re-use of N95 respirators for occupational use
- Specific to only other types of respiratory protection
- Surgical masks donned over N95 respirators
- Infection control for occupational settings

- Filtration efficiency for biological hazards or nanoparticles
- Workplace protection factors
- Compared effectiveness between respirators
- Decontamination of the mask

Studies were tracked and stored using Zotero (Zotero: Corporation for Digital Scholarship, Vienna, VA, USA). One of the challenges with these methods is that N95 respirators have multiple labels they are referred to as (e.g. N95's, N95 mask, dust mask, half mask, particulate respirator, filtering face piece, etc.)

To summarize the current state-of-knowledge and apply important information to the novel use of N95 respirators for wildfire smoke exposure, we analyzed the content of the selected studies, identified key findings, and used deductive coding methods to classify literature by the following qualitative themes: (1) occupational use pertinent for non-traditional application, (2) policies and regulations, (3) use for ambient air pollution, (4) use for disasters, (5) training and risk communication, and (6) ethics, behavior theory, and attitudes and perceptions. Qualitative themes and code definitions were developed to classify literature *a priori* (Table 1); and studies were coded by the primary author.

Aim #2

Ethics

This project was approved by the University of Washington Institutional Review Board (IRB), and all participants went through an informed consent process prior to data collection. The application to the IRB can be found in Appendix G and the consent form in Appendix J.

Participant Recruitment and Selection

The target population of this study included University of Washington students, faculty, and staff as a representation of untrained individuals on the proper use of N95 respirators.

Potential participants were recruited through convenience sampling by members of the research team. A variety of recruitment materials were used including in-person conversations during university classes, social media messaging in academic groups, and flyers posted throughout campus (Appendix H). Interested individuals were then selected for the study based on selected inclusion and exclusion criteria. No exclusions were made on the basis of gender, race, ethnicity, sex, or religion. Those who had a pre-existing respiratory or cardiovascular disease; were unwilling to refrain from smoking 60 minutes prior to and during the study; did not read in English (training materials were limited to English); had received previous training on how to wear an N95 respirator; had received a previous fit testing for a respirator; or had motor impairments that prevented them from being able to put on the mask themselves; or hear verbal training to watch the video were excluded. Although it is not recommended to wear an N95 respirator with facial hair, we still expect members of the general public to do so; thus, we chose not to exclude those with facial hair to best simulate a study population representative of the general public.

Members of the research team communicated with participants primarily via email to conduct a screening of eligibility and to schedule 60-minute appointment slots (Appendix I) . In total, 40 participants were recruited and completed the study. Participants received an $20 Amazon gift card as an appreciation for their participation.

All participants were assigned a unique subject ID to protect personal information. The unique subject ID and study records could not be linked to identifying information. Study records were stored in a locked room in a secure building and will be shredded after completion of the study.

Intervention Selection

Based on experience in the practice, we selected three training materials that are available to the general public and frequently used. A control group, where participants received no training, was used to control for the potential of fit and fit factor changing with each subsequent donning of the N95 respirator. Two of the selected training materials are available on the Washington State Department of Health's (DOH) Smoke from Fires website, a common source of information regarding wildfire smoke for the general public (WA DOH, 2020). The manufacturer's instructions that come with the purchase of an N95 respirator was selected as the third training material. Forty participants were randomized into one of these four intervention arms, with a total of 10 in each arm, and only received one unique training due to the lost ability to test complete efficacy after a single training.

<u>Intervention Arm #1:</u> The Washington State Department of Health (DOH) N95 factsheet, titled "Wildfire Smoke and Face Masks," and designed to answer two questions by the public: (1) Will face masks protect me from wildfire smoke? (2) How do I use my respirator mask? (WA DOH, 2019)

<u>Intervention Arm #2</u>: the "Smoke from Fires: N95 Respirator Masks" video for how to properly don and doff an N95 mask, made in partnership between the University of Washington Department of Environmental Occupational Health Sciences (DEOHS) and Seattle and King County Public Health Department (KCPHD) (Ting, 2018). Part of the content of this video was originally created by the Ashland Chamber of Commerce (2018). This video was chosen because it was specifically designed to train members of the general public about proper N95 respirator use for wildfires. There are many instructional videos available but were designed for different audiences and hazard use.

Intervention Arm #3: the instructions that come with purchasing an N95 respirator (Appendix O). This was selected as it tests the bare minimum of publicly available training and represents a training material that does not include health risk messaging for wildfire smoke. The minimum requirement of the voluntary use of N95 respirators in an occupational setting, includes supplying the employee with Appendix D of the OSHA Respiratory Protection Standard 1910.134. Appendix D of the OSHA code recommends that the employee read the instruction manual that comes with the mask.

Intervention Arm #4: no training material (control).

N95 Respirator Selection

An N95 respirator is classified by OSHA as a filtering facepiece respirator (FFP) where the filter material is not resistant to oil (N designation) and have a minimum filtration of 95% of the most penetrating particles of 0.3 microns in size N95 respirators are also classified as an air-purifying negative pressure respirator, where the air pressure inside the respirator is negative compared to the air pressure outside the respirator during inhalation. This allows for filtration of particles through the N95 filter medium (Respiratory Protection, 1998).

The face-fitting characteristics of N95 respirators varies among the manufacturer models available on the market (CDC, 1998; Coffey et al., 2004). Due to the capacity of this pilot project, we selected only one brand of respirator for use in the study. The selection of brand was based on what is commercially available to the general public from a source that is easily accessible. We also wanted to select a brand that had all the sizes available that we were testing (small, medium/large, and one size fits all) and was marketed as such. This was also done to prevent effect modification among tests (e.g. pre, post, one size) due to variability between manufacturers. Based on these criteria the HDX N95 respirators were selected: H950S (small), H950 (medium/large), and H950V (one size fits all). The HDX brand is available at Home

Depot; hardware stores are frequently recommended as a source for the general public to purchase a respirator.

Sizing

N95 respirators available to the general public are generally one size fits all or size is not discernable. Although sized respirators (S, M, L) are available, it is unlikely the general public know how to select the proper size for their face shape. In designing the study, members of the research identified that if the respirator fit poorly on the individual due to the inherent characteristics of the respirator or size, it would wash out the impact of training on the fit. It was determined to conduct the initial fit tests with participants in the appropriately sized respirator and then conduct a third with a one size N95 respirator to adjust for this effect modifier.

Another consideration for using sized respirators was the impact of face shape on fit, especially as this was a pilot study with limited capacity to ensure recruiting a diverse study population representative of the general U.S. population. When face shape and subsequent respirator size is defined by arthrometric measurements and facial dimensions (i.e. bizygomatic breadth and menton-sellion length), there is no significant difference in fit based on gender and race (Oestenstad et al., 2007, Brazile et al. 1998). This addresses the possibility of effect modification from the race and ethnicity of participants. Anthropometric measurement guidelines developed by NIOSH and NPPTL were used to take participants' facial measurements (Zhuang et al., 2007). Mento-sellion length (face length) was taken using a sliding caliper, and bizygomatic breadth (face width) using a spreading caliper; both of which are traditional anthropometric instruments. These measurements were then applied to the NIOSH-NPPTL bivariate respirator fit panel to determine correct size. One measurement of mento-sellion length and bizygomatic breadth was taken. If the measurements were on the border of the size panels limits, a second measurement was taken and then averaged with the first. Participants that were measured to be a medium or large received the H950 (medium/large) model, as there was no manufacturer brand widely available to the general public that included all three individual sizes and a one size fits all.

We were still interested in the impact on fit when using a one size fits all N95 respirator. A third quantitative fit test was done with participants donned in a one size fits all N95 respirator (H950V). However, the one size fits all respirator is closer in size to the M/L. To control for likely a larger difference in fit between the one size and smalls versus the one size and M/L, we controlled for an equal number of smalls and medium/larges across interventions group (Table 4).

Quantitative Fit Testing & Fit Factors

In an occupational setting the wearer undergoes a fit test to evaluate the fit of the N95 respirator on the individual. During the fit test the particles that cannot pass through the filter cartridge in the mask and thus all detected particles are assumed to be a result of the poor fit. The protocols for fit testing are located in Appendix A of the OSHA standard 29 CFR 1910.134. There are two types of fit testing, qualitative and quantitative. To quantify the transfer of knowledge from training materials into fit for our study, we selected the quantitative fit test as it produces a fit factor—a quantitative number that estimates the fit of the respirator on the individual by calculating a ratio of the substance concentration in the ambient air to the concentration inside the respirator when donned. We also selected a quantitative fit test because there is no subject sensory variability, no irritant smoke used in the procedure, and has improved accuracy. A quantitative fit test will calculate an overall fit factor using fit factors produced by eight separate exercises, with the exception of the grimace exercise, which the individual completes each for 60 seconds while wearing the respirator. The eight exercises in order of complete are: (1) Normal Breathing (2) Deep Breathing (3) Head side-to-side (4) Head up-and-down (5) Talking out loud (6) Grimace (7) Bending (8) Normal Breathing. The equation to calculate a fit factor is as followed:

$$Fit\ Factor = C_B + C_A / 2C_R$$

where C_B = particle concentration in the ambient sample before the respirator sample; C_A = particle concentration in the ambient sample after the respirator sample; and C_R = particle concentration in the respirator sample. There is a new modified version of the ambient aerosol condensation nuclei counter quantitative fit test protocol that is more streamlined, with fewer exercises and duration (Respiratory Protection, 1998). However, this modified protocol was issued and finalized after this study had started and thus, we continued to follow the original protocol. This protocol uses a TSI PortaCount Pro + 8038 machine to detect particulates in the air via a Condensation Nucleus Counter (CNC). Air is drawn into the instrument by a diaphragm pump, with the flow entering the ambient or sample port directed by the switching valve. This flow then enters the saturator; saturated particles pass through the condenser; and the laser diode optical sensors scatter to determine the concentration. We utilized the N95 respirator companion setting of the TSI PortaCount Pro + 8038, which uses a negatively charged test particle size of 40-60nm under the notion that this size and charge is best captured by the filter material and therefore detection of it indicates a seal leak.

In addition to seeing how much training improved the fit factor, we wanted to know if it was enough to be considered protective. The required passing fit factor in an occupational setting is 100. However, it is unlikely that the general public needs to achieve this high of a fit factor, as they are not exposed to contaminants at such high levels as in a workplace setting. When classifying respirators for the general public to use during public health emergencies, guidance set by Food and Drug Administration (FDA) requires testing of the percentage of users who achieve fit factors of 2, 5, 10, 50, and 100 (FDA, 2007). Thus, we decided to select fit factors of

2, 5, 10, 50, and 100 for our analysis. The standard programming of the TSI PortaCount Pro + 8038 will automatically stop the fit test, if the individual will not achieve at least a FF of 100 and thus fail according to occupational standards. To be able to collect data on FF's below 100, we programed the TSI PortaCount Pro + 8038 to have a passing FF of 1.

Participants were not informed of their fit factors during the study in case knowing whether they had a high or low fit factor impacted their sense of security and affected how they received the training and donned the N95 respirator.

KAP Survey Design

A Knowledge, Attitude, and Practice (KAP) Survey was designed and administered to participants prior to and after the intervention to assess knowledge transference, attitudes around, and commitment to N95 respirator use. The questions were designed based on a combination of the following: (1) information commonly in training materials for N95 respirator use, (2) the research team's experience and knowledge in practice, and (3) a previous KAP survey administered about N95 respirators by this research group.

The pre-intervention survey consisted of 21 questions (Appendix Q). The post-intervention survey included two additional questions about the training for groups that received either the factsheet, video, or manufacturer's instructions (Appendix R). Participants responded to questions on a 5-point Likert scale, with an option to answer, "I do not know." It was decided by the research team to include the 6th option, as participants may not have had an opinion or basic understanding of an N95 respirator prior to participation in the study.

Observation Analysis Design

To describe the transference of knowledge from training materials into respirator use by identifying actions and inactions taken associated with proper fit, participants were video recorded during the donning process and key actions were later analyzed by a member of the research team. The key actions selected for analysis were based on a combination of the following (1) OSHA code, (2) information commonly in training materials for N95 respirator use, (3) the research team's experience and knowledge in practice, and methods described in Harber et al. (2013b). Actions were coded as yes or no did they complete the action. Code descriptions can be found in Appendix B, Table B6.

Due to the subjective nature of analyzing the videos, two members of the research team reviewed 20% of the videos together to adjudicate differences in interpreting the actions taken. The actions in the identified checklist were also matched against what is included in each training intervention group, as not every intervention called for all the actions in the checklist.

Study Design & Protocols

We employed a pre/post experimental study with four intervention arms. The study was completed at the University of Washington's Roosevelt building. Before starting the study procedures, participants went through the informed consent process. A member of the research team started by measuring the dimensions of the participants face while standing, including face length and width to determine the size mask the subject needs using the NIOSH-NPPTL Bivariate Test Panel, which can be found in Appendix M. Participants then filled out the pre-intervention Knowledge, Attitudes, and Practice (KAP) survey. After completing the survey, participants were given an appropriately sized N95 respirator to don, or put on, their mask. Once donned, participants completed their pre-intervention fit test, administered by a member of the research team following the Occupational Safety and Health Administration's (OSHA) ambient aerosol condensation nuclei counter quantitative fit test protocol using a TSI PortaCount Pro + 8038. Participants were then randomized into one of the four intervention arms, control, video, factsheet, or manufacturer's instructions, using a R generated randomization list (Appendix L). Participants received their intervention and were allotted as much time as they needed to learn the material. If they were in the control group, subjects were allotted a break. When ready, subjects donned a new N95 respirator of the correct size and completed another quantitative fit test. Participants then completed a third quantitative fit test donned in a one-size fits all N95 respirator. Fit factors produced by the quantitative fit tests were recorded on a data sheet by a member of the research team. After the fit testing portion of the protocols, participants completed the post-intervention KAP survey and filled out the demographic questionnaire (Appendices R, S). After completion of study protocols, participants received their $20 gift card as an appreciation and signed the payment tracking form. Additional details on study protocols can be found in Appendix K.

Statistical Analysis

Consultation was done with the University of Washington's Statistical Consulting Service to develop statistical analysis methods. All participant data was imported into the program, R studio, for data analysis (RStudio: Integrated Development for R RStudio, Inc., Boston, MA, USA). Figures were developed using the '*ggplot2*' package (v3.3.2; Wickham, 2016). Previous studies log transformed fit factor data prior to data analysis because fit factors can be lognormally distributed (Myers et al., 1996; Zhuang et al., 2008). Our team decided this was not needed with the design of our statistical analysis methods.

Descriptive analysis of participant characteristics, survey data, and observation data was done using the '*summarytools*' package in Rstudio (v0.9.6; Comtois, 2020).

Fit Factor Analysis #1

To compare the effectiveness of the training materials into improving N95 respirator fit, we built a multivariate linear regression model. To be more efficient, we used the Y_{post} as the outcome with adjustment for the $Y_{pre\ t}$, instead of using the change in fit factors as the model outcome (α=.05). The model is as followed:

$$Y_{post} = \beta_0 + \beta_V I\{V\} + \beta_M I\{M\} + \beta_F I\{F\} + \beta_{pre} Y_{pre};$$

where $I\{V\}$, $I\{M\}$, $I\{F\}$ are the indicators for membership in each intervention group, such that

$$I\{intervention\} = \{ 1, \text{ if the participant is in intervention group and } 0 \text{ otherwise};$$

$\beta_V, \beta_M, \beta_F$ are the coefficients associated with the group membership variables; and β_{pre} is the coefficient associated with the adjusting variable Y_{pre}. The control group will be the reference group when interpreting the results.

To compare the change in N95 respirator fit donned in the correct size respirator versus a one size fits all respirator, we also built a separate multivariate linear regression model, and used the Y_{one} size as the outcome with adjustment for the Y_{post} (α=.05). The model is as followed:

$$Y_{one} = \beta_0 + \beta_V I\{V\} + \beta_M I\{M\} + \beta_F I\{F\} + \beta_{post} Y_{post};$$

with the indicators and coefficients are the same as the model above.

<u>Fit Factor Analysis #2</u>

To determine the efficacy of training materials in achieving different fit factor thresholds (>2, >5, >10, >50, >100) and to compare the change of the proportion of participants achieving those fit factors, we built a linear regression model of post-results results on whether the participants were in the treatment group, adjusting for the pre-test results (α=.05). The example of the model for at least a fit factor of >2 is as followed:

$$I\{Y_{post} > 2\} = \beta_0 + \beta_1 I\{treatment\} + \beta_{pre} I\{Y_{pre} > 2\}$$

Where the outcome is defined as

$$I\{Y_{post} > 2\} = \{1, \text{ if } Y_{post} > 2 \text{ and } 0, \text{ if } Y_{post} \leq 2;$$

the main effect is defined as

I{treatment} = { 1, if the participant is in treatment and 0, if the participant is in control group;

and the adjustment variable is defined as

$I\{Y_{pre} > 2\} = \{1, \text{ if } Y_{pre} > 2 \text{ and } 0, \text{ if } Y_{pre} \leq 2.$

We selected a linear regression model for the binary outcome rather than a logistic regression, as it is more interpretable for comparing differences in the change in proportions.

KAP Survey

The change in KAP survey responses prior to and post intervention was analyzed using a paired sample T test allowing for unequal variance. The Wilcoxon rank sum test was considered, but not selected because it discounts data points where there is no change in value, which occurred in our data set. Data points where participants answered six, or "I don't know," on the survey were removed from the analysis as this answer choice was not formally part of the Likert scale.

No additional analysis was done on the observation data as it is beyond the scope of this pilot project. Code for data analysis can be found in Appendix T.

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Appendix B. Aim 2 Additional Plots and Tables

Table B1. Distribution of participants by NIOSH-NPPTL Bivariate Test Panel

			All		No Training		Video		Manufactuer's Instructions		Factsheet	
Panel Number	**Size**	**National Percentage**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
1	Small	5.50%	14	35	2	20	4	40	6	60	2	20
2	Small	5.30%	5	12.5	1	10	1	10	1	10	2	20
3	Small	10.50%	7	17.5	3	30	2	20	0	0	2	20
4	Medium	25.00%	6	15	2	20	1	10	1	10	2	20
5	Medium	7.10%	2	5	1	10	0	0	1	10	0	0
6	Medium	5.70%	4	10	0	0	1	10	1	10	2	20
7	Medium	21.30%	2	5	1	10	1	10	0	0	0	0
8	Large	8.70%	0	0	0	0	0	0	0	0	0	0
9	Large	5.20%	0	0	0	0	0	0	0	0	0	0
10	Large	3.50%	0	0	0	0	0	0	0	0	0	0

Table B2. Summary of the proportion of participants achieving fit factors of 2, 5, 10, 50, 100

	Control			Factsheet			Manufacturer's Instructions			Video		
# of participants above	Pre	Post	One Size	Pre	Post	One Size	Pre	Post	One Size	Pre	Post	One Size
Fit Factor > 2	8	8	7	9	10	10	7	10	10	7	10	10
Fit Factor > 5	2	4	4	3	10	9	1	9	8	3	9	7
Fit Factor > 10	1	3	3	3	10	8	1	7	5	3	8	7
Fit Factor > 50	0	0	1	0	2	0	0	3	0	0	0	0
Fit Factor > 100	0	0	0	0	0	0	0	0	0	0	0	0

Table B3. List of the KAP survey questions asked to participants

Number	Question
K1.	I know how to properly wear an N95 respirator
A2.	I think N95 respirators are easy to use
K3.	I know how to recognize medical symptoms that may limit or prevent the effective use of an N95 respirator
K4.	N95 respirators are approved for the general public to use during a wildfire smoke event
K5.	N95 respirators do not work effectively on people with beards
K6.	N95 respirators are approved for children to use
K7.	N95 respirators should be certified by the National Institute of Occupational Safety and Health
K8.	An appropriately sized N95 respirator will fit over your nose and under your chin
K9.	An N95 respirator with a broken or missing elastic strap is ok to use
K10.	Molding the nosepiece to your face shape on an N95 respirator can prevent air leakage
K11.	It is important to perform a check for a tight seal after adjusting an N95 respirator on your face
K12.	If an N95 respirator does not properly fit, it may not provide effective protection
K13.	N95 respirators filter out fine particles in smoke
K14.	N95 respirators filter out hazardous gas
K15.	I know how to properly maintain and store an N95 respirator
K16.	I should dispose of an N95 respirator when breathing through it becomes increasingly difficult
A17.	I think N95 respirators are a convenient way to reduce personal exposure to wildfire smoke
A18.	I think N95 respirators are comfortable enough to wear to reduce personal exposure to wildfire smoke
P19.	I would wear an N95 respirator during a wildfire smoke event when the air quality is poor
A20.	I think that N95 respirators are an effective way to reduce personal exposure to wildfire smoke
P21.	I would wear an N95 respirator before taking other actions to reduce personal exposure to wildfire smoke
P22.	The training I received today improved my knowledge about the use of an N95 respirator to reduce personal exposure to wildfire smoke
P23.	The training I received today improved my ability to properly wear an N95 respirator
K = Knowledge, A = Attitude, P = Practice	

Table B4. Change in number of participants who answered "I don't know" prior to and after the intervention

	Control				Factsheet				Manufacturer's Instructions				Video			
	Pre		Post		Pre		Post		Pre		Post		Pre		Post	
Question	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
K1	2	20	2	20	0	0	0	0	3	30	0	0	1	10	0	0
A2	2	20	1	10	1	10	0	0	1	10	0	0	0	0	0	0
K3	3	30	4	40	1	10	0	0	3	30	4	40	0	0	0	0
K4	8	80	9	90	8	80	1	10	9	90	9	90	8	80	1	10
K5	7	70	6	60	5	50	0	0	6	60	8	80	4	40	0	0
K6	7	70	5	50	8	80	0	0	8	80	9	90	6	60	0	0
K7	2	20	3	30	4	40	0	0	6	60	7	70	2	20	0	0
K8	3	30	2	20	4	40	0	0	3	30	1	10	1	10	0	0
K9	1	10	0	0	3	30	0	0	2	20	2	20	0	0	0	0
K10	1	10	1	10	2	20	0	0	4	40	1	10	1	10	0	0
K11	1	10	1	10	5	50	0	0	3	30	1	10	3	30	0	0
K12	1	10	0	0	1	10	0	0	2	20	1	10	0	0	0	0
K13	4	40	4	40	5	50	0	0	6	60	4	40	7	70	0	0
K14	7	70	7	70	6	60	0	0	9	90	4	40	7	70	0	0
K15	4	40	3	30	2	20	1	10	3	30	2	20	2	20	0	0
K16	2	20	2	20	3	30	1	10	6	60	3	30	5	50	1	10
A17	3	30	1	10	2	20	0	0	5	50	1	10	1	10	0	0
A18	0	0	1	10	1	10	0	0	2	20	2	20	1	10	0	0
P19	0	0	0	0	1	10	0	0	1	10	1	10	1	10	0	0
A20	2	20	2	20	5	50	0	0	5	50	7	70	5	50	0	0
P21	1	10	2	20	3	30	1	10	3	30	1	10	1	10	0	0
P22	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
P23	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table B5. Summary of the participants' KAP survey answers

Table B5i. Summary of the control group's KAP survey answers

	1: Strongly Disagree				2: Disagree				3: Neutral				4: Agree				5: Strongly Agree			
	Pre		Post		Pre		Post		Pre		Post		Pre		Post		Pre		Post	
Question	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
K1	2	20	1	10	3	30	4	40	2	20	2	20	1	10	1	10	0	0	0	0
A2	0	0	0	0	1	10	1	10	1	10	2	20	5	50	5	50	1	10	1	10
K3	2	20	2	20	1	10	0	0	1	10	1	10	2	20	2	20	1	10	1	10
K4	0	0	0	0	0	0	0	0	0	0	0	0	2	20	1	10	0	0	0	0
K5	0	0	0	0	1	10	1	10	2	20	3	30	0	0	0	0	0	0	0	0
K6	1	10	2	20	1	10	1	10	0	0	0	0	1	10	2	20	0	0	0	0
K7	0	0	0	0	0	0	0	0	2	20	0	0	3	30	4	40	3	30	3	30
K8	0	0	0	0	0	0	0	0	1	10	1	10	3	30	4	40	3	30	3	30
K9	6	60	7	70	3	30	3	30	0	0	0	0	0	0	0	0	0	0	0	0
K10	0	0	0	0	0	0	0	0	0	0	0	0	5	50	3	30	0	0	6	60
K11	0	0	0	0	0	0	0	0	1	10	0	0	3	30	1	10	5	50	8	80
K12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	20	9	90	8	80
K13	0	0	0	0	0	0	0	0	0	0	1	10	5	50	4	40	1	10	1	10
K14	0	0	0	0	1	10	1	10	0	0	1	10	1	10	0	0	1	10	1	10
K15	2	20	2	20	4	40	5	50	0	0	0	0	0	0	0	0	0	0	0	0
K16	0	0	0	0	1	10	1	10	1	10	0	0	4	40	7	70	2	20	0	0
A17	0	0	0	0	1	10	1	10	0	0	0	0	3	30	5	50	3	30	3	30
A18	0	0	0	0	2	20	2	20	1	10	3	30	3	30	1	10	4	40	3	30
P19	0	0	0	0	0	0	0	0	0	0	1	10	3	30	3	30	7	70	6	60
A20	0	0	0	0	0	0	0	0	1	10	0	0	4	40	6	60	3	30	2	20
P21	0	0	0	0	0	0	0	0	3	30	2	20	6	60	5	50	0	0	1	10
P22	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
P23	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table B5ii. Summary of the factsheet group's KAP survey answers

		1: Strongly Disagree				2: Disagree				3: Neutral				4: Agree				5: Strongly Agree			
		Pre		Post		Pre		Post		Pre		Post		Pre		Post		Pre		Post	
Question	Key	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
K1	Yes	1	10	0	0	2	20	0	0	6	60	0	0	1	10	4	40	0	0	6	60
A2	N/A	0	0	0	0	0	0	0	0	1	10	0	0	7	70	5	50	1	10	5	50
K3	No	3	30	1	10	3	30	2	20	1	10	2	20	2	20	2	20	0	0	3	30
K4	No	0	0	0	0	0	0	0	0	0	0	0	0	2	20	6	60	0	0	3	30
K5	Yes	0	0	0	0	4	40	0	0	0	0	0	0	1	10	1	10	0	0	9	90
K6	Yes	0	0	8	80	0	0	0	0	0	0	1	10	2	20	1	10	0	0	0	0
K7	Yes	0	0	0	0	0	0	0	0	1	10	0	0	4	40	0	0	1	10	10	100
K8	Yes	0	0	0	0	0	0	0	0	0	0	0	0	6	60	1	10	0	0	9	90
K9	Yes	3	30	9	90	4	40	1	10	0	0	0	0	0	0	0	0	0	0	0	0
K10	Yes	0	0	0	0	0	0	0	0	2	20	0	0	4	40	2	20	2	20	8	80
K11	Yes	0	0	0	0	1	10	0	0	1	10	0	0	3	30	2	20	0	0	8	80
K12	Yes	0	0	0	0	1	10	0	0	0	0	0	0	4	40	0	0	4	40	10	100
K13	Yes	0	0	0	0	0	0	0	0	0	0	0	0	4	40	1	10	1	10	9	90
K14	Yes	0	0	9	90	3	30	0	0	0	0	0	0	1	10	0	0	0	0	0	0
K15	No	2	20	2	20	5	50	2	20	1	10	2	20	0	0	3	30	0	0	0	0
K16	Yes	0	0	0	0	0	0	1	10	1	10	1	10	6	60	1	10	0	0	7	70
A17	N/A	0	0	0	0	0	0	0	0	1	10	1	10	6	60	4	40	1	10	5	50
A18	N/A	0	0	0	0	1	10	0	0	2	20	0	0	4	40	5	50	2	20	5	50
P19	N/A	0	0	0	0	0	0	1	10	1	10	0	0	5	50	2	20	3	30	7	70
A20	N/A	0	0	0	0	0	0	0	0	1	10	0	0	4	40	5	50	0	0	5	50
P21	N/A	1	10	1	10	0	0	1	10	0	0	2	20	4	40	1	10	2	20	4	40
P22	N/A	N/A	N/A	0	0	N/A		0	0	N/A	N/A	0	0	N/A	N/A	2	20	N/A	N/A	8	80
P23	N/A	N/A	N/A	0	0	N/A		0	0	N/A	N/A	1	10	N/A	N/A	2	20	N/A	N/A	7	70

Table B5iii. Summary of the manufacturer's instructions group’s KAP survey answers

		1: Strongly Disagree				2: Disagree				3: Neutral				4: Agree				5: Strongly Agree			
		Pre		Post		Pre		Post		Pre		Post		Pre		Post		Pre		Post	
Question	**Key**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
K1	Yes	4	40	0	0	2	20	0	0	0	0	0	0	1	10	5	50	0	0	5	50
A2	N/A	0	0	0	0	0	0	1	10	4	40	0	0	5	50	5	50	0	0	4	40
K3	No	6	60	3	30	1	10	2	20	0	0	0	0	0	0	0	0	0	0	1	10
K4	No	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	10	1	10
K5	No	0	0	0	0	0	0	0	0	0	0	0	0	3	30	0	0	1	10	2	20
K6	No	0	0	0	0	2	20	1	10	0	0	0	0	0	0	0	0	0	0	0	0
K7	No	0	0	0	0	0	0	0	0	1	10	0	0	0	0	0	0	3	30	3	30
K8	No	0	0	0	0	0	0	0	0	0	0	0	0	4	40	4	40	2	20	5	50
K9	No	3	30	6	60	4	40	2	20	1	10	0	0	0	0	0	0	0	0	0	0
K10	Yes	0	0	0	0	0	0	0	0	0	0	0	0	4	40	2	20	2	20	7	70
K11	Yes	0	0	0	0	0	0	0	0	0	0	0	0	3	30	3	30	4	40	6	60
K12	Yes	0	0	0	0	0	0	0	0	0	0	0	0	3	30	2	20	5	50	7	70
K13	Yes	0	0	0	0	0	0	0	0	0	0	0	0	2	20	4	40	2	20	2	20
K14	Yes	0	0	2	20	0	0	2	20	0	0	0	0	0	0	0	0	1	10	0	0
K15	No	6	60	1	10	0	0	1	10	1	10	1	10	0	0	2	20	0	0	0	0
K16	Yes	0	0	0	0	0	0	0	0	0	0	0	0	1	10	1	10	3	30	6	60
A17	N/A	0	0	0	0	0	0	0	0	1	10	0	0	3	30	5	50	1	10	4	40
A18	N/A	0	0	1	10	2	20	1	10	2	20	1	10	3	30	2	20	1	10	4	40
P19	N/A	0	0	0	0	0	0	0	0	1	10	0	0	4	40	3	30	4	40	6	60
A20	N/A	0	0	1	10	0	0	1	10	1	10	0	0	4	40	0	0	0	0	2	20
P21	N/A	1	10	0	0	0	0	0	0	3	30	3	30	1	10	3	30	2	20	3	30
P22	N/A	N/A	N/A	1	10	N/A	N/A	1	10	N/A	N/A	0	0	N/A	N/A	5	50	N/A	N/A	4	40
P23	N/A	N/A	N/A	0	0	N/A	N/A	0	0	N/A	N/A	1	10	N/A	N/A	4	40	N/A	N/A	5	50

Table B5iii. Summary of the video group’s KAP survey answers

		1: Strongly Disagree				2: Disagree				3: Neutral				4: Agree				5: Strongly Agree			
		Pre		Post		Pre		Post		Pre		Post		Pre		Post		Pre		Post	
Question	**Key**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
K1	Yes	1	10	0	0	4	40	0	0	3	30	0	0	1	10	4	40	0	0	6	60
A2	N/A	0	0	0	0	0	0	0	0	4	40	0	0	5	50	6	60	1	10	4	40
K3	No	2	20	0	0	2	20	0	0	1	10	2	20	4	40	5	50	1	10	3	30
K4	No	1	10	0	0	0	0	0	0	1	10	0	0	0	0	1	10	0	0	8	80
K5	Yes	1	10	0	0	0	0	0	0	2	20	0	0	1	10	1	10	2	20	9	90
K6	Yes	1	10	9	90	0	0	0	0	3	30	0	0	0	0	1	10	0	0	0	0
K7	Yes	0	0	0	0	0	0	0	0	0	0	0	0	2	20	0	0	6	60	10	100
K8	Yes	0	0	0	0	0	0	0	0	3	30	0	0	5	50	1	10	1	10	9	90
K9	Yes	7	70	9	90	2	20	1	10	1	10	0	0	0	0	0	0	0	0	0	0
K10	Yes	0	0	0	0	0	0	0	0	0	0	0	0	5	50	0	0	4	40	10	100
K11	Yes	0	0	0	0	0	0	0	0	1	10	0	0	3	30	0	0	3	30	10	100
K12	Yes	0	0	0	0	0	0	1	10	0	0	0	0	3	30	0	0	7	70	9	90
K13	Yes	0	0	0	0	0	0	0	0	1	10	0	0	1	10	2	20	1	10	8	80
K14	Yes	1	10	9	90	2	20	1	10	0	0	0	0	0	0	0	0	0	0	0	0
K15	No	5	50	1	10	2	20	2	20	1	10	7	70	0	0	0	0	0	0	0	0
K16	No	0	0	0	0	0	0	0	0	0	0	1	10	5	50	3	30	0	0	5	50
A17	N/A	0	0	0	0	0	0	0	0	3	30	1	10	5	50	5	50	1	10	4	40
A18	N/A	1	10	0	0	1	10	1	10	4	40	2	20	2	20	6	60	1	10	1	10
P19	N/A	0	0	0	0	0	0	1	10	3	30	1	10	5	50	5	50	1	10	3	30
A20	N/A	0	0	0	0	1	10	0	0	2	20	0	0	1	10	4	40	1	10	6	60
P21	N/A	0	0	1	10	3	30	1	10	2	20	2	20	3	30	3	30	1	10	3	30
P22	N/A	N/A	N/A	0	0	N/A	N/A	0	0	N/A	N/A	0	0	N/A	N/A	0	0	N/A	N/A	10	100
P23	N/A	N/A	N/A	0	0	N/A	N/A	0	0	N/A	N/A	1	10	N/A	N/A	9	90	N/A	N/A	9	90

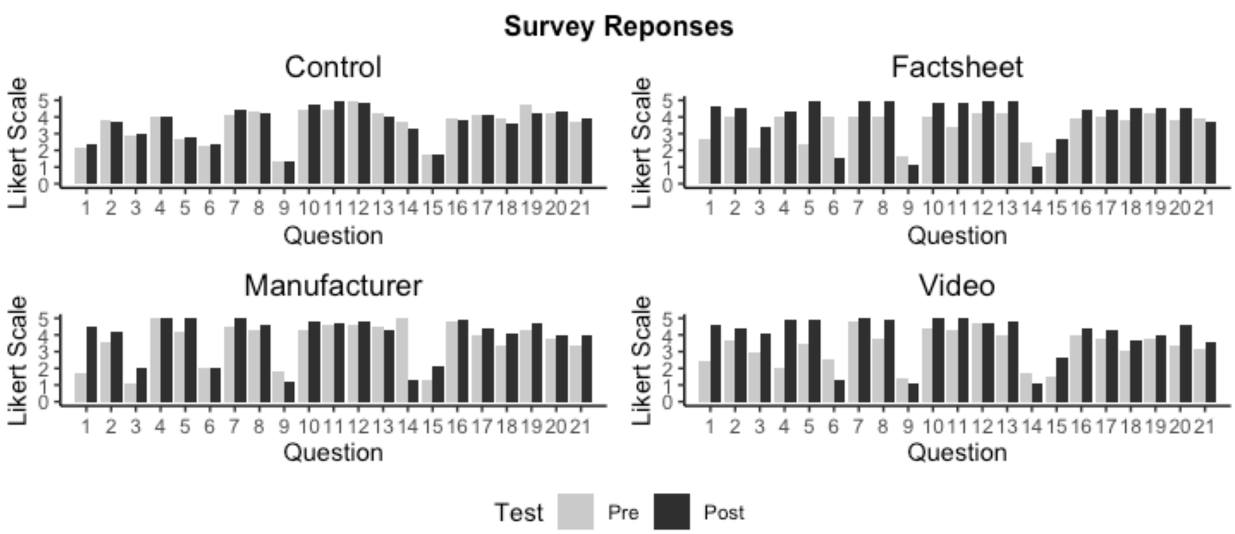
Table B6. List and codes of the observed actions taken by participants

Code	Description
Donn_Inspect_Mask	Inspected mask[1]
Donn_Cuppped	Cupped respirator in hand to prepare for placement[2]
Donn_Cuppped_Nose	When cupped in hand, nosepiece at fingertips[2]
Donn_Cuppped_Strap	When cupped in hand, straps hanging freely below hand[2]
Donn_Strap_Order	Pulled top strap over head first, then bottom second [2]
Donn_Strap_Position	Top strap above ears, bottom strap below ears[2]
Donn_Strap_Straight	Straps straight, not twisted/criss-crossed[1]
Donn_Position	Mask is over nose, under the chin, centered properly on face[1]
Donn_Nosepiece	Respirator positioned with nosepiece up[2]
Donn_Molded_Nose	Molded metal nose piece the shape of your nose [1, 2]
Donn_Movement	Moved mask during fit testing (e.g. once the fit test started)[1]
Donn_Movement_1	Adjustment was minimal (e.g. light touch, no apparent movement)
Donn_Movement_2	Adjustment was moderate (e.g. shift that resulted in small break of seal)
Donn_Movement _3	Adjustment was significant (e.g. moved mask entirely resulting in the breaking of the seal)
Seal_Check	Checked Seal [1, 2]
Seal_Check_Hands	Placed both hands completely over the respirator and exhaled during seal check[2]
Seal_Check_Positon	Disturbed the position of the respirator while performing seal check[2]
Seal_Check_Leak	If they thought there was a leak, did they readjust nosepiece or straps to fix[2]
Seal_Check_2	If they re-adjusted nosepiece/straps, did they re-perform a seal check
Glasses	Wearing glasses
Glasses_Obstruction	Glasses obstructing the mask (e.g. between face and the mask, visibly break the seal)

Table B7. Summary of the observed actions taken by participants

	Control						Factsheet							Manufacturer's Instructions							Video						
	Pre		Post		One Size		Key	Pre		Post		One Size		Key	Pre		Post		One Size		Key	Pre		Post		One Size	
Question	n	%	n	%	n	%		n	%	n	%	n	%		n	%	n	%	n	%		n	%	n	%	n	%
Donn_Inspect_Mask	0	0	0	0	0	0	No	0	0	0	0	0	0	No	0	0	0	0	0	0	Yes	0	0	0	0	0	0
Donn_Cuppped	1	10	1	10	1	10	No	0	0	0	0	0	0	Yes	0	0	7	70	5	50	Yes	0	0	7	70	5	50
Donn_Cuppped_Nose	1	10	1	10	1	10	No	0	0	0	0	0	0	Yes	0	0	7	70	5	50	Yes	0	0	6	60	3	30
Donn_Cuppped_Strap	0	0	0	0	0	0	No	0	0	0	0	0	0	Yes	0	0	4	40	2	20	Yes	0	0	5	50	2	20
Donn_Strap_Order	1	10	1	10	1	10	No	3	30	3	30	2	20	Yes	0	0	4	40	4	40	Yes	0	0	10	100	8	80
Donn_Strap_Position	6	60	6	60	5	50	Yes	6	60	10	100	9	90	Yes	5	50	9	90	9	90	Yes	4	40	8	8	7	70
Donn_Strap_Straight	8	80	8	80	8	80	Yes	9	90	10	100	10	100	Yes	7	70	10	100	9	90	Yes	5	50	10	100	10	100
Donn_Position	10	100	10	100	10	100	Yes	10	100	10	100	9	90	Yes	10	10	10	100	10	100	Yes	9	90	10	100	10	100
Donn_Nosepiece	9	90	9	90	9	90	Yes	10	100	10	100	10	100	Yes	9	90	10	100	10	100	Yes	8	80	10	100	10	100
Donn_Molded_Nose	2	20	3	30	3	30	Yes	3	30	10	100	10	100	Yes	2	20	9	90	9	90	Yes	1	10	10	100	10	100
Donn_Movement	1	10	0	0	1	10	N/A	0	0	0	0	0	0	N/A	0	0	0	0	0	0	N/A	1	10	0	0	3	30
Donn_Movement_1	0	0	0	0	1	10	N/A	0	0	0	0	0	0	N/A	0	0	0	0	0	0	N/A	0	0	0	0	1	10
Donn_Movement_2	1	10	0	0	0	0	N/A	0	0	0	0	0	0	N/A	0	0	0	0	0	0	N/A	0	0	0	0	2	20
Donn_Movement _3	0	0	0	0	0	0	N/A	0	0	0	0	0	0	N/A	0	0	0	0	0	0	N/A	1	10	0	0	0	0
Seal_Check	0	0	0	0	0	0	No	0	0	0	0	0	0	Yes	0	0	7	70	4	40	Yes	0	0	9	90	7	70
Seal_Check_Hands	0	0	0	0	0	0	No	0	0	0	0	0	0	Yes	0	0	6	60	3	30	Yes	0	0	7	70	6	60
Seal_Check_Positon	0	0	0	0	0	0	No	0	0	0	0	0	0	Yes	0	0	6	60	3	30	No	0	0	5	50	5	50
Seal_Check_Leak	0	0	0	0	0	0	No	0	0	0	0	0	0	No	0	0	3	30	0	0	Yes	0	0	5	50	6	60
Seal_Check_2	0	0	0	0	0	0	No	0	0	0	0	0	0	No	0	0	2	20	0	0	Yes	0	0	3	30	4	40
Glasses	2	20	2	20	1	10	N/A	1	10	1	10	1	10	N/A	3	30	3	30	3	30	N/A	2	20	2	20	2	20
Glasses_Obstruction	0	0	0	0	1	10	N/A	1	10	1	10	1	10	N/A	3	30	2	20	2	20	N/A	1	10	1	10	1	10

Figure B1. Bar graphs of participant's survey answers prior to and after the intervention



Appendix C. PNASH Grant Application

Project Title: Knowledge transference effect on N95 mask fit, by communication medium
Principle Investigator: Tania Busch Isaksen PhD MPH & **Student Investigator:** Kaitlyn Kelly (MPH Candidate)
Technical Advisors: Marty Cohen and Marc Beaudreau, DEOHS Field Research and Consultation Group

Research AIM: The aim of this pilot project is to quantify the transference of knowledge from different communication mediums into N95 respirator mask fit in a convenience sample of the "lay public". We will test written and video communication knowledge transference and to what degree the newly acquired knowledge affects mask fit and performance on a convenience sample of healthy adults. We will utilize existing equipment owned by the Field Research and Consultation Group, to test fit on approximately 30 volunteers, split into 3 different intervention groups: pictorial card; written factsheet; and video instruction. To our knowledge no other research has been conducted regarding N95 mask communication efficacy. The results from this pilot will be helpful to practice and research partners as they consider the appropriateness of N95 masks as a public health intervention for use in reducing wildfire smoke exposure.
What is the emerging issue? Wildfires are becoming an increasingly important issue across the Western United States as human populations living at the wildland-urban interface continue to grow. Climate change is leading to increased frequency, duration, and intensity of wildfires, and longer regional fire seasons. Wildfire smoke exposure is associated with respiratory morbidity in the general population, as well as exacerbations for those with asthma and chronic obstructive pulmonary disease, and all-cause mortality.[1] Children, the elderly, and those who spend large amounts of time outdoors are at highest risk of exposure and the associated health impacts.[1] Despite the lack of epidemiological studies in outdoor workers, they have been described by researchers to be at high risk due to their increased exposure.
Why is it a high impact and timely opportunity? The frequency of wildfires is increasing in WA State, as well as the impact from transboundary smoke originating from distant wildfires. The use of N95 masks as a personal exposure reduction intervention, by the general public, has increased over the last two years. In 2017, a total 72,460 masks were distributed between the following counties or Tribes: Chelan/Douglas, Klickitat, Colville Tribe, and Medical Lake. The number increased in 2018 to 249,040 distributed masks in Chelan, Douglas, Okanogan, Whatcom, Tacoma-Pierce Counties and in Yakama Nation, Spokane, Sauk-Suiattle, and Nisqually tribes. The distribution of N95 masks in an occupational setting may require medical clearance, proper training, and fit testing unless the option to wear a "filtering facepiece" is voluntary.[2] Public and voluntary occupational use of N95 masks, and the description of information and/or training provided, is incomplete.
How does it address issues/priorities raised by stakeholders? In October 2018, the PI's research group hosted a wildfire smoke risk stakeholder symposium that brought together 90 practitioners, researchers and students, representing 35 organizations across Washington State, to develop a practice-based wildfire smoke research agenda. The symposium participants called for better understanding of the physical and mental health impacts of wildfire smoke, evidence-based intervention strategies (specifically N95 mask efficacy research), and risk communication strategies to protect population health during prolonged and extreme smoke events.
How is it distinct from existing projects? Currently, there are no projects testing the fit of N95 masks on the lay public and the relative effect of educational training tools. Previous studies have shown the filtration efficiency of particulate matter, as well as cardiovascular benefits of wearing respirators around ambient particulate matter.[3]
How are these stakeholders engaged in the project? The project is a direct request from stakeholders. Results will be communicated to these stakeholders, as well as to the Pacific Northwest Agricultural Safety and Health Center and the newly formed Washington State Wildfire Smoke Impacts Workgroup - of which the PI is a member.
How does it extend research into practice? N95 masks are currently being used as an intervention in response to wildfire smoke; however, proper fit, or lack thereof, may affect the effectiveness of N95 masks as a public health measure. Environmental Public Health professionals are in urgent need of this research to support their decisions in continuing to promote this widely-used intervention and/or to support accompanying risk communication messages.
Budget request and breakdown by key personnel and budget categories

Summer RA Kaitlyn Kelly, Hourly Graduate Student Assistant, 1.15SM, about $33.86/hr for about 200 hours 0180 Kaitlyn Kelly, Summer Hourly Grad Student Assistant, 20.9% Fringe	$6773 $1416
Participant Incentives ($25 gift cards*30 participants)	$750
N95 masks (3 packages of 20)	$60
Open source publication fee	$1000
Total	**$9,999**

[1]Cascio, W. E. Wildland fire smoke and human health. Sci. Total Environ. 624, 586–595 (2018).
[2]29 CFR 1910.134(c)(2)(ii)
[2]Shi, Jingjin, Lin, Zhijing, Chen, Renjie, Wang, Cuicui, Yang, Changyuan, Cai, Jing, . . . Kan, Haidong. (2017). Cardiovascular Benefits of Wearing Particulate-Filtering Respirators: A Randomized Crossover Trial. *Environmental Health Perspectives (Online), 125*(2), 175-180.

Appendix D. PNASH Grant Budget

Kaitlyn Kelly, Hourly Graduate Student Assistant, 1.15SM, about $33.86/hr for about 228 hours	$7,500
Student Assistant Bus Pass for Summer	$50
Participant Incentives ($20 gift cards*40 participants)	$800
Face Measuring Tools	$45
N95 masks (3 boxes of M/L Home Depot Masks, 2 boxes of S Home Depot Masks, 3 boxes of 15 One Size Home Depot Masks)	$250
10 packs of 2, 3M "Air Pollution Mask"	$68.80
Practice Masks	$20.26
Probes needed for fit test	$50
Nitrile Gloves	$10
Budget Total	$8,725
Grant Total	$8,999

Appendix E. PNASH Year-End Report

Project Title: Knowledge transference effect on N95 mask fit, by communication medium
Principle Investigator: Tania Busch Isaksen PhD MPH & Student Investigator: Kaitlyn Kelly

Methods:

In this pre/post-test, quasi-experimental study subjects will be randomized into one of the four intervention arms, control or one of three educational interventions designed to improve N95 mask use ("Smoke From Fires: N95 Respirator Masks" video, DOH Wildfire Smoke and Face Masks factsheet, manufacturer's instructions). Subjects will be given and then don, or put on, an N95 mask that is their size, based on facial measurements taken by a member of the research team. All subjects will complete their pre-intervention fit test, administered by a member of the research team following the OSHA fit testing procedures. The codes and standards for proper respirator use and fit testing in the workplace can be found in WAC 296-842-150 or the, specifically the ambient aerosol condensation nuclei counter quantitative fit test protocol. The respirator fit test will produce a fit factor, by taking the ratio of the average ambient concentration to the concentration measured inside the respirator of all the test exercises, excluding the grimace exercise. Subjects will then receive their intervention, or communication medium. Subjects will re-don an N95 mask of the selected size and complete a second fit test. Finally, subjects will be given a one-size fits all mask, don, and complete a third fit test. Statistical methods will be used to assess the effect size of the knowledge transfer of each communication medium and to see if participants achieved a fit factor of 100, the minimum fit factor indicative of proper fit. A Knowledge, Attitude and Practices (KAP) survey will also be administered to quantify the change in knowledge, as well as additional analysis of the observed behavior of participants while donning the mask.

Progress:

Aim: Quantify the transference of knowledge from different communication mediums into N95 respirator mask fit in a convenience sample of the "lay public."

In progress. *Recruitment of participants has started and data collection will begin this fall.*

Outcomes:

The results of this study will:

I. Identify the gaps in knowledge in proper use of N95 masks
II. Identify challenges and gaps in proper use of N95 masks, including the process of donning the masks
III. Identify how knowledge and actions translate into proper fit and thus protection
IV. Identify the effect of correct respirator size, in addition to training, on proper fit
V. Results will assist public health practice and research partners as they consider the appropriateness of N95 masks as a public health intervention
VI. Results will be translated into new or improved communication mediums for the general public regarding N95 use and training
VII. Research Needs for future work include:
  A. The effect of the correct size on respirator fit
  B. Understand perceptions and attitudes of N95 mask use by outdoor workers during wildfire smoke events
  C. Evaluation of risk reduction when using N95 masks during wildfire smoke event

Appendix F. Literature Review Search Terms

Search Terms					
#1	**#2**		**#1**	**#2**	**#3**
dust mask	air pollution		N95 mask	health effects	
dust mask	education		N95 mask	education	
dust mask			N95 Mask	fit	
face mask	air pollution		N95 mask	effectiveness	
N-95 mask			N95 mask	evaluation	
N95 Mask	wildfire		N95 mask	communication	
N95 Mask	training		N95 respirator	outdoor worker	
N95 mask	education		N95 respirator	agriculture	
N95 Mask	fit		N95 respirator	evaluation	
N95 mask	volcanic ash		N95 respirator	effectiveness	
N95 mask	smoke		N95 respirator	particulate matter	
N95 mask	air pollution		N95 respirator	communication	
N95 mask	silica		N95 respirator	air pollution	
N95 mask	health effects		N95 respirator	wildfire	
N95 mask	effectiveness		N95 respirator	training	
N95 mask	evaluation		N95 respirator	education	
N95 mask	silica		N95 respirator	fit	
N95 mask	health effects		respirator	wildfire	
N95 mask	effectiveness		respirator	air pollution	
N95 mask	particulate matter		respirator mask	training	
N95 Mask	wildfire		respirators	half mask	communication
N95 Mask	training		respirators	half mask	training
N95 mask	education		respirators	half mask	fit
N95 mask	volcanic ash		N95 Mask	wildfire	
N95 mask	smoke		N95 mask	air pollution	
N95 mask	air pollution		N95 mask	education	
N95 mask	silica		N95 mask	effectiveness	
N95 mask	health effects		N95 mask	evaluation	
N95 mask	evaluation		N95 Mask	fit	
N95 mask	effectiveness		N95 mask	health effects	
N95 mask			N95 mask	particulate matter	
N95 Mask	wildfire		N95 mask	silica	
N95 Mask	training		N95 mask	smoke	
N95 mask	air pollution		N95 Mask	training	
N95 mask	silica		N95 mask	volcanic ash	
N95 mask	volcanic ash		N95 Mask	wildfire	
N95 mask	smoke		N95 mask		
N95 mask	particulate matter		N95 mask	communication	

Appendix G. IRB Application

UNIVERSITY *of* WASHINGTON
HUMAN SUBJECTS DIVISION

ZIPLINE APPLICATION: IRB Protocol

The Human Subjects Division (HSD) strives to ensure that people with disabilities have access to all services and content. **If you experience any accessibility-related issues with this form or any aspect of the application process, email hsdinfo@uw.edu for assistance.**

INSTRUCTIONS

- **This form is only for studies that will be reviewed by the UW IRB**. Before completing this form, check HSD's website to confirm that this should not be reviewed by an external (non-UW) IRB.
- **If you are requesting a determination** about whether your activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a . For example **1.1** must be answered.
- **Answer all questions**. If a question is not applicable to your research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- The word "you" refers to the researcher and all members of the research team, unless otherwise specified.
- For collaborative research, describe only the information that is relevant to you unless you are requesting that the UW IRB provide the review and oversight for your collaborators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.

INDEX

1 OVERVIEW

Study Title: Knowledge transference effect on N95 mask fit, by communication medium

1.1 Home institution. Identify the institution through which the lead researcher listed on the IRB application will conduct the research. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the ***SOP: Use of the UW IRB****.*

University of Washington

1.2 Consultation history. Have you consulted with anyone at HSD about this study?

It is not necessary to obtain advance consultation. If you have: answering this question will help ensure that the IRB is aware of and considers the advice and guidance you were provided.

X	**No**
	Yes → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

1.3 Similar and/or related studies. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

X	**No**
	Yes → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

1.4 Externally-imposed urgency or time deadlines. Are there any externally-imposed deadlines or urgency that affect your proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

	No
X	**Yes**

→ If yes, briefly describe the urgency or deadline as well as the reason for it.

Project is already funded, and research cannot begin until we have IRB determination. This research is for the student researcher's thesis who has limited time to complete the study.

1.5 Objectives Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If your application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

Wildfires are becoming an increasingly important issue across the Western United States as human populations living at the wildland-urban interface continue to grow. Wildfire smoke exposure is associated with respiratory morbidity in the general population, as well as exacerbations for those with asthma and chronic obstructive pulmonary disease, and all-cause mortality. N95 masks are currently being communicated as an intervention in response to wildfire smoke; however, communication methods and proper fit, or lack thereof, may affect the effectiveness of N95 masks as a public health measure. In Washington State the use of N95 masks as a personal exposure reduction intervention, by the general public, has increased over the last two years. In 2017, a total 72,460 masks were distributed across several counties in WA, and the number increased 249,040 distributed masks in 2018. However, the mandatory use of N95 masks in an occupational setting requires medical clearance, proper training, and fit testing. This practice is not required for public distribution or use of masks, and the description of information and/or training provided is incomplete. A need for better understanding of evidence-based intervention strategies (specifically N95 mask efficacy research) and risk communication strategies to protect population health during prolonged and extreme smoke events has been identified by the University of Washington and practice partners.

The objective of this project is to quantify the transference of knowledge from different communication mediums and education methods into N95 respirator mask fit to identify the use of N95 respirator masks as an effective and appropriate public health intervention to reduce wildfire smoke exposure. A fit test, which assesses the adequacy of respirator fit by numerically measuring the amount of leakage into the respirator, will be done before and after the intervention to determine the change in fit resulting from training of proper use. We will also conduct analysis to see if participants achieve proper fit, which is defined has having a fit factor, the quantitative estimate of a fit produced by fit testing, of at least 100, as defined by the Occupational Health and Safety Association. This will identify which current communication mediums are effective, and which if, any, translate into proper use by the user. The results from this pilot will be helpful to practice and research partners as they consider the appropriateness of N95 masks as a public health intervention for reducing wildfire smoke exposure.

1.6 Study design. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.

This will be a quasi-experimental study, with data collected pre and post educational intervention.

1.7 Intent. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

	Descriptor
	1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).
	2. Part of an institution, organization, or program's own internal operational monitoring.
	3. Improve the quality of service provided by a specific institution, organization, or program.
X	4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that: • Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or • Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
	5. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.
X	6. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.
	7. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.
X	8. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)
	9. Expanded access use of a drug or device not yet approved for this purpose

☐ 10. Use of a Humanitarian Use Device

☐ 11. Other. Explain:

1.8 Background, experience, and preliminary work. Answer this question **only** if your proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

a. Background. Provide the rationale and the scientific or scholarly background for your proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that your project is intended to address.

This should be a plain language description. Do not provide scholarly citations. Limit your answer to less than one page, or refer to an attached document with background information that is no more than three pages long.

NA

b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you or your team have that supports the feasibility and/or safety of this study.

It is not necessary to summarize all discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: You have already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study you are now proposing to do; you have already done a small pilot study showing that the reading skills intervention you plan to use is feasible in an after-school program with classroom aides; you have experience with the type of surgery that is required to implant the study device; you have a study coordinator who is experienced in working with subjects who have significant cognitive impairment.

NA

1.9 Supplements. Check all boxes that apply, to identify Supplements you should complete and upload to the **Supporting Documents** SmartForm in ***Zipline***.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all That Apply	Type of Research	Supplement Name

☐	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Defense
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Energy
☐	**Drug, biologic, botanical, supplement** Procedures involve the use of <u>any</u> drug, biologic, botanical or supplement, even if the item is not the focus of your research	*ZIPLINE* SUPPLEMENT: Drugs
☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk	*ZIPLINE* SUPPLEMENT: Exception from Informed Consent for Emergency Research (EFIC)
☐	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers, and you are asking the UW to provide the required certification or to ensure that the consent forms can be certified	*ZIPLINE* SUPPLEMENT: Genomic Data Sharing
☐	**Medical device** Procedures involve the use of <u>any</u> medical device, even if the device is not the focus of your research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	*ZIPLINE* SUPPLEMENT: Devices
☐	**Multi-site study** You are asking the UW IRB to review one or more sites in a multi-site study.	*ZIPLINE* SUPPLEMENT: Participating Site in Multi-Site Research
X	None of the above	

2 PARTICIPANTS

2.1 Participants. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

We will enroll potential subjects of all ages, genders, races and ethnicities. Our subject population will not have pre-existing respiratory or cardiovascular diseases.

2.2 Inclusion and exclusion criteria.

a. Inclusion criteria. Describe the specific criteria you will use to decide who will be included in your study from among interested or potential subjects. Define any technical terms in lay language.

We will include all potential subjects over the age of 18 and who do not have a pre-existing respiratory or cardiovascular disease.

b. Exclusion criteria. Describe the specific criteria you will use to decide who will be excluded from your study from subjects who meet the inclusion criteria listed above. Define any technical terms in lay language.

Subjects who are unwilling to refrain from smoking 60 minutes prior to and during the study will be excluded. Non-English speaking subjects will be excluded due to the training materials being in English. Subjects who have previous training on how to wear an N95 mask will be excluded, due to the objective of this study. Subjects who have been formally fit tested for a respirator, including for an occupational setting, will also be excluded. Subjects who have sensory or motor impairments that prevent them from being able to put on the mask themselves or hear verbal training will be excluded.

2.3 Prisoners. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

a. Will you recruit or obtain data from individuals that you know to be prisoners?

For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the WORKSHEET: Prisoners for the definition of "prisoner".

X	**No**
	Yes → If yes, answer the following questions (i – iv).

i. Describe the type of prisoners, and which prisons/jails:

ii. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. What will you do to reduce the chances of this?

iii. Describe what you will do to make sure that (a) your recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

iv. If your research will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide your assurance that you will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole.

☐ **Confirmed**

b. Is your research likely to have subjects who become prisoners while participating in your study?

For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.

[X] **No**
[ ] **Yes** → If yes, if a subject becomes a prisoner while participating in your study, will you continue the study procedures and/or data collection while the subject is a prisoner?

[ ] **No**
[ ] **Yes** → If yes, describe the procedures and/or data collection you will continue with prisoner subjects

2.4 Protected populations. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that you will purposefully include in your research. (In other words, being a part of the population is an inclusion criterion for your study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed and should not be submitted.

Population	Worksheet
[ ] Fetuses in utero	WORKSHEET: Pregnant Women
[ ] Neonates of uncertain viability	WORKSHEET: Neonates
[ ] Non-viable neonates	WORKSHEET: Neonates
[ ] Pregnant women	WORKSHEET: Pregnant Women

a. If you check any of the boxes above, use this space to provide any information you think may be relevant for the IRB to consider.

2.5 Native Americans or non U.S. indigenous populations. Will you actively recruit from Native American or non-U.S. indigenous populations through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering

[X] **No**

☐ Yes → If yes, name the tribe, tribal-focused organization, or similar community based organization. The UW IRB expects that you will obtain tribal/indigenous approval before beginning your research.

2.6 Third party subjects. Will you collect private identifiable information about *other individuals* from your subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of your research team to readily identify the person. For example, suppose that you are studying immigration history. If you ask your subjects several questions about their grandparents but you do not obtain names or other information that would allow you to readily identify the grandparents, then you are not collecting private identifiable information about the grandparents.

☒ No
☐ Yes → If yes, these individuals are considered human subjects in your study. Describe them and what data you will collect about them.

2.7 Number of subjects. Can you predict or describe the maximum number of subjects (or subject units) you need to complete your study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

Subject group means categories of subjects that are meaningful for your research. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- *By intervention – for example, an intervention group and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

The IRB reviews the number of subjects you plan to study in the context of risks and benefits. Unless otherwise specified, if the IRB determines that your research involves no more than minimal risk: there are no restrictions on the total number of subjects you may enroll in the study. If your research involves more than minimal risk: you may only enroll the number of subjects described here in your application. Submit a Modification if you wish to increase the number of subjects. Exceeding the IRB-approved number (over-enrollment) will be considered non-compliance.

☐ No → If no, provide your rationale in the box below. Also, provide any information you can about the scope/size of the research. You do not need to complete the table.

Example: you may not be able to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that you will post your survey for two weeks and the number who respond is the number who will be in your study.

X **Yes**

→ If yes, for each subject group, use the table below to provide your estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number of individuals (or other subject unit, such as families) who will complete the research **For clinical trials: provide numbers for your site and for the study-wide total number*
Control Group (no education)	15 individuals
Communication Medium Intervention #1 (video)	15 individuals
Communication Medium Intervention #2 (health agency factsheet)	15 individuals
Communication Medium Intervention #3 (manufacturer's instructions)	15 individuals

3 NON-UW RESEARCH SETTING
Complete this section only if your research will take place outside of UW and Harborview

3.1 Reason for sites. Describe the reason(s) why you selected the sites where you will conduct the research.

N/A

3.2 Local context. Culturally-appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect your research, how it is conducted, or how you obtain or document consent.

Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group. In some distinct cultural groups, signing forms may not be the norm.

This federal site maintains an international list of human research standards and requirements: [*http://www.hhs.gov/ohrp/international/index.html*](http://www.hhs.gov/ohrp/international/index.html)

N/A

3.3 Site-specific laws. Describe any local laws that may affect your research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and across countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

N/A

3.4 Site-specific administrative or ethical requirements. Describe local administrative or ethical requirements that affect your research.

Example: A school district may require you to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow you to interview factory workers but not allow you to pay them.

N/A

3.5 Students: Does your research involve traveling outside of the US?

[X] **No**
[ ] **Yes** → If yes, confirm by checking the box that (1) you will register with the **UW Office of Global Affairs** before traveling; (2) you will notify your advisor when the registration is complete; and (3) you will request a UW Travel Waiver if your research involves travel to the list of countries requiring a UW Travel Waiver.

[ ] **Confirmed**

4 RECRUITING and SCREENING PARTICIPANTS

4.1 Recruiting and Screening. Describe how you will identify, recruit, and screen subjects. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

We will be recruiting UW students, faculty, and staff. Subjects will be identified based on inclusion and exclusion criteria. Subjects will be recruited through convenience sampling by members of the research team. A variety of recruitment materials will be used including in-person conversations, social media messaging, and flyers for posting throughout campus. All recruitment materials will provide a brief overview of the study, provide information on eligibility, and who to contact about enrolling. When potential subjects contact members of the research team, they will be screened through a questionnaire by a member of the research team to determine eligibility.

4.2 Recruitment materials.

a. What materials (if any) will you use to recruit and screen subjects?

Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.

Talking points for in-person conversations and social media messages, flyers for posting, screening questionnaire to determine eligibility

b. Upload descriptions of each type of material (or the materials themselves) to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline***. If you will send letters or emails to the subjects, these should include a statement about how you obtained the subject's name and contact information. However, no sensitive information about the person (such as a diagnosis of a medical condition) should be included in the letter.

HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:

- *You could provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, you might include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). In doing so, you would not need to submit a Modification if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, you might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, you might include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

4.3 Relationship with participant population. Do any members of the study team have an existing relationship with the study population(s)?

Examples: a study team member may have a dual role with the study population (for example, being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for his/her research).

X	**No**
	Yes

→ If yes, describe the nature of the relationship.

4.4 Payment to participants. Describe any payment you will provide, including:

- The total amount/value
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

The IRB expects the consent process or study information provided to the subjects to include information about the number and amount of payments, and especially the time when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.

Do not include a description of any expenses that will be reimbursed.

The participant will receive a gift card of $20 value on the day they complete the experiment. The payment will not be pro-rated. Participants who are selected for the study and begin the experiment, but then for any reason choose to withdraw, will still receive the gift card for making the effort of participating.

4.5 Non-monetary compensation. Describe any non-monetary compensation you will provide. Example: extra credit for students; a toy for a child. If you will be offering class credit to students, you must provide (and describe) an alternate way for the students to earn the extra credit without participating in your research.

N/A

4.6 Will you access or obtain data or specimens for recruiting and screening procedures prior to enrollment?

Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.

X	**No**	→ If no, skip the rest of this section; go to question **5.1**.
	Yes	→ If yes, describe any data and/or specimens (including PHI) you will access or obtain for recruiting and screening and whether you will retain it as part of the study data.

4.7 Consent for recruiting and screening. Will you obtain consent for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.

Examples:

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

☐ **No** → If no, skip the rest of this section; go to question **5.1**.

X **Yes** → If yes, describe the consent process.

We will obtain verbal consent to ask eligibility questions. When potential subjects contact a member of the research team about enrollment, the subject will be informed that the screening procedure is voluntary, may discontinue participation at any time, and may ask questions to the member of the research team.

a. Documentation of consent. Will you obtain a written or verifiable electronic signature from the subject on a consent form to document consent for all of the **recruiting and screening procedures**?

X **No** → If no, describe the information you will provide during the consent process and for which procedures.

When potential subjects contact a member of the research team about enrollment, the subject will be informed that the screening procedure is voluntary, may discontinue participation at any time, and may ask questions to the member of the research team.

☐ **Yes** → If yes, upload the consent form to the **Consent Forms and Recruitment Materials** page of ***Zipline***.

5 PROCEDURES

5.1 Study procedures. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), drug dosing information (if any), use of records, time required, and setting/location. If it is available and you think it would be helpful to the IRB: Upload a study flow sheet or table to the **Supporting Documents** SmartForm in ***Zipline***.

For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB ***POLICY: Risks of Harm from Standard Care*** *and the draft guidance from the federal Office of Human Research Protections,* ***"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";*** *October 20, 2014.*

This experimental study will occur at the University of Washington Roosevelt building. Subjects will be asked to come in for one period of 60 to 90 minutes and will select from a variety of time slots that will be provided. Upon arrival subjects will give informed consent and receive information about the procedures from a member of the research team. Subjects will fill out a knowledge and demographic survey. Subjects will then select between different size N95 masks and don, or put on, their mask. All subjects will complete their pre-intervention fit test, administered by a member of the research team following the OSHA fit testing procedures. The codes and standards for proper respirator use and fit testing in the workplace can be found in WAC 296-842-150 or 29 CFR 1910.134. Subjects will be randomized into one of the four intervention arms, control or one of three educational interventions (video, factsheet, manufacturer's instructions). Subjects will receive their intervention, or communication medium, that is designed to provide them information on how to use an N95 mask. If they are in the control group, subjects will be allotted a break of the same duration it takes to receive the intervention. Subjects will be given the option to choose a different size N95 mask if desired. Subjects will re-don an N95 mask. After receiving the intervention or not, subjects will complete another fit test, administered by a member of the research team. The fit factors resulting from the fit test will be recorded on a data sheet by a member of the research team. Members of the research team may take photos of participants, who consent to doing so, while wearing the mask and during fit testing procedures. After their post-intervention fit test, a member of the research term will measure the dimensions of their face, including length and width. After completing the study procedures, subjects will complete an exit survey.

5.2 Recordings. Does your research involve creating audio or video recordings?

- [X] **No** → If no, go to question **5.3.**
- [ ] **Yes** → If yes, describe what you will record (if not already described in 5.1) and answer question **a**.

a. Before recording, will you obtain the consent of subjects and any other individuals who may be recorded?

- [ ] **No** → If no, email hsdinfo@uw.edu before submitting your application in Zipline. In your email, include a brief description of your research and a note that you intend to record individuals without their consent.
- [ ] **Yes**

5.3 MRI scans. Will any subjects have a Magnetic Resonance Imaging (MRI) scan as part of the study procedures?

This means scans that are performed solely for research purposes or clinical scans that are modified for research purposes (for example, using a gadolinium-based contrast agent when it is not required for clinical reasons).

- [X] **No** → If no, go to question **5.4**.
- [ ] **Yes** → If yes, answer questions **a** through **c**.

a. Describe the MRI scan(s). Specifically:

- What is the purpose of the scan(s)? *Examples: obtain research data; safety assessment associated with a research procedure.*
- Which subjects will receive a MRI scan?
- Describe the minimum and maximum number of scans per subject, and over what time period the scans will occur. *For example: all subjects will undergo two MRI scans, six months apart.*

b. Use of gadolinium. Will any of the MRI scans involve the use of a gadolinium-based contrast agent (GBCA?)

- [ ] **No**
- [ ] **Yes** → If yes, which agents will be used? *Check all that apply.*

	Brand Name	Generic Name	Chemical Structure
[ ]	Dotarem	Gadoterate meglumine	Macrocylic
[ ]	Eovist / Primovist	Gadoxetate disodium	Linear
[ ]	Gadavist	Gadobutro	Macrocyclic
[ ]	Magnevist	Gadpentetate dimeglumine	Linear
[ ]	MultiHance	Gadobenate dimeglumine	Linear
[ ]	Omniscan	Gadodiamide	Linear
[ ]	OptiMARK	Gadoversetamide	Linear
[ ]	ProHance	Gadoteridol	Macrocyclic
[ ]	Other, provide name:		

1.) The FDA has concluded that gadolinium is retained in the body and brain for a significantly longer time than previously recognized, especially for linear GBCAs. The health-related risks of this longer retention are not yet clearly established. However, the UW IRB expects researchers to provide a compelling justification for using a linear GBCA instead of a macrocyclic GBCA, to manage the risks associated with GBCAs.

Describe why it is important to use a GBCA with your MRI scan(s). Describe the dose you will use and (if it is more than the standard clinical dose recommended by the manufacturer) why it is necessary to use a higher dose. If you plan to use a linear GBCA, explain why you cannot use a macrocyclic GBCA.

2.) Information for subjects. Confirm by checking this box that you will either provide subjects with the FDA-approved Patient Medication Guide for this GBCA you are using or that the same information will be inserted into the consent form.

☐ **Confirmed**

c. MRI facility. At which facility(ies) will the MRI scans occur? Check all that apply.

☐ UWMC Radiology/Imaging Services (the UWMC clinical facility)
☐ DISC Diagnostic Imaging Sciences Center (UWMC research facility)
☐ BMIC Biomolecular Imaging Center (South Lake Union research facility)
☐ Harborview Radiology/Imaging Services (the Harborview clinical facility)
☐ SCCA Imaging Services
☐ Northwest Diagnostic Imaging
☐ Other: identify in the text box below:

Personnel. For MRI scans that will be conducted at the DISC or BMIC research facilities: The role, qualifications, and training of individuals who will operate the scanner, administer the GBCA (if applicable), and/or insert and remove the IV catheter should be listed on the Study Team addendum.

5.4 Data variables. Describe the specific data you will obtain (including a description of the most sensitive items). If you would prefer, you may upload a list of the data variables to the **Supporting Documents** SmartForm instead of describing the variables below.

-Fit Factor: a quantitative estimate of the fit of a particular respirator, typically estimates the ratio of the concentration of a substance in ambient air to its concentration inside the respirator
-Demographic Data & baseline knowledge data: sex, age, education attainment, occupational information, ethnicity and race, smoking history, prior respirator use, baseline knowledge data of N95 masks
-Face and Head data: length and width of subject's face presence of head coverings, facial hair, scars on face. We anticipate this being the most sensitive item, but there is no protected health information.
- Exit-Survey Data: post-training knowledge, general N95 mask usage and fit, training, and experience with the research activities

5.5 Data sources. For all types of data that you will access or collect for this research: Identify whether you are obtaining the data from the subjects (or subjects' specimens) or whether you are obtaining the data from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

All the data we will access or collect for this research will be obtained from the subjects.

5.6 Identifiability of data and specimens. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and to assist you in identifying relevant compliance requirements. Review the following definitions before answering the questions:

Access *means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".*
Identifiable *means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.*
Direct identifiers *are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of your data that is (when taken together) identifiable.*
Indirect identifiers *are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.*
Key *refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.*
Obtain *means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from* ***accessing****, which means to view or perceive data.*

a. Will you or any members of your team have <u>access</u> to any direct or indirect identifiers?

[X] **Yes** → If yes, describe which identifiers and for which data/specimens.

The name of the subject recorded on the consent form, and a unique subject identification code attached to any other data derived.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

- [ ] There will be no identifiers.
- [ ] Identifiers or the key have been (or will have been) destroyed before you have access.
- [ ] You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

  You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.
- [ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

b. Will you <u>obtain</u> any direct or indirect identifiers?

☒ **Yes** → If yes, describe which identifiers and for which data/specimens.

The name of the subject will be recorded on the consent form, and a unique subject identification code will be created for each participant and attached to data derived from the study.

☐ **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

☐ There will be no identifiers.

☐ Identifiers or the key have been (or will have been) destroyed before you have access.

☐ You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

c. If you obtain any identifiers, indicate how the identifiers will be stored (and for which data). NOTE: Do not describe your data security plan here – we will ask for that information in section 9.6.

☐ You will store the identifiers with the data. Describe the data to which this applies:

☐ You will store identifiers and study data separately but you will maintain a link between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

☒ You will store identifiers separately from the study data, with no link between the identifiers and the study data. Describe the data to which this applies:

The consent form with the subject's name and study data with the unique identification code will be kept separately. There will be no link between the subject's name and the unique identification code.

d. Research collaboration. Will individuals who provide you with coded information or specimens for your research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

N/A

5.7 Protected Health Information (PHI). Will you access, obtain, use, or disclose a participant's identifiable PHI for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually-identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral. ***If you will use UW Medical Records, you must answer yes to this question.***

X	**No**	→ If no, skip the rest of this question; go to question **5.8**
	Yes	→ If yes, answer all of the questions below.

a. Describe the PHI you will access or obtain, and the reason for obtaining it. *Be specific.*

b. Is any of the PHI located in Washington State?

☐ **No**
☐ **Yes**

c. Describe how you will access or obtain the PHI. *Be specific. For example, you might: directly view records; search through your department's clinical database; submit a request to Leaf.*

d. For which PHI will you obtain HIPAA authorization from the subjects by having them sign a HIPAA Authorization form, before obtaining and using the PHI?

Confirm by checking the box that you will use the UW Medicine HIPAA Authorization form maintained on the HSD website if you will access, obtain, use, or disclose UW Medicine PHI.

☐ **Confirmed**

e. For which PHI will you NOT obtain HIPAA authorization from the subjects?

Provide the following assurances by checking the boxes.

☐ You will access, obtain and/or use only the minimum necessary amount of PHI to accomplish the purposes described in this application.

☐ The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

☐ You will fulfill the HIPAA "accounting for disclosures" requirement. See UW Medicine Compliance Policy #104. THIS IS ONLY FOR UW RECORDS.

☐ There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.8 Genomic data sharing. Will you obtain or generate genomic data (as defined at http://osp.od.nih.gov/scientific-sharing/genomic-data-sharing-faqs/)?

X	**No**
	Yes → If yes, answer the question below.

a. Do you plan to send genomic data from this research to a national database (for example, NIH's dbGaP database)?

	No
	Yes → If yes, complete the ***ZIPLINE* SUPPLEMENT Genomic Data Sharing** and upload it to the **Supporting Documents** SmartForm of ***Zipline***.

5.9 Whole genome sequencing. For research involving biospecimens: Will the research include whole genome sequencing?

Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

X	**No**
	Yes

5.10 Possible secondary use or sharing of information, specimens, or subject contact information. Are you likely to use the information, specimens, or subject contact information you obtain or collect for any of the following:

- Future research not described in this application (in other words, secondary research)
- Submission to a repository, registry, or database managed by you, colleagues, or others for research purposes
- Sharing with others for their own research

You are strongly encouraged to consider the broadest possible future plans you might have, and whether you will obtain consent now from the subjects for future sharing or research uses (which you may or may not be able to describe at this time). Answer **YES** even if you will only share information without identifiers. Answer **NO** if you are unlikely to do any sharing, or if your only sharing will be through the NIH Genomic Data Sharing described in question 5.8.

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include (for example): informal arrangements to share your banked data/specimens with other investigators; establishing a repository from which you formally share with others through written agreements; or sending your data/specimens to a third party repository/archive/entity such as the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

X	**No**

☐ **Ye s** → If yes, answer all of the questions below.

a. Describe <u>what you will store for future use,</u> including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

b. Describe <u>what will be shared with other researchers or with a repository/database/registry</u>, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

c. Who will oversee and/or manage the sharing?

d. Describe <u>the possible future uses</u>, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.

e. <u>Consent</u>. Will you obtain consent now from subjects for the secondary use, banking and/or future sharing?

☐ **No**

☐ **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in your answers to the consent questions in Section 8.

f. <u>Withdrawal</u>. Will subjects be able to withdraw their data/specimens from secondary use, banking or sharing?

☐ **No**

☐ **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

g. <u>Agreements for sharing or release</u>. Confirm by checking the box that you will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement between you and the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data). Do not attach your template agreement forms; the IRB neither reviews nor approves them

☐ **Confirmed**

5.11 Communication with subjects during the study. Describe the types of communication (if any) you will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

Enrolled subjects will be communicated through email or phone to set up a time for the experiment, reminders about experiment, questions participants have prior to and after the experiment, and general information about the experiment.

5.12 Future contact with subjects. Do you plan to retain any contact information you obtain for your subjects so that they can be contacted in the future?

X	**No**
	Yes

→ If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to your team; if not, describe who else could be provided with the contact information. Describe your criteria for approving requests for the information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

5.13 Alternatives to participation. Are there any alternative procedures or treatments <u>that might be advantageous</u> to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

X	**No**
	Yes

→ If yes, describe the alternatives.

5.14 Upload to the Supporting Documents SmartForm of ***Zipline*** all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points you will use to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records, or video recordings.

- ***Examples****: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE:*** *Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics you will cover and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded****: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*

- ***For data that will be gathered in an evolving way**: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to your research, provide a description of the process by which you will establish the data collection/questions as you interact with subjects, how you will document your data collection/questions, the topics you plan to address, the most sensitive type of information you will plan to gather, and the limitations (if any) on topics you will raise or pursue.*

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process you will use for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which you are seeking general approval. (See the **NOTE** bullet point in the instructions above.)

(1) Demographic Data Form and Baseline Knowledge Survey: Subjects will out a form to collect general demographic data, including sex, age, education attainment, occupational information, ethnicity and race, smoking history, and prior respirator use. Subjects will also denote the presence of head coverings, facial hair, scars on face, or other physical features on head that may impact the fit of a respirator; we expect these to be the most personal and sensitive questions. The survey will ask you about baseline knowledge related to N95 masks. Participants will not be required to answer any questions they do not want to. A member of the research team will be there to provide assistance if needed.

(2) Exit-Survey: Subjects will complete an electronic survey after completely study procedures. The scope of the topics in the survey include general N95 mask usage and fit, training, and experience with the research activities. The questions will be designed to ascertain the subject's attitude, knowledge, and beliefs about N95 masks and usage; and include if these changed after the training received during study procedures. The most personal and sensitive questions will include questions about their experience of wearing the mask during study procedures.

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does your research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State.
- The generic age of consent may be different in other states, and in other countries.

[X] **No** → If no, go to Section 8.

☐ Yes → If yes, provide the age range of the minor subjects for this study and the legal age for consent in your population(s). If there is more than one answer, explain.

☐ **Don't know** → This means is it not possible to know the age of your subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that you obtain from another researcher or from a government agency. Go to Section 8.

6.2 Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

a. Will you obtain parental permission for:

☐ All of your research procedures → Go to question **6.2b.**

☐ None of your research procedures → Use the table below to provide your justification, and skip question 6.2b.

☐ Some of your research procedures → Use the table below to identify the procedures for which you will not obtain written parental permission.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission[2]	Reason why you will not obtain parental permission	Will you inform them about the research?[3] YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*
2. *If you plan to obtain identifiable information or biospecimens without parent permission, any waiver granted by the IRB does not override parents' refusal to provide broad consent (for example, through the Northwest Biotrust).*

3. Will you inform them about the research beforehand even though you are not obtaining active permission?

b. Indicate by checking the appropriate box(es) your plan for obtaining parental permission

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child

☐ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If you checked both boxes, explain:

6.3 Children who are wards. Will any of the children be wards of the State or any other agency, institution, or entity?

☐ **No**

☐ **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). Your answer must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

7 ASSENT OF CHILDREN (MINORS)

Go to Section 8 if your research does not involve children (minors).

7.1 Assent of children (minors). Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may also provide a written assent if they are older. See **WORKSHEET: Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

a. Will you obtain assent for:

☐ All of your research procedures and child groups → Go to question **7.2.**

☐ None of your research procedures and child groups → Use the table below to provide your justification, then skip to question **7.6**

☐ Some of your research procedures and child groups

→ Use the table below to identify the procedures for which you will not obtain assent.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be obtained	Reason why you will not obtain assent

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

7.2 Assent process. Describe how you will obtain assent, for each child group. If your research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how you will ensure that they comprehend the information you provide.

7.3 Dissent or resistance. Describe how you will identify a child's objection or resistance to participation (including non-verbal indications) during the research, and what you will do in response.

7.4 E-consent. Will you use any electronic processes (email, websites, electronic signatures, etc.) to present assent information to subjects/and or to obtain documentation (signatures) of assent? If yes, describe how you will do this.

7.5 Documentation of assent. Which of the following statements describes whether you will obtain documentation of assent?

☐ None of your research procedures and child groups	→ Use the table below to provide your justification, then go to question **7.5.b**
☐ All of your research procedures and child groups	→ Go to question **7.5.a**, do not complete the table
☐ Some of your research procedures and/or child groups	→ Complete the table below and then to go question **7.5.a**

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

a. Describe how you will document assent. If the children are functionally illiterate or are not fluent in English, include a description of what you will do.

b. Upload all assent materials (talking points, videos, forms, etc.) to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

7.6 Children who reach the legal age of consent during participation in longitudinal research.

Children who were enrolled at a young age and continue for many years: It is best practice to re-obtain assent (or to obtain it for the first time, if you did not at the beginning of their participation).
Children who reach the legal age of consent: You must obtain informed consent from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

a. Describe your plans (if any) to re-obtain assent from children.

b. Describe your plans (if any) to obtain consent for children who reach the legal age of consent.

- If you plan to obtain consent, describe what you will do about now-adult subjects whom you are unable to contact.
- If you do not plan to obtain consent or think that you will be unable to do so, explain why.

7.7 Other regulatory requirements. (This is for your information only; no answer or response is required.)
Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act
- COPPA – Children's Online Privacy Protection Act

8 CONSENT OF ADULTS

Review the following definitions before answering the questions in this section.

CONSENT	is the process of informing potential subjects about the research and asking them whether they want to participate. It does not necessarily include the signing of a consent form.
CONSENT DOCUMENTATION	refers to how a subject's decision to participate in the research is documented. This is typically obtained by having the subject sign a consent form.
CONSENT FORM	is a document signed by subjects, by which they agree to participate in the research as described in the consent form and in the consent process.
ELEMENTS OF CONSENT	are specific information that is required to be provided to subjects.
CHARACTERISTICS OF CONSENT	are the qualities of the consent process as a whole. These are: • Consent must be legally effective. • The process minimizes the possibility of coercion or undue influence. • Subjects or their representatives must be given sufficient opportunity to discuss and consider participation. • The information provided must: ○ Begin with presentation of key information (for consent materials over 2,000 words) ○ Be what a reasonable person would want to have ○ Be organized and presented so as to facilitate understanding ○ Be provided in sufficient detail ○ Not ask or appear to ask subjects to waive their rights
PARENTAL PERMISSION	is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements.
SHORT FORM CONSENT	is an alternative way of obtaining written documentation of consent that is most commonly used with individuals who are illiterate or whose language is one for which translated consent forms are not available.
WAIVER OF CONSENT	means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process. **NOTE**: If you plan to obtain identifiable information or identifiable biospecimens without consent, any waiver granted by the IRB does not override a subject's refusal to provide broad consent (for example, the Northwest Biotrust).
WAIVER OF DOCUMENTATION OF CONSENT	means that there is IRB approval for not obtaining written documentation of consent.

8.1 Groups Identify the groups to which your answers in this section apply.

- [X] Adult subjects
- [ ] Parents who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

8.2 The consent process and characteristics. This series of questions is about whether you will obtain consent for all procedures except recruiting and screening and, if yes, how.

The issue of consent for recruiting and screening activities is addressed in question 4.7. You do not need to repeat your answer to question 4.6.

a. Are there any procedures for which you will not obtain consent?

- [X] **No**
- [ ] **Yes** → If yes, use the table below to identify the procedures for which you will not obtain consent. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.

Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO consent process	Reason why you will not obtain consent	Will you provide subjects with info about the research after they finish? YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If your answer is the same for all groups you can collapse your answer across the groups and/or procedures.*

b. Describe the consent process, if you will obtain consent for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

Be sure to include:

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names)*
- *How you will provide sufficient opportunity for the subjects to discuss the study with the research team and consider participation*

Subjects will be given a consent form, by a member of the research team, upon arrival on the day they are to perform the study. The consent form will be completed first, before subjects move on with study procedures. They will be given a paper consent form, which describes the responsibilities of the researchers and participants, to sign. A member of the research team will walk the subject through the consent form in a private room. Subjects will be given the option to discuss the study with a member of the research team and ask questions. Subjects will be provided the opportunity to consider continuing their participation in the study, without pressure from the research team. Study participants will be informed that they can withdrawal from the study at any point. Non-English speaking subjects will be excluded from the study, and thus accommodations for consent for non-English speaking subjects will likely not be needed.

c. Comprehension**.** Describe how you will ensure or test the subjects' understanding of the information during the consent process.

Subjects will be asked to read the consent form, which will contain key information about study participation. A member of the research team will be available during the entirety of the consent process to answer any questions and concerns of the subject. The member of the research team will ask the subject for understanding throughout different times of walking through the consent form together.

d. Influence**.** Does your research involve any subject groups that might find it difficult to say "no" to your research because of the setting or their relationship with you, even if you don't pressure them to participate?

Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research, study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.

X	**No**
	Yes → If yes, describe what you will do, for each of these subject groups, to reduce any effect of the setting or relationship on their decision.

Examples: a study coordinator will obtain consent instead of the subjects' physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.

e. Information provided is tailored to needs of subject population. Describe how you have ascertained that the information you will provide to subjects (via written or oral methods) is what a *reasonable member of the subject population(s)* would want to know. If you have consent materials that contain a key information section, also describe how you have identified that the information presented in that section is that which is *most likely* to assist the selected subject population with making a decision. See **GUIDANCE: Key Information for Consent Materials**.

For example, you may have consulted with publications about research subjects' preferences, disease-focused nonprofit groups, patient interest groups, or other researchers/study staff with experience with the specific population. It may also involve directly consulting selected members of the study population.

To ascertain that the information provided to the subjects, including during the consent process, is what a reasonable member of the subject population would want to know, researchers with experiences with the specific population were included on the study team. These members of the study team were consulted with.

f. Ongoing process. For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) you will give subjects to ask questions or to change their minds about participating.

N/A

8.3 Electronic presentation of consent information. Will any part of the consent-related information be provided electronically for some or all of the subjects?

This refers to the use of electronic systems and processes instead of (or in addition to) a paper consent form. For example, an emailed consent form, a passive or an interactive website, graphics, audio, video podcasts. See GUIDANCE: Electronic Informed Consent for information.

X	**No**	→ If no, skip to question 8.4
	Yes	→ If yes, answer questions **a** through **e**

a. Describe your methodology and the information that will be provided.

All informational materials must be made available to the IRB. Website content should be provided as a Word document. It is considered best practice to give subjects information about multi-page/multi-screen information that will help them assess how long it will take them to complete the process. For example, telling them that it will take about 15 minutes, or that it involves reading six screens or pages.

b. Describe how the information can be navigated (if relevant). *For example, will the subject be able to proceed forward or backward within the system, or to stop and continue at a later time?*

c. In a standard paper-based consent process, the subjects generally have the opportunity to go through the consent form with study staff and/or to ask study staff about any question they may have after reading the consent form. Describe what, if anything, you will do to facilitate the subject's comprehension and opportunity to ask questions when consent information is presented electronically. Include a description of any provisions to help ensure privacy and confidentiality during this process.

Examples: hyperlinks, help text, telephone calls, text messages or other type of electronic messaging, video conference, live chat with remotely located study team members.

d. What will you do if you encounter individuals who wish to participate but who do not have access to the methodology you are using or who do not wish to use it? Are there alternative ways in which they can obtain the information, or will there be some assistance available? If this is a clinical trial, you cannot exclude these individuals from your study unless you have a compelling rationale.

For example, consider individuals who lack familiarity with electronic systems, have poor eyesight or impaired motor skills, or who do not have easy email or internet access.

e. How will you provide additional information, including any significant new findings (such as new risk information) to subjects during the research? If this is not an issue, explain why.

8.4 Written documentation of consent. Which of the statements below describe whether you will obtain documentation of consent? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.7.

Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent

a. Are you obtaining written documentation of consent for:

☐ None of your research procedures	→ Use the table below to provide your justification then go to question **8.5.**
☒ All of your research procedures	→ Do not complete the table; go to question **8.4.b.**
☐ Some of your research procedures	→ Use the table below to identify the procedures for which you will not obtain written documentation of consent from your adult subjects.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will you provide them with a written statement describing the research (optional)? YES	NO
		☐	☐

	☐	☐
	☐	☐
	☐	☐
	☐	☐

Table footnotes

1. *If your answer is the same for all adult groups or all procedures, you can collapse your answer across the groups and/or procedures.*

b. Electronic consent signature. For studies in which documentation of consent will be obtained: will subjects use an electronic method to provide their consent signature?

- *FDA-regulated studies must use a system that complies with the FDA's "Part 11" requirements about electronic systems and records. Note that the UW-IT supported DocuSign e-signature system does not meet this requirement.*
- *Having subjects check a box at the beginning of an emailed or web-based questionnaire is not considered legally effective documentation of consent.*

X **No**

☐ **Yes** → If yes, describe the methodology you will use.

See the GUIDANCE: Electronic Informed Consent for information about options (including the DocuSign system available through UW-IT) and requirements.

b.1 Is this method legally valid in the jurisdiction where the research will occur?

☐ **No**

☐ **Yes** → If yes, what did you use as your source of information about legal validity?

b.2 Will you obtain verification of the subject's identity if the signature is not personally witnessed by a member of the study team? Note that this is required for FDA-regulated studies.

See the GUIDANCE: Electronic Informed Consent for information and examples

☐ **No** → If no, provide your rationale for why this is appropriate. Also, what would be the risks to the actual subject if somebody other than the intended signer provides the consent signature?

☐ **Yes** → If yes, how?

b.3 How will you meet the requirement to provide a copy of the consent information (consent form) to individuals who provide an e-signature?

The copy can be paper or electronic and may be provided on an electronic storage device or via email. If the electronic consent information uses hyperlinks or other websites or podcasts to convey information specifically related to the research, the information in these hyperlinks should be included in the copy provided to the subjects and the website must be maintained for the duration of the entire study.

8.5 Non-English-speaking or -reading adult subjects. Will you enroll adult subjects who do not speak English or who lack fluency or literacy in English?

X **No**

☐ **Yes** → If yes, describe the process you will use to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

a. Interpretation. Describe how you will provide interpretation and when. Also, describe the qualifications of the interpreter(s) – for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

b. Translations. Describe how you will obtain translations of all study materials (not just consent forms) and how you will ensure that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the locale in which they will be used.

8.6 Barriers to written documentation of consent. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

a. Describe your plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form). Skip this question if you are not obtaining written documentation of consent for any part of your research.

Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person before they sign it; excluding individuals who cannot read and understand the consent form.

For the study we are excluding subjects who cannot read and understand English, as well as subjects who have sensory or motor impairments.

8.7 Deception. Will you deliberately withhold information or provide false information to any of the subjects?
Note: "Blinding" subjects to their study group/condition/arm is not considered to be deception, but not telling them ahead of time that they will be subject to an intervention or about the purpose of the procedure(s) is deception.

[X] **No**
[ ] **Yes** → If yes, describe what information and why.
Example: you may wish to deceive subjects about the purpose of the study.

a. Will you inform subjects beforehand that they will be unaware of or misled regarding the nature or purposes of the research? (Note: this is not necessarily required.)
[ ] **No**
[ ] **Yes**

b. Will you debrief the subjects later? (Note: this is not necessarily required.)
[ ] **No**
[ ] **Yes** → If yes, describe how you will debrief the subjects. Upload any debriefing materials, including talking points or a script, to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***.

8.8 Cognitively impaired adults, and other adults unable to consent. Do you plan to include such individuals in your research?

Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.

[X] **No** → If no, go to question **8.9**.
[ ] **Yes** → If yes, answer the following questions.

a. Rationale. Provide your rationale for including this population in your research.

b. Capacity for consent / decision making capacity. Describe the process you will use to determine whether a cognitively impaired individual is capable of consent decision making with respect to your research protocol and setting.

b.1. If you will have repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) you will reassess decision-making capacity and obtain consent during that time.

c. Permission (surrogate consent). If you will include adults who cannot consent for themselves, describe your process for obtaining permission ("surrogate consent") from a legally authorized representative (LAR).

For research conducted in Washington State, see the ***SOP: Legally Authorized Representative*** *to learn which individuals meet the state definition of "legally authorized representative".*

d. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process you will use to obtain and document assent from the subjects.

e. Dissent or resistance. Describe how you will identify the subject's objection or resistance to participation (including non-verbal) during the research, and what you will do in response.

8.9 Consent-related materials. Upload to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent-related materials you will use.

- *Translations must be included. However, you are strongly encouraged to wait to provide them until you know that the IRB will approve the English versions.*
- *Combination forms: It may be appropriate to combine parental permission with consent, if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*

9 PRIVACY AND CONFIDENTIALITY

9.1 Privacy protections. Describe the steps you will take, if any, to address possible privacy concerns of subjects and potential subjects.

Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.
Examples:

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedures (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g. details about sexual behavior) may feel like an invasion of privacy to some individuals.*

We do not anticipate any privacy concerns. However, subjects will be informed that participation in the study is voluntary, and they may discontinue participation at any time. To address possible privacy concerns about email communication, we will inform subjects that confidentiality of email communication cannot be guaranteed and can contact a member of the research team through phone. Fit testing procedures may require a member of the research team to be in close proximity of the subject. Subjects will be informed of this, and if they are uncomfortable, the research team will provide an alternative. We will obtain consent for the use of visual recordings of subject in publications or presentations; photos will not include names or contact information.

9.2 Identification of individuals in publications and presentations. Do you plan to use potentially identifiable information about subjects in publications and presentations, or is it possible that individual identities could be inferred from what you plan to publish or present?

[X] **No**
[ ] **Yes** → If yes, will you obtain subject consent for this use?

[ ] **Yes**
[ ] **No** → If no, describe the steps you will take to protect subjects (or small groups of subjects) from being identifiable.

9.3 State mandatory reporting. Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of your research team likely to learn of any of the above events or circumstances while conducting your research **AND** feel obligated to report it to state authorities?

[X] **No**

☐ Yes → If yes, the UW IRB expects you to inform subjects of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

9.4 **Retention of identifiers and data.** Check the box below to indicate your assurance that you will not destroy any identifiers (or links between identifiers and data/specimens) and data that are part of your research records until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration) for your research. If you think it is important for your specific study to say something about destruction of identifiers (or links to identifiers) in your consent form, state something like "the link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law."

This question can be left blank for conversion applications (existing paper applications that are being "converted" into a Zipline application.)

See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data): ***http://f2.washington.edu/fm/recmgt/gs/research?title=R***

See the "Research Records and Data" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***https://www.uwmedicine.org/recordsmanagementuwm-records-retention-schedule.pdf***

X **Confirm**

9.5 **Certificates of Confidentiality**. Are you planning to obtain a federal Certificate of Confidentiality for your research data? *NOTE: Answer "No" if your study is funded by NIH or the CDC, because all NIH-funded and CDC-funded studies automatically have a Certificate.*

X **No**
☐ **Yes**

9.6 **Data and specimen security protections**. Identify your data classifications and the security protections you will provide, referring to the ***ZIPLINE* GUIDANCE: Data and Security Protections** for the minimum requirements for each data classification level. ***You cannot answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

a. Which level of protections will you apply to your data and specimens? If you will use more than one level, describe which level will apply to which data and which specimens.

The data derived from this study will be Level 1, de-identified and of very low risk of harm if disclosed. We will follow standard University expectations and adopt data security protections described for level 2 data.

b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels. If there are any protections within the level listed in 9.6.a which you will *not* follow, list those here.

Only members of the research team who are directly involved with the study will have access to the data, which will be treated confidentially and kept in locked offices and storage cabinets. The consent form recorded with the name of the subject, will be stored separately from all other data derived from the study.

10 RISK / BENEFIT ASSESSMENT

10.1 Anticipated risks. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how you will manage or reduce the risks. Do not describe data security protections here, these are already described in Question 9.6.

- *Consider possible physical, psychological, social, legal, and economic harms, including possible negative effects on financial standing, employability, insurability, educational advancement or reputation. For example, a breach of confidentiality might have these effects.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data; taking blood samples to monitor something that indicates drug toxicity.*
- *As with all questions on this application, you may refer to uploaded documents.*

The degree of risk contributed to this proposed study is minimal. The N95 masks selected will be NIOSH approved, and we will follow OSHA standards for fit testing. N95 masks are available for purchase by the general public and are voluntarily used frequently. In occupational settings, where employees may experience harmful exposures, N95 masks may be required. For voluntary use in an occupation setting, OSHA does not require medical evaluation, formal training, or fit testing, During the study for each fit test, the subject will only be wearing the mask for a limited amount of time, less than 30 minutes. N95 masks are frequently worn for extended periods of time in an occupational setting. Subjects may experience discomfort when wearing the mask. Those who are not used to wearing masks might find that there is resistance to breathing, especially when performing exercises as part of the fit test. We will insure that any subjects who express discomfort with any aspect of the research protocol may choose to withdrawal from the study. Research study personal will be prepared to recognize and address subject discomfort. If at any time during the study a participant experiences headache, nausea, dizziness, difficulty breathing, or any other medical symptom a member of the research team will take appropriate action.

To prevent biological contamination between subjects, each subject will be provided with their own mask. The fit testing equipment will be cleaned by a member of the research team between each subject.

10.2 Reproductive risks. Are there any risks of the study procedures to men and women (who are subjects, or partner of subjects) related to pregnancy, fertility, lactation or effects on a fetus or neonate?

Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.

X	**No**	→ If no go to question 10.3
	Yes	→ If yes, answer the following questions:

a. Risks. Describe the magnitude, probability, duration and/or reversibility of the risks.

b. Steps to minimize risk. Describe the specific steps you will take to minimize the magnitude, probability, or duration of these risks.

Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.

If you will require the use of contraception: describe the allowable methods and the time period when contraception must be used.

c. Pregnancy. Describe what you will do if a subject (or a subject's partner) becomes pregnant

For example; will you require the subject to immediately notify you, so that you can discontinue or modify the study procedures, discuss the risks, and/or provide referrals or counseling?

10.3 MRI risk management. *Answer this question only if your subjects will receive MRI scans*. A rare but serious adverse reaction called nephrogenic systemic fibrosis (NSF) has been observed in individuals with kidney disease who received gadolinium-based contrast agents (GBCAs) for the scans. Also, a few healthy individuals have a severe allergic reaction to GBCAs.

a. Describe how you will assess the renal function of your subjects prior to MRI scans and how you will use that information to exclude subjects at risk for NSF.

N/A

b. Describe your protocol for handling a sever allergic reaction to the GBCA or any other medical event/memergency during the MRI scan, including who will be responsible for which actions.

N/A

10.4 Unforeseeable risks. Are there any research procedures that may have risks that are currently unforeseeable?

Example: using a drug that hasn't been used before in this subject population.

[X] **No**
[ ] **Yes** → If yes, identify the procedures.

10.5 Subjects who will be under regional or general anesthesiology. Will any research procedures occur while subjects-patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

[X] **No**
[ ] **Yes** → If yes, check all the boxes that apply.

- [ ] Administration of any drug for research purposes
- [ ] Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes

☐ Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes

☐ Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery

☐ Administration of a radio-isotope for research purposes**

☐ Implantation of an experimental device

☐ Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If you checked any of the boxes:
You must provide the name and institutional affiliation of a physician anesthesiologist who is a member of your research team or who will serve as a safety consultant about the interactions between your research procedures and the general or regional anesthesia of the subject-patients. If your procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member, and you must consult with the Vice Chair of Clinical Research in the UW Department of Anesthesiology and Pain Medicine for feasibility, safety and billing.

*** If you checked the box about radio-isotopes: you are responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.*

10.6 Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for your research, or if you have one regardless, upload your DSMP to the **Supporting Documents** SmartForm in ***Zipline***. If it is embedded in another document you are uploading (for example, a Study Protocol) use the text box below to name the document that has the DSMP. Alternatively, you can provide a description of your DSMP in the text box below.

N/A

10.7 Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or you do not know the group to which the participant is assigned: describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

N/A

10.8 Withdrawal of participants. If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

Participants may be withdrawn from the research without their consent if it is found they do not meet the inclusion and exclusion criteria. This will include withdrawal from the entire study and no continued data collection. Participants will be notified that they do not meet the inclusion and exclusion criteria and will be withdrawn by a member of the research team. A member of the research team will provide information about accessing the training materials if they participant still desires.

10.9 Anticipated direct benefits to participants. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.

The anticipated benefits for individual study subjects are learning information on N95 mask use to reduce wildfire smoke exposure.

10.10 Return of individual research results.

In this section you are asked to provide your plans for the return of individual results. An "individual research result" is any information collected, generated or discovered in the course of a research study that is linked to the identity of a research participant. These may be results from screening procedures, results that are actively sought for purposes of the study, results that are discovered unintentionally, or after analysis of the collected data and/or results has been completed.

See the ***GUIDANCE Return of Individual Results*** *for information about results that should and should not be returned, validity of results, the Clinical Laboratory Improvement Amendment (CLIA), consent requirements and communicating results.*

a. Do you anticipate that the research will produce any individual research results that are clinically actionable?

"Clinically actionable" means that there are established therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of the disease/condition, or lead to an improved health outcome.

In general, every effort should be made to offer results that are clinically actionable, valid and pose life-threatening or severe health consequences if not treated or addressed quickly. Other clinically actionable results should be offered if this can be accomplished without compromising the research.

[X] **No**
[ ] **Yes** → If yes, answer the following questions (a.1-a.3).

a.1. Describe the clinically actionable results that are anticipated and explain which results, if any, could be urgent (i.e. because they pose life-threatening or severe health consequences if not treated or addressed quickly).

Examples of urgent results include very high calcium levels, highly elevated liver function test results, positive results for reportable STDs.

a.2. Explain which of these results will be offered to subjects.

a.3. Explain which results will not be offered to subjects and provide the rationale for not offering these results.

Reasons not to offer the results might include:

- *There are serious questions regarding validity or reliability*
- *Returning the results has the potential to cause bias*
- *There are insufficient resources to communicate the results effectively and appropriately*
- *Knowledge of the result could cause psychosocial harm to subjects*

b. Do you plan to offer subjects any results that are not clinically actionable?

Examples: non-actionable genetic results, clinical tests in the normal range, experimental and/or uncertain results.

[X] **No**
[ ] **Yes** → If yes, explain which results will be offered to subjects and provide the rationale for offering these results.

c. Describe the validity and reliability of any results that will be offered to subjects.

The IRB will consider evidence of validity such as studies demonstrating diagnostic, prognostic, or predictive value, use of confirmatory testing, and quality management systems.

N/A

d. Describe the process for communicating results to subjects and facilitating understanding of the results. In the description, include who will approach the participant with regard to the offer of results, who will communicate the result (if different), the circumstances, timing, and communication methods that will be used.

N/A

e. Describe any plans to share results with family members (e.g. in the event a subject becomes incapacitated or deceased).

N/A

f. Check the box to indicate that you have described your plans for return of individual research results in the consent document. If there are no plans to provide results to participants, this should be stated in the consent form.

*See the **GUIDANCE Return of Individual Results** for information about consent requirements.*

[X] **Confirmed**

10.11 Commercial products or patents. Is it possible that a commercial product or patent could result from this study?

[X] **No**
[ ] **Yes** → If yes, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

11 ECONOMIC BURDEN TO PARTICIPANTS

11.1 Financial responsibility for research-related injuries. Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

N/A

11.2 Costs to subjects. Describe any research-related costs for which subjects and/or their health insurance may be responsible (examples might include: CT scan required for research eligibility screening; co-pays; surgical costs when a subject is randomized to a specific procedure; cost of a device; travel and parking expenses that will not be reimbursed).

Travel and parking expenses will not be reimbursed, although parking may be available at the UW Roosevelt building and on near-by residential streets.

11.3 Reimbursement for costs. Describe any costs to subjects that will be reimbursed (such as travel expenses).

N/A

12 RESOURCES

12.1 Faculty Advisor. (For researchers who are students, fellows, or post-docs.) Provide the following information about your faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

Dr. Tania Busch Isaksen, graduate advisor
The advisor will be informed and updated of the progress of the experiment, problems, and changes during regular meetings with the graduate student researcher. The study researcher will follow up by email if needed.

12.2 Study team communication. Describe how you will ensure that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

The graduate student researcher will develop a standard operating procedure with experiment protocols that will be distributed to the study team. Prior to conducting the study, the graduate student researcher will also review procedures and any changes to the study team. The study team will also review respiratory protection standards by the Occupational Safety and Health Administration, including fit testing procedures, prior to assisting with the study. The study team will be informed of the progress of the experiment, problems, and changes at study team meetings.

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

13.1 Other regulatory approvals. Identify any other regulatory approvals that are required for this research, by checking applicable boxes

Do not attach the approvals unless requested by the IRB.

Approval	Research for which this is required
☐ Radiation Safety	Procedures involving the use of radioactive materials or an ionizing radiation producing machine radiation, if they are conducted for research rather than clinical purposes. Approvals need to be attached to the Supporting Documents page in ***Zipline***.
☐ Institutional Biosafety	Procedures involving the transfer/administration of recombinant DNA, DNA/RNA derived from recombinant DNA, or synthetic DNA.
☐ RDRC	Procedures involving a radioactive drug or biological product that is not approved by the FDA for the research purpose and that is being used without an IND, for basic science research (not to determine safety and effectiveness, or for immediate therapeutic or diagnostic purposes).
☐ ESCRO	Procedures involving the use of some types of human embryonic stem cells.

13.2 Approvals and permissions. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

N/A

13.3 Financial Conflict of Interest. Does any member of the team have ownership or other Significant Financial Interest (SFI) with this research as defined by UW policy GIM 10?

X **No**

☐ **Yes** → If yes, has the Office of Research made a determination regarding this SFI as it pertains to your proposed research?

☐ **No** → If no, contact the Office of Research (206.616.0804, research@uw.edu) for guidance on how to obtain the determination

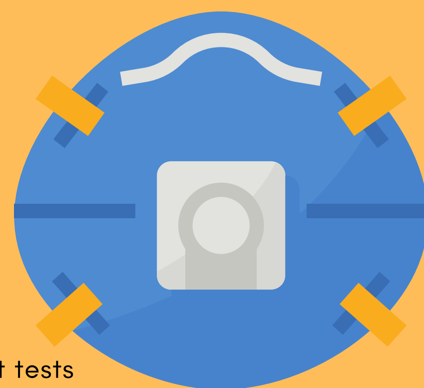
☐ **Yes** → If yes, upload the Conflict Management Plan for every team member who has a FCOI with respect to the research, to the **Supporting Documents** page of ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research and include the FIDS Disclosure ID if available.

Appendix H. Recruitment Materials: Flyer, In Person Script, Facebook Post

RESEARCH STUDY

RECIEVE A $20 AMAZON GIFT CARD

Researchers in the Department of Environmental and Occupational Health Sciences at UW are conducting a research study to better understand the use of N95 dust masks and training materials as a public health intervention to reduce personal exposure to wildfire smoke. **We are seeking UW students, faculty, and staff of all ages and race/ethnicities.**



Participation Includes:

- Study visit of up to 60 minutes
- Wearing an N95 dust mask, completing respiratory fit tests and informational surveys, and having facial measurements taken

You are eligible to participate if the following applies to you:

- UW student, faculty, or staff
- Over the age of 18
- English literate
- No pre-existing respiratory or cardiovascular diseases
- No sensory or motor impairments
- No previous training or fit testing on N95 dust masks
- Willing to refrain from smoking and vaping for 60 minutes prior to and during the study

IF YOU ARE INTERESTED IN PARTICIPATING, PLEASE DO NOT DO ANY BACKGROUND RESEARCH ABOUT N95 MASKS TO PREPARE, FOR THIS MAY IMPACT YOUR ELIGIBILITY.

For more information on this study or to sign up, please contact Kaitlyn Kelly at **CEER@uw.edu** or **206-616-1457**

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206-616-1457

Recruitment Script

"Knowledge transference effect on N95 mask fit, by communication medium"

The following script will be used to guide a member of the research team in describing study participation. The script will be used in Fall of 2019 classes at the University of Washington, where the professor has approved the use of class time to inform students of the study and the steps they will take if they are interested in participating.

"We are part of a research team in the Department of Environmental and Occupational Health Sciences, and we are here to describe to you today a research study that we are conducting and to talk with you about how you can be involved in this study as a participant. Participating in research studies is a voluntary activity, and you are not required to participate in this study. If you sign up for this study, you can change your mind at any time.

Wildfires are becoming an increasingly important issue across the Western United States. Wildfire smoke contains a mixture of air pollutants, which when exposed to can have a variety of respiratory-related health effects. N95 masks, often referred as dust masks, are currently being communicated as an intervention to reduce personal exposure. In this study, we are trying to better understand this public health intervention to inform public use and training materials.

To be eligible for the study, you must be a UW student, faculty, or staff, over the age of 18 and not have any pre-existing respiratory or cardiovascular diseases. If you are interested in participating, we will determine if you meet other eligibility requirements after contact.

Participating in this study involves several procedures that will take up to 60 minutes to complete. You will be asked to wear an N95 mask for up to 30 minutes, which includes completing three respiratory fit tests, and answering surveys. We will also take facial measurements You may feel discomfort while wearing the mask.

If you decide to participate in this study, we will ask you to read through and sign a form before you begin participating in the procedures. The consent form will have all the information I am sharing with you today, as well as information about your rights as a research participant.

We understand that participating in this study will take time and effort. As a thank you, we will offer you a $20 Amazon gift card for participation in research activities. Travel and parking expenses will not be reimbursed, although parking may be available at the UW Roosevelt building and on near-by residential streets.

If you are interested in signing up for this study, you can contact Kaitlyn Kelly at CEER@uw.edu or 206-616-1457. [We will also pass along this contact information to your instructor]. After contact, we will screen you for eligibility and provide additional information about scheduling. We also ask that if you are interested in participating, please do not do any background research about N95 masks to prepare, for this may impact your eligibility.

Thank you for your time. Contact us at CEER@uw.edu or 206-616-1457 with any additional questions.

Facebook Post: (UW student page)

Researchers in the Department of Environmental and Occupational Health Sciences at UW are conducting a research study to better understand the use of N95 dust masks and training materials as a public health intervention to reduce personal exposure to wildfire smoke. We are currently recruiting participants for a study that will take up to 1 hour to complete with a $20 Amazon gift card as thank you. To be eligible you must be a UW student, faculty, or staff, over the age of 18 and not have any pre-existing respiratory or cardiovascular diseases. Additional exclusion criteria will be screened for after initial contact.

You will be asked to wear an N95 mask for up to 30 minutes, which includes completing three respiratory fit tests, and answering surveys. We will also take facial measurements.

For more information and/or to sign up, please contact us at CEER@uw.edu or 206-616-1457. We also ask that if you are interested in participating, please do not do any background research about N95 masks to prepare, for this may impact your eligibility.

Thank you for your consideration!

** Attach Flyer**

Appendix I. Eligibility Screening Questionnaire

Hi [Insert Participant Name],

Thank you for your interest in participating in our research study. Participating in this study involves several procedures that will take up to 60 minutes to complete in a single visit to the UW Roosevelt building. We have open time slots throughout the quarter and on different days and times of the week.

We will be asking you to wear an N95 mask for up to 30 minutes of that time. You may feel discomfort while wearing the mask. To complete study procedures, research study personnel will be in close proximity to your person. You will also be standing for most of the duration of the visit. Inconveniences include the need to come in person for study procedures and the length of the study visit. If you complete the research activities, we will offer you a $20 Amazon gift card as a thank you. Travel and parking expenses will not be reimbursed, although parking may be available at the UW Roosevelt building and on near-by residential streets.

To help us determine your eligibility for our study, we need you to answer a short list of questions. Then, once we know if you are eligible for this study, we will follow up with you to schedule a study visit, provide directions, and more details about study procedures.

Participation in this screening procedure is voluntary, and you may discontinue participation at any time. If you do not feel comfortable answering these questions over email, as the confidentiality of email communication cannot be guaranteed, feel free to call Kaitlyn Kelly at (206)-616-1457.

The questions are as follows:

1. Are you a UW student, faculty, or staff? (Yes/No)
2. What is your year of birth?
3. Are you able to read, speak, write, and understand English? (Yes/No)
4. Are you highly sensitive to natural rubber latex?
5. To the best of your knowledge, do you have any pre-existing respiratory or cardiovascular diseases? (Yes/No)
6. To the best of your knowledge, do you have any motor or sensory impairments that will inhibit putting on a mask or hearing audio cues? (Yes/No)
7. Have you previously received training on how to wear a respirator mask (e.g. N95 masks or dust masks)? (Yes/No)
8. Have you completed an occupational respiratory fit test? (Yes/No)
9. Are you willing to refrain from smoking and vaping for 60 minutes prior to and during the study, a total of up to 2 hours? (Yes/No)
10. Will you need parking to be able to participate? (Yes/No)

We also ask you to not do any background research about N95 masks, for this may impact your eligibility.

If you have any additional questions about this study, you may contact us at any time. If you have questions regarding your rights as a research subject, you can call the University of Washington's Human Subjects Division at 206-543-0098.

Thank you again for your interest. We look forward to your response.

Appendix J. Consent Form

UNIVERSITY OF WASHINGTON
CONSENT FORM

KNOWLEDGE TRANSFERENCE EFFECT ON N95 MASK FIT, BY COMMUNICATION MEDIUM

Principal Investigator: Tania Busch Isaksen, PhD, Department of Environmental & Occupational Health Sciences, Phone: 206-685-4919

Contact Person: Kaitlyn Kelly, MPH candidate, Department of Environmental & Occupational Health Sciences, Email: ceer@uw.edu*, Phone: 206-616-1457.
*Please note we cannot guarantee the confidentiality of communication sent via email.

KEY INFORMATION ABOUT THIS STUDY

Your participation in this research study is completely voluntary. The purpose of this consent form is to give you the information you will need to help you decide whether to participate in the study.

The purpose of this study is to describe the effect educational training materials have on N95 respirator fit worn by individuals not formally trained. The direct potential benefit to you from participating in the study is an increase in knowledge about how to wear an N95 mask to reduce wildfire smoke exposure.

The duration of your participation will be up to 60 minutes. The study procedures include: have facial measurements taken, complete a baseline knowledge survey, conduct three respiratory fit tests, receive a brief training intervention, and complete a post-training knowledge survey and demographic questionnaire.

You may feel discomfort while wearing a mask. If you are not used to wearing masks, you might find that there is resistance to breathing, especially when performing exercises as part of the testing procedures.

RESEARCHER'S STATEMENT

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all of your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

PURPOSE OF THE STUDY

The purpose of this study is to quantify the transference of knowledge from different communication mediums and education methods into N95 respirator mask fit. This study will help us identify the use of N95 respirator masks and their trainings as an effective and appropriate public health intervention to reduce wildfire smoke exposure. The results will be helpful to practice partners and health agencies as they consider recommending N95 masks as an appropriate action to take by the general public to reduce wildfire smoke exposure.

STUDY PROCEDURES

To participate in this study, you must be a student, staff, or faculty member of the University of Washington.

If you choose to participate in this study, we will ask you to participate in research activities for a time period of up to 60 minutes. Subjects will be asked to don, or put on, an N95 mask for this time period and complete three fit tests. Subjects will be asked to complete a questionnaire about baseline knowledge and demographic information and an exit survey to collect information about post-intervention knowledge and mask usage.

Descriptions of research activities for all enrolled subjects:

1. **Measurement of Face:** A member of the research team will measure the dimensions of your face, including length and width. You will only be asked to do this once during the study.

2. **Baseline Knowledge Survey:** You will complete a baseline knowledge survey. The survey will ask you about baseline knowledge related to N95 masks. This baseline knowledge survey will take about 10 minutes to complete. You will not be required to answer any questions you do not want to answer. You will only be asked to complete this questionnaire twice during the study.

3. **Respiratory Fit Test:** After receiving an N95 mask, you will don the mask. A member of the research team will administer a respiratory fit test, following the OSHA fit testing procedures. As part of the fit test you will complete eight exercises for 60 seconds each while wearing the mask. You will be asked to complete three respiratory fit tests during the study.

4. **Education Intervention:** We will provide you with one educational intervention designed to provide information on how to wear an N95 mask. You will be asked to read or watch the material. You will be given as much time needed to ascertain the information. You will only be asked to do this once during the study.

5. **Exit Knowledge Survey & Demographic Questionnaire**: After completing previously described research activities, you will complete an exit knowledge survey. This survey will ask you about general N95 mask knowledge, usage, training, and your experience with research activities. The questionnaire will ask you for demographic data. We will also ask about facial data, including the presence of facial hair, scars, glasses, or head covering. These questionnaires will take no more than 10 minutes to complete. You will not be required to answer any questions you do not want to answer.

RISKS, STRESS, OR DISCOMFORT

You may feel discomfort from having to wear a mask and spending time completing the questionnaires. If you are not used to wearing masks, you might find that there is resistance to breathing, especially when performing exercises as part of the testing procedures. The mask is lightweight and can be removed at any time you feel discomfort.

Research study personnel will be prepared to recognize and assist if you feel discomfort. To complete study procedures, research study personnel will be in close proximity to your person. You will be standing for most of the duration of the visit.

To prevent biological contamination, you will be provided with your own mask. The fit testing equipment will be cleaned by a member of the research team before and after your use.

Video recordings will be taken during your visit for secondary data collection. These videos will be destroyed after the data is aggregated.

Photographs of you may be taken and used in future presentations or publications. You may be asked to give consent to this through a separate personal release form. If you are not comfortable with this, you may opt out, and still participate in the study.

ALTERNATIVES TO TAKING PART IN THIS STUDY

If you choose not to be a part of this study, contact the person listed on the first page of this form to receive the training materials used in the study.

BENEFITS OF THE STUDY

Your participation in this study will help us identify the appropriateness of the use of N95 masks and their trainings as a public health intervention among the general public for reducing wildfire smoke exposure.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support to complete this research from the Pacific Northwest Agricultural Safety and Health Center.

CONFIDENTIALITY OF RESEARCH INFORMATION

Data collected from this study will be anonymous. You will be assigned a unique study ID. Your study ID will not include any information that can identify you. All of the data we collect from you will be coded with your study ID and stored in a secure location or on a password protected computer database. There will be no link between your identifying information (i.e. the name on this consent form) and your study ID (i.e. study data).

The results of this study will be made available to the community after we summarize the data from all subjects. You will not be identified in any of these reports.

USE OF INFORMATION

The results of this study will not be returned to you. The information collected as part of this research will not be used or distributed for future research studies.

OTHER INFORMATION

Your participation in this study is completely voluntary. You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

If it is determined that you do not meet the research criteria during the study, we may withdraw you from the study at any point.

You will not be charged for any study related procedures.

You will receive a $20 gift card as a thank you for participating in this study. You will receive this gift card on the day you come in to participate in the study.

You will not be reimbursed for travel costs, including parking.

If you have any questions about this research study at any time, please contact the person listed on the first page of this form. You ask questions at any time during your participation in the study.

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, have questions, complaints or concerns about this study contact the principal investigator Dr. Tania Busch Isaksen at 206-685-4919.

Printed name of study staff obtaining consent   Signature   Date

<u>SUBJECT'S STATEMENT</u>

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will receive a copy of this consent form.

Printed name of subject   Signature of subject   Date

Copies to: Researcher, Subject

Appendix K. Study Protocols

Study Protocols

Prior to Arrival *(Estimate Time: 15 minutes)*

- All materials are printed & prepared (*see Materials Checklist*)
  - Make sure rainbow passage is in an easily accessible spot next to fit test machine
- Set up interventions
  - Print out interventions
    - Make sure Spanish side is covered on manufacturer's instructions
  - iPad with video intervention
- Prepare masks
  - Probe masks for # of participants that day
  - *consult directions in TSI Portacount*
- Set up camera & video recording
  - Make sure has SD card
  - Take a test video
  - Tripod in the corner of the room with a full view of the participant, without blocking from research member
- Put up x2 signs that say “study in process”
- Set up fit test machine
  - *consult directions in TSI Portacount*
- Do daily check
  - *change to “demo-training mode” >* ***select N95 capability check box (really important) >*** *“load” > “exit” > no hepa filter attached >“start” > wait for directions on screen > then attach hepa filter white tip in clear tube >“start”*
- If not enough ambient particles, set up salt particle generator
  - *consult directions in machine*
- Set up PortaCount where passing is >1
  - Will need to do this every time you turn on because won’t save once you turn off. First Need to add a new respirator
  - *Database > Respirators > New > Enter info “HDX, N95, X, pass value of' “1” > save > exit*
  - Put a sticky note on the screen so they can’t see it
- Set up for fit test
  - *Activities > fit test> add new person “Kelly, Kaitlyn, 1234” > next*> “OSHA 29CFR1910.134 (N95) > more mask size put “REG”, operator put “KK” > next > *will continue when ready with participant*
- Assign subject ID number and prepare forms

Prior to Procedures, after arrival *(Estimate Time: 6 Minutes)*

- Tell them there will be that constant buzzing sound from the machine the entire time
- Confirm Eligibility Status with participant
  - Has anything happened that impacts your eligibility?
  - Have you smoked in the last hour?

    - Have you done any research on N95 masks or seen training materials since hearing about/signing up for this study?
    - Are you highly sensitive to natural rubber latex? If so, they may have an allergic reaction
    - If yes to any of these, they are ineligible to participate. Tell them that they are unfortunately no longer eligible to participate in this study. They still may receive the gift card, jump to "Post-Procedures"
- Have participant sign consent form
    - Walk through key aspects of the consent with them and remind them to ask any questions and can withdraw at any time
        - If they choose to withdraw, they still may receive the gift card, jump to "Post-Procedures"
- Have participant sign photo release
    - Explain that we will be video recording the procedures for secondary analysis, which will be later destroyed
    - Explain that the photo release form is for giving consent for us to take photos to use in presentations/publications
        - Tell them that they are still eligible to participate if they do not want to allow this
- While reviewing consent forms make sure gloves, face tools, surveys, and fit test machine, are ready to go
    - The spreading caliper should be expanded to widest setting
    - Calibrate sliding caliper
    - Put on gloves
    - **Start video recorder, make sure says rec/red, red light is on in front of camera**

Facial Measurements *(Estimate Time:<5 minutes)*

- See *Figures for Facial Measurements* for correct positioning
- If they have glasses, ask them to take off
- When measuring, be cautious, warn them that you will be getting close to their face
- Tell them it might be best to close their eyes
- When measuring width, squeeze in and fasten into place once in correct spot
- Measure the length of the spreading caliper with a tape measure to get width
- Record measurements in mm
        - Add 100 to ruler to convert o mm
- Using the bivariate panel figure, record what size and panel # they are
- Get 2 N95 masks of their size

Fit testing #1 (Pre- Intervention) *(Estimate Time: 12 minutes)*
- Prepare for fit test
    - Attach probed mask to attached to clear tube
    - Check mask size
        - Small = 5463
        - Medium/Large = 5411
    - Fit test > select Kaitlyn Kelly > select "3M N95 8210 [1]" *important to check to make sure it was a passing value of 1" > leave current protocol which should be "OSHA 29CFR1910.134 (N95), more mask size put "REG", operator put "KK"
- Start video recording

- Use the clip on the tube and attach to their collar so the tubes aren't pulling down and affect the fit of the mask (let them do this)
    - Make sure tubes are secure
- Tell the participant to stand on tape, facing camera
- Give them the mask with both straps above the probe
- Make sure you are not standing in front of the camera
- Have them put on the respirator
- <u>Have them wear respirator for 2-3 minutes before starting</u>
    - Use this time to explain fit test procedures
- Tell them the 7 exercises for first time
    - Normal breathing, deep breathing, head side to side, head up and down, talking, grimace, bending, normal breathing
- When they say they are ready then start fit test
    - Do not let them see screen so they don't know their fit factor so there is no bias
    - Remind them not to adjust the respirator during the fit test or anything on their head (take note if they do)
    - Tell them that you will walk them through each exercise, when they hear a beep that will be the first signal that they will begin a new one but to wait for instructions from a research team members
    - Tell them that you will not be talking to them, because then they will want to talk back
    - Tell them to try and not talk to you except if necessary (and during rainbow passage)
    - We know it's weird, but tell them to try not to laugh during the fit test
    - Always keep an eye on them using peripheral
    - Have rainbow passage ready, tell them to read out loud
    - Tell them during movements to take it at a nice even pace
    - During bending down, make sure they touch their toes (or get as close to)
        - Watch tubes during bending
    - After bending down, if they have it wrong the first time, it will hit their eyes and they will want to adjust it so beware
    - Record fit factors on "Data collection sheet"
- Let them doff the mask
- Let them Remove the clip from their collar
- Dispose of mask

Administer Baseline Knowledge Survey *(Estimate Time: <10 minutes)*

- While filling this out, randomize them into an intervention group using randomization list based on measurements
- Prepare intervention

Intervention *(Estimate Time: 5-10 minutes)*

- Tell them they are now going to receive an intervention to learn how to put on the mask, that they can take as much time to read/watch it, and they will be able to use it to put on the mask
    - If they are in the control group, skip to fit test #2, ask them if they would like a break before moving onto the next fit test
- Administer assigned intervention
    - If video, play on I-pad
    - If they have the factsheet intervention, and ask for manufacturer's instructions, give it to them and make a note on the data sheet

- Tell them to tell you when they're ready to don the mask, then move to next steps
- While their looking at their intervention, prepare for next fit test
    - Attach probed mask to attached to clear tube
    - Check mask size
        - Small = 5463
        - Medium/Large = 5411
    - New Fit test > select Kaitlyn Kelly > select "3M N95 8210 [1]" *important to check to make sure it was a passing value of 1" > leave current protocol which should be "OSHA 29CFR1910.134 (N95), more mask size put "REG", operator put "KK"

Fit Test #2 (After intervention) *(Estimate Time: 12 minutes)*

- Confirm that the video is still recording
- Use the clip on the tube and attach to their collar so the tubes aren't pulling down and affect the fit of the mask (let them do this)
    - Make sure tubes are secure
- Tell the participant to stand on tape, facing camera
- Give them the mask with both straps above the probe
- Make sure you are not standing in front of the camera
- Have them put on the respirator
    - Remind them that they may use the intervention to help them put on the mask
    - Make sure they are still facing camera, you may need to hold it out for them
- <u>Have them wear respirator for 2-3 minutes before starting</u>
    - Use this time to explain fit test procedures
- When they say they are ready then start fit test
    - Do not let them see screen so they don't know their fit factor so there is no bias
    - Remind them not to adjust the respirator during the fit test or anything on their head (take note if they do)
    - Tell them that you will walk them through each exercise, when they hear a beep that will be the first signal that they will begin a new one but to wait for instructions from a research team member
    - Tell them that you will not be talking to them, because then they will want to talk back
    - Tell them to try and not talk to you except if necessary (and during rainbow passage)
    - We know it's weird, but tell them to try not to laugh during the fit test
    - Always keep an eye on them using peripheral
    - Have rainbow passage ready, tell them to read out loud
    - Tell them during movements to take it at a nice even pace
    - During bending down, make sure they touch their toes (or get as close to)
        - Watch tubes during bending
    - Record fit factors on "Data collection sheet"
- Let them doff the mask
- Let them Remove the clip from their collar
- Dispose of mask

Fit Test #3 (One Size) 12 min *(Estimate Time: 12 minutes)*

- Get them a one size fits all mask
- Give them short break if they would like one
- Prepare for fit test
    - Attach probed mask to attached to clear tube
    - Check mask size

        - One size = 5460
    - New Fit test > select Kaitlyn Kelly > select “3M N95 8210 [1]” *important to check to make sure it was a passing value of 1” > leave current protocol which should be “OSHA 29CFR1910.134 (N95), more mask size put “REG”, operator put “KK”
- Confirm that the video is still recording
- Use the clip on the tube and attach to their collar so the tubes aren’t pulling down and affect the fit of the mask (let them do this)
    - Make sure tubes are secure
- Tell the participant to stand on tape, facing camera
- Give them the mask with both straps above the probe
- Make sure you are not standing in front of the camera
- Have them put on the respirator
    - Remind them that they may use the intervention to help them put on the mask
- <u>Have them wear respirator for 2-3 minutes before starting</u>
    - Use this time to explain fit test procedures
- When they say they are ready then start fit test
    - Do not let them see screen so they don’t know their fit factor so there is no bias
    - Remind them not to adjust the respirator during the fit test or anything on their head (take note if they do)
    - Tell them that you will walk them through each exercise, when they hear a beep that will be the first signal that they will begin a new one but to wait for instructions from a research team member
    - Tell them that you will not be talking to them, because then they will want to talk back
    - Tell them to try and not talk to you except if necessary (and during rainbow passage)
    - We know it’s weird, but tell them to try not to laugh during the fit test
    - Always keep an eye on them using peripheral
    - Have rainbow passage ready, tell them to read out loud
    - Tell them during movements to take it at a nice even pace
    - During bending down, make sure they touch their toes (or get as close to)
        - Watch tubes during bending
    - Record fit factors on “Data collection sheet”
- Let them doff the mask
- Let them Remove the clip from their collar
- Dispose of mask

Post Survey & Demographic Data Sheet ***(Estimate Time: 5-10 minutes)***

- Administer post-survey
    - If they are in control group, cross out last two questions
- Administer demographic data sheet
- While they are taking the post survey
    - Turn off video camera
    - Get the gift card and payment sheet

Post-Procedures ***(Estimate Time: <5 minutes)***

- Give them gift card
- Have them sign sheet
- Ask if they have any other questions, and tell them they can always contact if any questions come up
- If they were in the control group, offer to give them the interventions to look at

- If they want results of the study, tell them Kaitlyn's thesis will be posted on UW DEOHS's website at the end of the year
- Thank them for their time

After participant leaves and to prepare for the next ***(Estimate Time: 10 minutes)***

- Organize paperwork into their folder
    - Sign consent form
- Sanitize equipment with medical air and alcohol swabs
- Reset for the next participant, go to "prior to arrival"

At End of Day

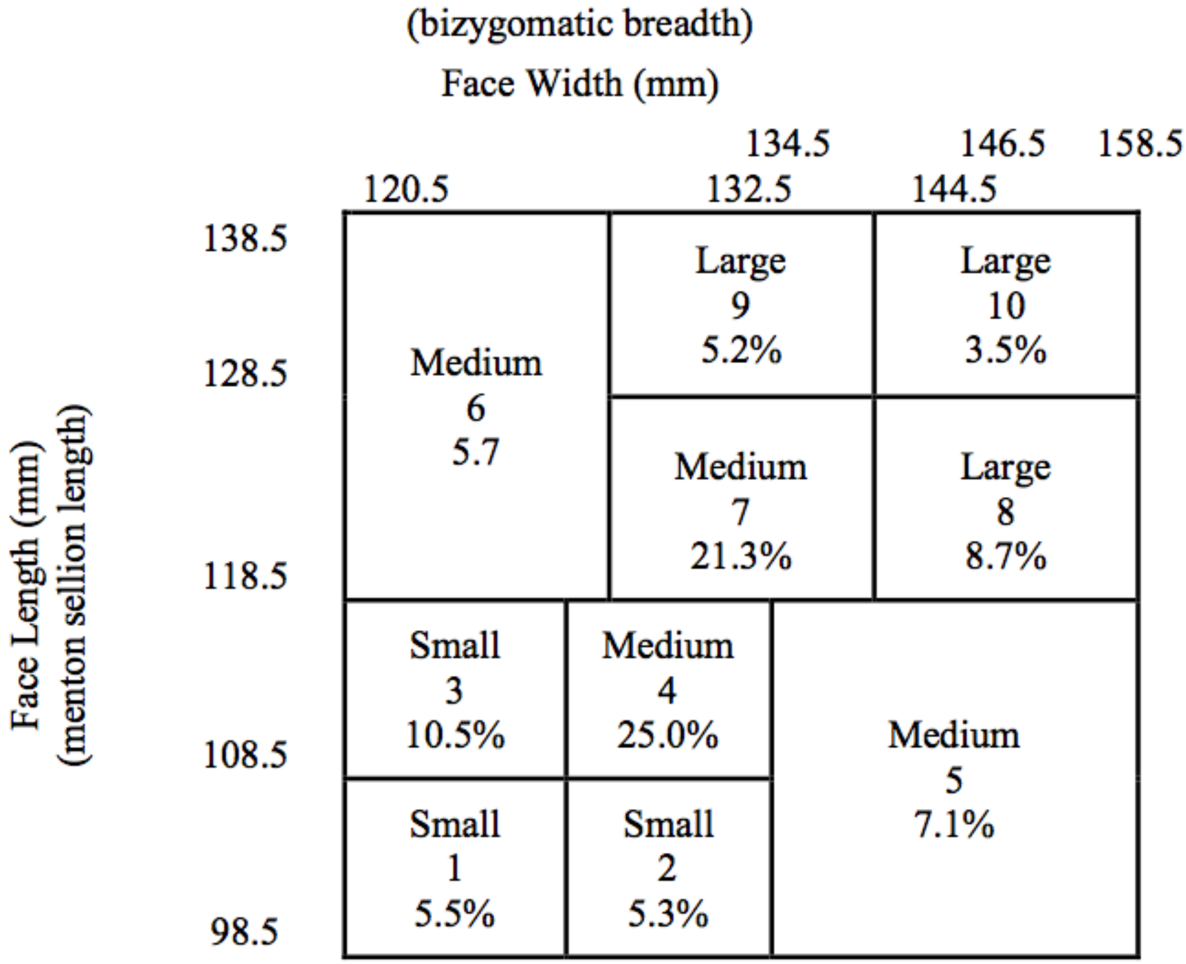
- Pack up fit test machine
- Digitize Data
- Upload video
- Lock data forms & gift cards away
- Email participants thanking them for coming in
- Check camera battery, charge if needed

Appendix L. Participant Randomization List, Small & Medium/Large

Subject ID	Size	Block ID	Block Size	Treatment	Subject ID	Size	Block ID	Block Size	Treatment
S1	Small	S01	4	Fact sheet	ML1	Medium/Large	ML01	4	Manufacturer
S2	Small	S01	4	Manufacturer	ML2	Medium/Large	ML01	4	Fact sheet
S3	Small	S01	4	Control	ML3	Medium/Large	ML01	4	Control
S4	Small	S01	4	Video	ML4	Medium/Large	ML01	4	Video
S5	Small	S02	4	Video	ML5	Medium/Large	ML02	4	Manufacturer
S6	Small	S02	4	Control	ML6	Medium/Large	ML02	4	Fact sheet
S7	Small	S02	4	Manufacturer	ML7	Medium/Large	ML02	4	Video
S8	Small	S02	4	Fact sheet	ML8	Medium/Large	ML02	4	Control
S9	Small	S03	4	Fact sheet	ML9	Medium/Large	ML03	4	Video
S10	Small	S03	4	Video	ML10	Medium/Large	ML03	4	Control
S11	Small	S03	4	Manufacturer	ML11	Medium/Large	ML03	4	Fact sheet
S12	Small	S03	4	Control	ML12	Medium/Large	ML03	4	Manufacturer
S13	Small	S04	4	Manufacturer	ML13	Medium/Large	ML04	4	Manufacturer
S14	Small	S04	4	Video	ML14	Medium/Large	ML04	4	Control
S15	Small	S04	4	Fact sheet	ML15	Medium/Large	ML04	4	Video
S16	Small	S04	4	Control	ML16	Medium/Large	ML04	4	Fact sheet
S17	Small	S05	4	Manufacturer	ML17	Medium/Large	ML05	4	Control
S18	Small	S05	4	Video	ML18	Medium/Large	ML05	4	Video
S19	Small	S05	4	Fact sheet	ML19	Medium/Large	ML05	4	Manufacturer
S20	Small	S05	4	Control	ML20	Medium/Large	ML05	4	Fact sheet
S21	Small	S06	4	Fact sheet	ML21	Medium/Large	ML06	4	Manufacturer
S22	Small	S06	4	Control	ML22	Medium/Large	ML06	4	Video
S23	Small	S06	4	Manufacturer	ML23	Medium/Large	ML06	4	Fact sheet
S24	Small	S06	4	Video	ML24	Medium/Large	ML06	4	Control
S25	Small	S07	4	Manufacturer	ML25	Medium/Large	ML07	4	Manufacturer
S26	Small	S07	4	Video	ML26	Medium/Large	ML07	4	Video
S27	Small	S07	4	Control	ML27	Medium/Large	ML07	4	Control
S28	Small	S07	4	Fact sheet	ML28	Medium/Large	ML07	4	Fact sheet
S29	Small	S08	4	Video	ML29	Medium/Large	ML08	4	Manufacturer
S30	Small	S08	4	Control	ML30	Medium/Large	ML08	4	Video
S31	Small	S08	4	Manufacturer	ML31	Medium/Large	ML08	4	Fact sheet
S32	Small	S08	4	Fact sheet	ML32	Medium/Large	ML08	4	Control
S33	Small	S09	4	Fact sheet	ML33	Medium/Large	ML09	4	Control
S34	Small	S09	4	Video	ML34	Medium/Large	ML09	4	Video
S35	Small	S09	4	Manufacturer	ML35	Medium/Large	ML09	4	Fact sheet
S36	Small	S09	4	Control	ML36	Medium/Large	ML09	4	Manufacturer
S37	Small	S10	4	Fact sheet	ML37	Medium/Large	ML10	4	Manufacturer
S38	Small	S10	4	Manufacturer	ML38	Medium/Large	ML10	4	Video
S39	Small	S10	4	Video	ML39	Medium/Large	ML10	4	Fact sheet
S40	Small	S10	4	Control	ML40	Medium/Large	ML10	4	Control

Appendix M. NIOSH-NPPTL Bivariate Test Panel

Figure 1
NIOSH - NPPTL BIVARIATE TEST PANEL



Zhuang, Z., Bradtmiller, B., & Shaffer, R. E. (2007). New Respirator Fit Test Panels Representing the Current U.S. Civilian Work Force. *Journal of Occupational and Environmental Hygiene*, *4*(9), 647–659. https://doi.org/10.1080/15459620701497538

Appendix N. WA DOH Wildfire Smoke and Face Masks Factsheet

Wildfire Smoke and Face Masks

Washington State Department of Health

Wildfire smoke can irritate your eyes, nose, throat, and lungs. It can make you cough and wheeze, and can make it hard to breathe. If you have a lung disease or heart disease, inhaling wildfire smoke can be especially harmful.

The most effective ways to protect yourself from wildfire smoke are to stay indoors, limit time outdoors and reduce physical activity. People who must be outside in smoky air may benefit from wearing masks called "particulate respirators." Most people will find it difficult to wear the masks correctly. If the mask does not fit properly, it will provide little or no protection. Using respirator masks can make it harder to breathe. Anyone with lung or heart disease should check with their health care provider before using any mask.

Will a face mask protect me from wildfire smoke?

Respirator masks worn correctly may provide some protection by filtering out fine particles in the smoke. Masks do not help with hazardous gases in the smoke.

What face mask should I get?

N95 respirators are the cheapest and most available mask to help protect your lungs from wildfire smoke. They are generally available at hardware stores and pharmacies. Make sure the mask is:

- Certified by the National Institute of Occupational Safety and Health (NIOSH).
- Not a one-strap paper dust mask or surgical mask. It should have two straps that go around your head.
- A size that fits over your nose and under your chin. It should seal tightly to your face. If the mask does not fit properly, it may not provide any protection. Masks with a relief valve will make breathing easier.

How do I use a face mask?

- Place the mask over your nose and under your chin, with one strap placed below the ears and one strap above.
- Adjust the mask so that air cannot get through at the edges. Any leakage around the edges of the mask allows unfiltered air to enter.
- Pinch the metal part of the mask tightly over the top of your nose.
- Follow instructions on the package to check for a tight face seal.
- Masks fit best on clean-shaven skin. Masks do not work for people with beards because they will not seal.
- Masks are not approved for children.
- Throw away your mask when breathing through it gets difficult, if it is damaged, or if the inside gets dirty.
- It is harder to breathe through a mask, so take breaks often if you work outside.
- If you feel dizzy or sick go to a less smoky area, take off your mask, and get medical help if you do not feel better.

N95 masks can help protect your lungs from wildfire smoke. Straps must go above and below the ears.

A one-strap paper mask will not protect your lungs from wildfire smoke.

A surgical mask will not protect your lungs from wildfire smoke.

For More Information:

Washington State Department of Health
doh.wa.gov/smokefromfires

NIOSH
Respirator – Trusted Source Information

DOH 334-353 July 2019
Adapted from
California Department of Public Health

For people with disabilities, this document is available in other formats. To submit a request, please call 1-800-525-0127 (TDD/TTY call 711).

Appendix O. HDX Manufacturer's Instructions

HDX™

LIMITED WARRANTY

IMPORTANT NOTICE TO PURCHASER:

This limited warranty is made in lieu of the warranties of merchantability, fitness for particular purposes and all other warranties, express or implied. There are no other warranties which extend beyond the description on the face herof.

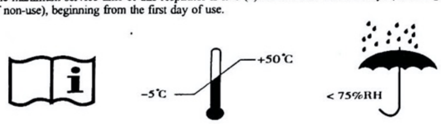
Exclusive Remedies: damages for the breach of this limited warranty are limited to the replacement of the product proved to be defectively manufactured. Except as provided above, Home Depot shall not be liable or responsible for any loss, damage, or liability , direct, indirect, incidental, special or consequential, arising out of sale, use, misuse or the inability to use products by the user.

DO NOT USE: Gases and vapors, including those present in paint spraying operations, oil aerosols,asbestos or sandblasting.

USE FOR: Solids such as those from processing minerals, coal, iron ore, flour and certain other substances.
Liquid or non-oil based particles from sprays that do not also emit oil aerosoles or vapors.

SERVICE TIME LIMITATION

1. Do not use the same respirator for more than 8 hours, continuous or intermittent, in dirty workplaces that could result in high filter loading.
2. Leave contaminated area and remove respirator if breathing becomes difficult or proper fit cannot be obtained or the respirator is damaged, soiled, or distorted. Do not use the same respirator again once removed.
3. The maximum service time of this respirator is five (5) consecutive calendar days (including days of non-use), beginning from the first day of use.



WARNINGS:

1. Wearer must read fitting instructions and use limitations before use.
2. This respirator does not protect against the risk of contracting disease or infection.
3. Individuals highly sensitive to natural rubber latex may have an allergic reaction.
4. Before use, the wearer should be trained in the proper use, including fit testing, in accordance with applicable safety and health standards for the contaminant and exposure level in the work area as per OSHA guideline, 29 CFR 1910.134.
5. If you CANNOT achieve a proper seal, DO NOT enter the contaminated area.

For additional information on this product, please call 1-844-251-0275.

RESPIRATOR FITTING INSTRUCTION:

STEP 1
Hold the respirator in hand with the nosepiece at your fingertips, allowing the headbands to hang freely below your hand.

STEP 2
Press the respirator firmly against your face with the nosepiece on the bridge of your nose.

STEP 3
Stretch and position the top band high on the back of the head. Stretch the bottom band over the head and position below your ears.

STEP 4
Using both hands, mold nosepiece to the shape of your nose.

STEP 5
To test fit: a) Cup both hands over the respirator being careful not to distrub position, and b) inhale vigorously. If air leaks around the edges, reposition the straps or adjust strap tension for better fit.
Please carefully follow these fitting instructions during each use to achieve proper fit.

The Home Depot
2455 Paces Ferry Road
Atlanta, GA 30339.
Tel:770-433-8211

NIOSH

This respirator is approved only in the following configuration:

TC-	Protection[1]	Respirator	Cautions and Limitations[2]
84A-5411	N95	H950	ABCJMNOPS
84A-5460	N95	H950V	ABCJMNOPS
84A-5463	N95	H950S	ABCJMNOPS

1. Protection

N95-Particulate Filter (95% filter efficiency level)effective against particulate aerosols free of oil,time use restrictions may apply

2. Cautions and Limitations

A - Not for use in atmospheres containing less than 19.5% oxygen.
B - Not for use in atmospheres immediately dangerous to life or health.
C - Do not exceed maximum use concentrations established by regulatory standards.
J - Failure to properly use and maintain this product could result in injury or death.
M - All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA and other applicable regulations.
N - Never substitute, modify, add, or omit parts. Use only exect replacement parts in the configuration as specified by the manufacturer.
O - Refer to users instructions, and/or mainterance manuals for information on use and maintenance of these respirators.
P - NIOSH does not evaluate respirators for use as surgical masks.
S - Special or critical User's Instructions and/or specific use limitations apply. Refer to User's Instructions before donning.

S - Special or Critical User's Instructions: The model H950 & H950V & H950S filtering facepiece respirator has been manufactured by Approval Holder Makrite for The Home Depot under TC-84A-5411 & TC-84A-5460 & TC-84A-5463.

Appendix P. Participant Data Collection Sheet

Data Sheet

Facial Measurements

☐ Length: ________ (mm)
☐ Width: ________ (mm)
☐ Panel: ________
☐ Mask Size: _______

Intervention Group

☐ Control ☐ Factsheet ☐ Video ☐ Manufacturer's Instruction

1st Fit Test Fit Factors *(with sized mask)*

☐ Normal Breathing: ________ ☐ Deep Breathing: ________ ☐ Head side-to-side: ________

☐ Head up-and-down: ________ ☐ Talking out loud: ________

☐ Bending: ________ ☐ Normal Breathing: ________

☐ Overall Fit Factor: _________

→ Did they pass (>100)? ☐ Yes ☐ No

☐ Check if adjusted respirator during the test

Notes:

2nd Fit Test Fit Factors *(with sized mask)*

☐ Normal Breathing: ________ ☐ Deep Breathing: ________ ☐ Head side-to-side: ________

☐ Head up-and-down: ________ ☐ Talking out loud: ________

☐ Bending: ________ ☐ Normal Breathing: ________

☐ Overall Fit Factor: _________

→ Did they pass (>100)? ☐ Yes ☐ No

☐ Check if adjusted respirator during the test

Notes:

3rd Fit Test Fit Factors *(with one size fits all mask)*

☐ Normal Breathing: ________ ☐ Deep Breathing: ________ ☐ Head side-to-side: ________

☐ Head up-and-down: ________ ☐ Talking out loud: ________

☐ Bending: ________ ☐ Normal Breathing: ________

☐ Overall Fit Factor: _________

→ Did they pass (>100)? ☐ Yes ☐ No

Notes:

Other Notes

☐For those who had the factsheet,

→ Did they ask for the manufacturer's instructions to conduct a seal check? ☐ Yes ☐ No

Notes:

Appendix Q. Pre-Intervention KAP Participant Survey

Subject ID:__________________ Tech Initials:______________ Date:_____________

Please rank how much you agree with the following statements. Choose 1 if you **strongly disagree**, 2 if you **disagree**, 3 if you have **no opinion**, 4 if you **agree**, and 5 if you **strongly agree**. Choose 6 if **you do not know.**

		Strongly Disagree……..neutral………..Strongly Agree					**Do not Know**
1.	I know how to properly wear an N95 respirator	**1**	**2**	**3**	**4**	**5**	**6**
2.	I think N95 respirators are easy to use	**1**	**2**	**3**	**4**	**5**	**6**
3.	I know how to recognize medical symptoms that may limit or prevent the effective use of an N95 respirator	**1**	**2**	**3**	**4**	**5**	**6**
4.	N95 respirators are approved for the general public to use during a wildfire smoke event	**1**	**2**	**3**	**4**	**5**	**6**
5.	N95 respirators do not work effectively on people with beards	**1**	**2**	**3**	**4**	**5**	**6**
6.	N95 respirators are approved for children to use	**1**	**2**	**3**	**4**	**5**	**6**
7.	N95 respirators should be certified by the National Institute of Occupational Safety and Health	**1**	**2**	**3**	**4**	**5**	**6**
8.	An appropriately sized N95 respirator will fit over your nose and under your chin	**1**	**2**	**3**	**4**	**5**	**6**
9.	An N95 respirator with a broken or missing elastic strap is ok to use	**1**	**2**	**3**	**4**	**5**	**6**
10.	Molding the nosepiece to your face shape on an N95 respirator can prevent air leakage	**1**	**2**	**3**	**4**	**5**	**6**
11.	It is important to perform a check for a tight seal after adjusting an N95 respirator on your face	**1**	**2**	**3**	**4**	**5**	**6**
12.	If an N95 respirator does not properly fit, it may not provide effective protection	**1**	**2**	**3**	**4**	**5**	**6**

Subject ID:__________________ Tech Initials:______________ Date:_____________

		Strongly Disagree……..neutral………..Agree Strongly					Do not Know
13.	N95 respirators filter out fine particles in smoke	**1**	**2**	**3**	**4**	**5**	**6**
14.	N95 respirators filter out hazardous gas	**1**	**2**	**3**	**4**	**5**	**6**
15.	I know how to properly maintain and store an N95 respirator	**1**	**2**	**3**	**4**	**5**	**6**
16.	I should dispose of an N95 respirator when breathing through it becomes increasingly difficult	**1**	**2**	**3**	**4**	**5**	**6**
17.	I think N95 respirators are a convenient way to reduce personal exposure to wildfire smoke	**1**	**2**	**3**	**4**	**5**	**6**
18.	I think N95 respirators are comfortable enough to wear to reduce personal exposure to wildfire smoke	**1**	**2**	**3**	**4**	**5**	**6**
19.	I would wear an N95 respirator during a wildfire smoke event when the air quality is poor	**1**	**2**	**3**	**4**	**5**	**6**
20.	I think that N95 respirators are an effective way to reduce personal exposure to wildfire smoke	**1**	**2**	**3**	**4**	**5**	**6**
21.	I would wear an N95 respirator before taking other actions to reduce personal exposure to wildfire smoke	**1**	**2**	**3**	**4**	**5**	**6**

Appendix R. Post-Intervention KAP Participant Survey

Subject ID:_________________ Tech Initials:_____________ Date:____________

Please rank how much you agree with the following statements. Choose 1 if you **strongly disagree**, 2 if you **disagree**, 3 if you have **no opinion**, 4 if you **agree**, and 5 if you **strongly agree**. Choose 6 if **you do not know.**

		Strongly Disagree……..neutral………..Strongly Agree					**Do not Know**
1.	I know how to properly wear an N95 respirator	**1**	**2**	**3**	**4**	**5**	**6**
2.	I think N95 respirators are easy to use	**1**	**2**	**3**	**4**	**5**	**6**
3.	I know how to recognize medical symptoms that may limit or prevent the effective use of an N95 respirator	**1**	**2**	**3**	**4**	**5**	**6**
4.	N95 respirators are approved for the general public to use during a wildfire smoke event	**1**	**2**	**3**	**4**	**5**	**6**
5.	N95 respirators do not work effectively on people with beards	**1**	**2**	**3**	**4**	**5**	**6**
6.	N95 respirators are approved for children to use	**1**	**2**	**3**	**4**	**5**	**6**
7.	N95 respirators should be certified by the National Institute of Occupational Safety and Health	**1**	**2**	**3**	**4**	**5**	**6**
8.	An appropriately sized N95 respirator will fit over your nose and under your chin	**1**	**2**	**3**	**4**	**5**	**6**
9.	An N95 respirator with a broken or missing elastic strap is ok to use	**1**	**2**	**3**	**4**	**5**	**6**
10.	Molding the nosepiece to your face shape on an N95 respirator can prevent air leakage	**1**	**2**	**3**	**4**	**5**	**6**
11.	It is important to perform a check for a tight seal after adjusting an N95 respirator on your face	**1**	**2**	**3**	**4**	**5**	**6**
12.	If an N95 respirator does not properly fit, it may not provide effective protection	**1**	**2**	**3**	**4**	**5**	**6**

Subject ID:__________________ Tech Initials:______________ Date:_____________

		Strongly Disagree……..neutral………..Strongly Agree					**Do not Know**
K13.	N95 respirators filter out fine particles in smoke	**1**	**2**	**3**	**4**	**5**	**6**
K14.	N95 respirators filter out hazardous gas	**1**	**2**	**3**	**4**	**5**	**6**
K15.	I know how to properly maintain and store an N95 respirator	**1**	**2**	**3**	**4**	**5**	**6**
K16.	I should dispose of an N95 respirator when breathing through it becomes increasingly difficult	**1**	**2**	**3**	**4**	**5**	**6**
A17.	I think N95 respirators are a <u>convenient</u> way to reduce personal exposure to wildfire smoke	**1**	**2**	**3**	**4**	**5**	**6**
A18.	I think N95 respirators are comfortable enough to wear to reduce personal exposure to wildfire smoke	**1**	**2**	**3**	**4**	**5**	**6**
P19.	I would wear an N95 respirator during a wildfire smoke event when the air quality is poor	**1**	**2**	**3**	**4**	**5**	**6**
A20.	I think that N95 respirators are an <u>effective</u> way to reduce personal exposure to wildfire smoke	**1**	**2**	**3**	**4**	**5**	**6**
P21.	I would wear an N95 respirator before taking other actions to reduce personal exposure to wildfire smoke	**1**	**2**	**3**	**4**	**5**	**6**
P22.	The training I received today improved my knowledge about the use of an N95 respirator to reduce personal exposure to wildfire smoke	**1**	**2**	**3**	**4**	**5**	**6**
P23.	The training I received today improved my ability to properly wear an N95 respirator	**1**	**2**	**3**	**4**	**5**	**6**

Appendix S. Participant Demographic Information Questionnaire

Demographic Information

Year of Birth

___ ___ ___ ___

Sex

☐ Male ☐ Female ☐ Other ☐ Prefer not to answer

Ethnicity

☐ Hispanic or Latino ☐ Not Hispanic or Latino

Race

☐ Asian ☐ American Indian/Alaska Native ☐ Native Hawaiian/Pacific Islander

☐ White ☐ Black or African American ☐ Other: _______________

Education

☐ High school or less ☐ Some College/technical training ☐ College Graduate

UW Status

☐ Student ☐ Faculty ☐ Staff

Have you ever used an N95 mask or another half-mask respirator before today?

☐ Yes ☐ No

→ If yes, how often do you use one? ☐ Occasional (< 5 times a year) ☐ Often (> 5 times a year)

Have you smoked or vaped today?

☐ Yes ☐ No

→ If yes, approximately how long ago? ________

Do you have or **currently** wearing any of the following?

☐ Facial Hair ☐ Facial Scar ☐ Glasses

☐ Religious Head Covering ☐ Other Facial Feature: _______________

Appendix T. R-Code

Randomization List

```
install.packages("blockrand")
library(blockrand)
set.seed(1234)
small <- blockrand(n=40,
                   num.levels = 4,
                   levels = c('Video','Manufacturer','Fact sheet','Control'),
                   block.prefix='S',stratum='Small',block.sizes = 1)
large <- blockrand(n=40,
                   num.levels = 4,
                   levels = c('Video','Manufacturer','Fact sheet','Control'),
                   block.prefix='L',stratum='Medium/Large', block.sizes = 1)
my.study <- rbind(small,large)
my.study
```

Descriptive Analysis of Participant Demographics & Characteristics (Table 3 &4)

```
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data")
DataAll <- read.csv("Participant Data All .csv")
DataControl <- read.csv("Participant Data Control.csv")
DataFactsheet <- read.csv("Participant Data Factsheet.csv")
DataVideo <- read.csv("Participant Data Video.csv")
DataManufactuer <- read.csv("Participant Data Manufactuer.csv")
library(knitr)
opts_chunk$set(results = 'asis',
        comment = NA,
        prompt = FALSE,
        cache = FALSE)
library(summarytools)
st_options(plain.ascii = FALSE,
        style = "rmarkdown",
        footnote = NA,
        subtitle.emphasis = FALSE)
st_css()
view(dfSummary(DataAll, style = 'grid', graph.magnif = 0.75, tmp.img.dir = "/tmp"))
view(dfSummary(DataControl, style = 'grid', graph.magnif = 0.75, tmp.img.dir = "/tmp"))
view(dfSummary(DataFactsheet, style = 'grid', graph.magnif = 0.75, tmp.img.dir = "/tmp"))
view(dfSummary(DataVideo, style = 'grid', graph.magnif = 0.75, tmp.img.dir = "/tmp"))
view(dfSummary(DataManufactuer, style = 'grid', graph.magnif = 0.75, tmp.img.dir = "/tmp"))
```

Box Plot Figures (Figure 2)

```
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data/Box Plot")
library(ggplot2)
```

```
BPDataControl <- read.csv("BPDataControl.csv")
BPDataFactsheet <- read.csv("BPDataFactsheet.csv")
BPDataManufacturer <- read.csv("BPDataManufactuer.csv")
BPDataVideo <- read.csv("BoxPlotDataVideo.csv")

### Control Box Plot ###
BPControl <-ggplot(BPDataControl, aes(x=Test, y=FitFactor))+
  geom_boxplot(fill="#336699", alpha=0.2) +
  geom_jitter(color="black", size=0.4, alpha=0.9)+
  xlab("Test") + ylab("Fit Factor") + ggtitle("Control") +  scale_y_continuous(limits =c(0,90),
breaks=c(20,40,60,80)) + theme(plot.title = element_text(hjust = 0.5))
BPControl
BPControlhoz <-BPControl + coord_flip()
BPControlhoz

### Factsheet Box Plot ###
BPFactsheet <-ggplot(BPDataFactsheet, aes(x=Test, y=FitFactor))+
  geom_boxplot(fill="#336699", alpha=0.2) +
  geom_jitter(color="black", size=0.4, alpha=0.9)+
  xlab("Test") + ylab("Fit Factor") + ggtitle("Fact Sheet")+ scale_y_continuous(limits =c(0,90),
breaks=c(20,40,60,80))+ theme(plot.title = element_text(hjust = 0.5))
BPFactsheet
BPFactsheethoz <-BPFactsheet + coord_flip()
BPFactsheethoz

### Manufactuer Box Plot ###
BPManufacturer <-ggplot(BPDataManufacturer, aes(x=Test, y=FitFactor))+
  geom_boxplot(fill="#336699", alpha=0.2) +
  geom_jitter(color="black", size=0.4, alpha=0.9)+
  xlab("Test") + ylab("Fit Factor")+ ggtitle("Manufacturer")+ scale_y_continuous(limits
=c(0,90), breaks=c(20,40,60,80))+ theme(plot.title = element_text(hjust = 0.5))
BPManufacturer
BPManufactuerhoz <-BPManufacturer + coord_flip()
BPManufactuerhoz

### Video Box Plot ###
BPVideo <-ggplot(BPDataVideo, aes(x=Test, y=FitFactor))+
  geom_boxplot(fill="#336699", alpha=0.2) +
  geom_jitter(color="black", size=0.4, alpha=0.9)+
  xlab("Test") + ylab("Fit Factor")+ ggtitle("Video")+ scale_y_continuous(limits =c(0,90),
breaks=c(20,40,60,80))+ theme(plot.title = element_text(hjust = 0.5))
BPVideo
BPVideohoz <-BPVideo + coord_flip()
BPVideohoz

###Combine Box Plots###
library(ggpubr)
BPallplots<-ggarrange(BPControlhoz, BPFactsheethoz, BPManufactuerhoz, BPVideohoz,
```

```
                    common.legend=TRUE, legend="bottom", nrow=2, ncol=2)
BPallplots
annotate_figure(
  BPallplots,
  top=text_grob("Fit Factors", color="black", face="bold", size=12))
```

Change in Fit Factor Analysis (Table 5)

```
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data")
DataAll <- read.csv("Participant Data All .csv")
DataControl <- read.csv("Participant Data Control.csv")
DataFactsheet <- read.csv("Participant Data Factsheet.csv")
DataVideo <- read.csv("Participant Data Video.csv")
DataManufactuer <- read.csv("Participant Data Manufactuer.csv")
library(ggplot)

###Model 1, training vs no training in proper size ###
ypost_model <- lm(FitTest2_Factor_Overall ~ Intervention  + FitTest1_Factor_Overall, data =
DataAll)
summary(ypost_model)
confint(ypost_model)

###Model 2, traing in one size vs. no training in proper size ###
ypost_model2 <- lm(FitTest3_Factor_Overall ~ Intervention  + FitTest1_Factor_Overall, data =
DataAll)
summary(ypost_model2)
confint(ypost_model2)

###Model 3, training in one size vs. training in proper size ###
ypost_model3 <- lm(FitTest3_Factor_Overall ~ Intervention  + FitTest2_Factor_Overall, data =
DataAll)
summary(ypost_model3)
confint(ypost_model3)
```

Line Graph Figures (Figure 3 & 4)

```
####Pre/Post Line Graph### Control
Pre.Post.LG.Control <- ggplot(DataControl) +
  geom_segment(aes(x = 1, xend = 2, y = FitTest1_Factor_Overall, yend =
FitTest2_Factor_Overall)) + theme_bw() + scale_x_discrete(breaks = c("1", "2"), labels =
c("Pre", "Post"), limits = c(1, 2)) +
  labs(y = "Fit Factor") + labs(x = "") + ggtitle("Control") + theme(plot.title = element_text(hjust
= 0.5)) + scale_y_continuous(limits =c(0,90), breaks=c(20,40,60,80))+ theme(plot.title =
element_text(hjust = 0.5))
Pre.Post.LG.Control

####Pre/Post Line Graph### Video
Pre.Post.LG.Video <- ggplot(DataVideo) +
```

```
  geom_segment(aes(x = 1, xend = 2, y = FitTest1_Factor_Overall, yend =
FitTest2_Factor_Overall)) + theme_bw() + scale_x_discrete(breaks = c("1", "2"), labels =
c("Pre", "Post"), limits = c(1, 2)) +
  labs(y = "Fit Factor") + labs(x = "") + ggtitle("Video") + theme(plot.title = element_text(hjust =
0.5)) + scale_y_continuous(limits =c(0,90), breaks=c(20,40,60,80))+ theme(plot.title =
element_text(hjust = 0.5))
Pre.Post.LG.Video

####Pre/Post Line Graph### Manufactuer
Pre.Post.LG.Manufactuer <- ggplot(DataManufactuer) +
  geom_segment(aes(x = 1, xend = 2, y = FitTest1_Factor_Overall, yend =
FitTest2_Factor_Overall)) + theme_bw() + scale_x_discrete(breaks = c("1", "2"), labels =
c("Pre", "Post"), limits = c(1, 2)) +
  labs(y = "Fit Factor") + labs(x = "")  + ggtitle("Manufacturer") + theme(plot.title =
element_text(hjust = 0.5)) + scale_y_continuous(limits =c(0,90), breaks=c(20,40,60,80))+
theme(plot.title = element_text(hjust = 0.5))
Pre.Post.LG.Manufactuer

####Pre/Post Line Graph### Factsheet
Pre.Post.LG.Factsheet <- ggplot(DataFactsheet) +
  geom_segment(aes(x = 1, xend = 2, y = FitTest1_Factor_Overall, yend =
FitTest2_Factor_Overall)) + theme_bw() + scale_x_discrete(breaks = c("1", "2"), labels =
c("Pre", "Post"), limits = c(1, 2)) +
  labs(y = "Fit Factor") + labs(x = "")  + ggtitle("Factsheet") + theme(plot.title =
element_text(hjust = 0.5))+ scale_y_continuous(limits =c(0,90), breaks=c(20,40,60,80))+
theme(plot.title = element_text(hjust = 0.5))
Pre.Post.LG.Factsheet

####Pre/One Size Line Graph### Control
Pre.One.LG.Control <- ggplot(DataControl) +
  geom_segment(aes(x = 1, xend = 2, y = FitTest1_Factor_Overall, yend =
FitTest3_Factor_Overall)) + theme_bw() + scale_x_discrete(breaks = c("1", "2"), labels =
c("Pre", "One Size"), limits = c(1, 2)) +
  labs(y = "Fit Factor") + labs(x = "")  + ggtitle("Control") + theme(plot.title = element_text(hjust
= 0.5))+ scale_y_continuous(limits =c(0,90), breaks=c(20,40,60,80))+ theme(plot.title =
element_text(hjust = 0.5))
 Pre.One.LG.Control

####Pre/One Size Line Graph### Video
Pre.One.LG.Video <- ggplot(DataVideo) +
  geom_segment(aes(x = 1, xend = 2, y = FitTest1_Factor_Overall, yend =
FitTest3_Factor_Overall)) + theme_bw() + scale_x_discrete(breaks = c("1", "2"), labels =
c("Pre", "One Size"), limits = c(1, 2)) +
  labs(y = "Fit Factor") + labs(x = "")  + ggtitle("Video") + theme(plot.title = element_text(hjust
= 0.5))+ scale_y_continuous(limits =c(0,90), breaks=c(20,40,60,80))+ theme(plot.title =
element_text(hjust = 0.5))
Pre.One.LG.Video
```

```
####Pre/One Size Line Graph### Manufactuer
Pre.One.LG.Manufactuer <- ggplot(DataManufactuer) +
  geom_segment(aes(x = 1, xend = 2, y = FitTest1_Factor_Overall, yend =
FitTest3_Factor_Overall)) + theme_bw() + scale_x_discrete(breaks = c("1", "2"), labels =
c("Pre", "One Size"), limits = c(1, 2)) +
  labs(y = "Fit Factor") + labs(x = "")  + ggtitle("Manufactruer") + theme(plot.title =
element_text(hjust = 0.5))+ scale_y_continuous(limits =c(0,90), breaks=c(20,40,60,80))+
theme(plot.title = element_text(hjust = 0.5))
Pre.One.LG.Manufactuer

####Pre/One Size Line Graph### Factsheet
Pre.One.LG.Factsheet <- ggplot(DataFactsheet) +
  geom_segment(aes(x = 1, xend = 2, y = FitTest1_Factor_Overall, yend =
FitTest3_Factor_Overall)) + theme_bw() + scale_x_discrete(breaks = c("1", "2"), labels =
c("Pre", "One Size"), limits = c(1, 2)) +
  labs(y = "Fit Factor") + labs(x = "")  + ggtitle("Factsheet") + theme(plot.title =
element_text(hjust = 0.5))+ scale_y_continuous(limits =c(0,90), breaks=c(20,40,60,80))+
theme(plot.title = element_text(hjust = 0.5))
Pre.One.LG.Factsheet

####Post/One Size Line Graph### Control
Post.One.LG.Control <- ggplot(DataControl) +
  geom_segment(aes(x = 1, xend = 2, y = FitTest2_Factor_Overall, yend =
FitTest3_Factor_Overall)) + theme_bw() +  scale_x_discrete(breaks = c("1", "2"), labels =
c("Post", "One Size"), limits = c(1, 2)) +
  labs(y = "Fit Factor") + labs(x = "")  + ggtitle("Control") + theme(plot.title = element_text(hjust
= 0.5))+ scale_y_continuous(limits =c(0,90), breaks=c(20,40,60,80))+ theme(plot.title =
element_text(hjust = 0.5))
Post.One.LG.Control

####Post/One Size Line Graph### Video
Post.One.LG.Video <- ggplot(DataVideo) +
  geom_segment(aes(x = 1, xend = 2, y = FitTest2_Factor_Overall, yend =
FitTest3_Factor_Overall)) + theme_bw() + scale_x_discrete(breaks = c("1", "2"), labels =
c("Post", "One Size"), limits = c(1, 2)) + labs(y = "Fit Factor") + labs(x = "")  + ggtitle("Video")
+ theme(plot.title = element_text(hjust = 0.5))+ scale_y_continuous(limits =c(0,90),
breaks=c(20,40,60,80))+ theme(plot.title = element_text(hjust = 0.5))
Post.One.LG.Video

####Post/One Size Line Graph### Manufactuer
Post.One.LG.Manufactuer <- ggplot(DataManufactuer) +
  geom_segment(aes(x = 1, xend = 2, y = FitTest2_Factor_Overall, yend =
FitTest3_Factor_Overall)) +  theme_bw() + scale_x_discrete (breaks = c("1", "2"), labels =
c("Post", "One Size"), limits = c(1, 2)) +
 labs(y = "Fit Factor") + labs(x = "")  + ggtitle("Manufacturer") + theme(plot.title =
element_text(hjust = 0.5))+ scale_y_continuous(limits =c(0,90), breaks=c(20,40,60,80))+
theme(plot.title = element_text(hjust = 0.5))
Post.One.LG.Manufactuer
```

```
####Post/One Size Line Graph### Factsheet
Post.One.LG.Factsheet <- ggplot(DataFactsheet) +
  geom_segment(aes(x = 1, xend = 2, y = FitTest2_Factor_Overall, yend =
FitTest3_Factor_Overall)) + theme_bw() + scale_x_discrete( breaks = c("1", "2"), labels =
c("Post", "One Size"), limits = c(1, 2)) +
  labs(y = "Fit Factor") + labs(x = "") + ggtitle("Factsheet") + theme(plot.title =
element_text(hjust = 0.5))+ scale_y_continuous(limits =c(0,90), breaks=c(20,40,60,80))+
theme(plot.title = element_text(hjust = 0.5))
Post.One.LG.Factsheet

####Combine Pre/Post Line Graph ##
library(ggpubr)
Pre.Post.LG.All<-ggarrange(Pre.Post.LG.Control,Pre.Post.LG.Factsheet,
Pre.Post.LG.Manufactuer, Pre.Post.LG.Video,
                    common.legend=TRUE, legend="bottom", nrow=2, ncol=2)
Pre.Post.LG.All
annotate_figure(Pre.Post.LG.All,
  top=text_grob("Pre/Post", color="black", face="bold", size=12)) + ggtitle("Pre/Post Line
Graph")

####Combine Pre/One Size Line Graph ##
Pre.One.LG.All<-ggarrange(Pre.One.LG.Control, Pre.One.LG.Video, Pre.One.LG.Manufactuer,
Pre.One.LG.Factsheet,
                    common.legend=TRUE, legend="bottom", nrow=2, ncol=2)
Pre.One.LG.All
annotate_figure(Pre.One.LG.All,
  top=text_grob("Pre/One", color="black", face="bold", size=12)) + ggtitle("Pre/One Size Line
Graph")

####Combine Post/One Size Line Graph ##

Post.One.LG.All<-ggarrange(Post.One.LG.Control, Post.One.LG.Factsheet,
Post.One.LG.Manufactuer, Post.One.LG.Video,
                    common.legend=TRUE, legend="bottom", nrow=2, ncol=2)
Post.One.LG.All
annotate_figure(Post.One.LG.All,
  top=text_grob("Post/One", color="black", face="bold", size=12)) + ggtitle("Post/One Size
Line  Graph")
```

<u>Change in the Proportion Achieving Fit Factor Thresholds Analysis (Table 6)</u>

```
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data")
Data2Facthsheet <- read.csv("Participant Data Factsheet.Control.csv")
Data2Manufactuer <- read.csv("Participant Data Manufactuer.Control.csv")
Data2Video <- read.csv("Participant Data Video.Control.csv")

## Create indicator for treatment ##
```

```
Data2Facthsheet$treatment <- as.factor(ifelse(Data2Facthsheet$Intervention == "Control", 0, 1))
Data2Manufactuer$treatment <- as.factor(ifelse(Data2Manufactuer$Intervention == "Control",
0, 1)
Data2Video$treatment <- as.factor(ifelse(Data2Video$Intervention == "Control", 0, 1))

###Model 1 Fit Factor > 2 Factsheet####
Data2Facthsheet$ypre2F <- ifelse(Data2Facthsheet$FitTest1_Factor_Overall >= 2, 1, 0)
Data2Facthsheet$ypost2F <- ifelse(Data2Facthsheet$FitTest2_Factor_Overall >= 2, 1, 0)
ypost_cutoff2F_model <- lm(ypost2F ~ treatment + ypre2F, data = Data2Facthsheet)
summary(ypost_cutoff2F_model)
confint(ypost_cutoff2F_model)

###Model 1 Fit Factor > 5 Factsheet####
Data2Facthsheet$ypre5F <- ifelse(Data2Facthsheet$FitTest1_Factor_Overall >= 5, 1, 0)
Data2Facthsheet$ypost5F <- ifelse(Data2Facthsheet$FitTest2_Factor_Overall >= 5, 1, 0)
ypost_cutoff5F_model <- lm(ypost5F ~ treatment + ypre5F, data = Data2Facthsheet)
summary(ypost_cutoff5F_model)
confint(ypost_cutoff5F_model)

###Model 1 Fit Factor > 10 Factsheet####
Data2Facthsheet$ypre10F <- ifelse(Data2Facthsheet$FitTest1_Factor_Overall >= 10, 1, 0)
Data2Facthsheet$ypost10F <- ifelse(Data2Facthsheet$FitTest2_Factor_Overall >= 10, 1, 0)
ypost_cutoff10F_model <- lm(ypost10F ~ treatment + ypre10F, data = Data2Facthsheet)
summary(ypost_cutoff10F_model)
confint(ypost_cutoff10F_model)

###Model 1Fit Factor > 50 Factsheet####
Data2Facthsheet$ypre50F <- ifelse(Data2Facthsheet$FitTest1_Factor_Overall >= 50, 1, 0)
Data2Facthsheet$ypost50F <- ifelse(Data2Facthsheet$FitTest2_Factor_Overall >= 50, 1, 0)
ypost_cutoff50F_model <- lm(ypost50F ~ treatment + ypre50F, data = Data2Facthsheet)
summary(ypost_cutoff50F_model)
confint(ypost_cutoff50F_model)

###Model 2 Fit Factor > 2 Factsheet####
Data2Facthsheet$ypre2.2F <- ifelse(Data2Facthsheet$FitTest1_Factor_Overall >= 2, 1, 0)
Data2Facthsheet$ypost2.2F <- ifelse(Data2Facthsheet$FitTest3_Factor_Overall >= 2, 1, 0)
ypost_cutoff2.2F_model <- lm(ypost2.2F ~ treatment + ypre2.2F, data = Data2Facthsheet)
summary(ypost_cutoff2.2F_model)
confint(ypost_cutoff2.2F_model)

###Model 2 Fit Factor > 5 Factsheet####
Data2Facthsheet$ypre2.5F <- ifelse(Data2Facthsheet$FitTest1_Factor_Overall >= 5, 1, 0)
Data2Facthsheet$ypost2.5F <- ifelse(Data2Facthsheet$FitTest3_Factor_Overall >= 5, 1, 0)
ypost_cutoff2.5F_model <- lm(ypost2.5F ~ treatment + ypre2.5F, data = Data2Facthsheet)
summary(ypost_cutoff2.5F_model)
confint(ypost_cutoff2.5F_model)

###Model 2 Fit Factor > 10 Factsheet####
```

```
Data2Facthsheet$ypre2.10F <- ifelse(Data2Facthsheet$FitTest1_Factor_Overall >= 10, 1, 0)
Data2Facthsheet$ypost2.10F <- ifelse(Data2Facthsheet$FitTest3_Factor_Overall >= 10, 1, 0)
ypost_cutoff2.10F_model <- lm(ypost2.10F ~ treatment + ypre2.10F, data = Data2Facthsheet)
summary(ypost_cutoff2.10F_model)
confint(ypost_cutoff2.10F_model)

###Model 2 Fit Factor > 50 Factsheet####
Data2Facthsheet$ypre2.50F <- ifelse(Data2Facthsheet$FitTest1_Factor_Overall >= 50, 1, 0)
Data2Facthsheet$ypost2.50F <- ifelse(Data2Facthsheet$FitTest3_Factor_Overall >= 50, 1, 0)
ypost_cutoff2.50F_model <- lm(ypost2.50F ~ treatment + ypre2.50F, data = Data2Facthsheet)
summary(ypost_cutoff2.50F_model)
confint(ypost_cutoff2.50F_model)

###Model 3 Fit Factor > 2 Factsheet####
Data2Facthsheet$ypre3.2F <- ifelse(Data2Facthsheet$FitTest2_Factor_Overall >= 2, 1, 0)
Data2Facthsheet$ypost3.2F <- ifelse(Data2Facthsheet$FitTest3_Factor_Overall >= 2, 1, 0)
ypost_cutoff3.2F_model <- lm(ypost3.2F ~ treatment + ypre3.2F, data = Data2Facthsheet)
summary(ypost_cutoff3.2F_model)
confint(ypost_cutoff3.2F_model)

###Model 3 Fit Factor > 5 Factsheet####
Data2Facthsheet$ypre3.5F <- ifelse(Data2Facthsheet$FitTest2_Factor_Overall >= 5, 1, 0)
Data2Facthsheet$ypost3.5F <- ifelse(Data2Facthsheet$FitTest3_Factor_Overall >= 5, 1, 0)
ypost_cutoff3.5F_model <- lm(ypost3.5F ~ treatment + ypre3.5F, data = Data2Facthsheet)
summary(ypost_cutoff3.5F_model)
confint(ypost_cutoff3.5F_model)

###Model 3 Fit Factor > 10 Factsheet####
Data2Facthsheet$ypre3.10F <- ifelse(Data2Facthsheet$FitTest2_Factor_Overall >= 10, 1, 0)
Data2Facthsheet$ypost3.10F <- ifelse(Data2Facthsheet$FitTest3_Factor_Overall >= 10, 1, 0)
ypost_cutoff3.10F_model <- lm(ypost3.10F ~ treatment + ypre3.10F, data = Data2Facthsheet)
summary(ypost_cutoff3.10F_model)
confint(ypost_cutoff3.10F_model)

###Model 3 Fit Factor > 50 Factsheet####
Data2Facthsheet$ypre3.50F <- ifelse(Data2Facthsheet$FitTest2_Factor_Overall >= 50, 1, 0)
Data2Facthsheet$ypost3.50F <- ifelse(Data2Facthsheet$FitTest3_Factor_Overall >= 50, 1, 0)
ypost_cutoff3.50F_model <- lm(ypost3.50F ~ treatment + ypre3.50F, data = Data2Facthsheet)
summary(ypost_cutoff3.50F_model)
confint(ypost_cutoff3.50F_model)

###Model 1 Fit Factor > 2 Manufactuer####
Data2Manufactuer$ypre2M <- ifelse(Data2Manufactuer$FitTest1_Factor_Overall >= 2, 1, 0)
Data2Manufactuer$ypost2M <- ifelse(Data2Manufactuer$FitTest2_Factor_Overall >= 2, 1, 0)
ypost_cutoff2M_model <- lm(ypost2M ~ treatment + ypre2M, data = Data2Manufactuer)
summary(ypost_cutoff2M_model)
confint(ypost_cutoff2M_model)
```

```
###Model 1 Fit Factor > 5 Manufactuer####
Data2Manufactuer$ypre5M <- ifelse(Data2Manufactuer$FitTest1_Factor_Overall >= 5, 1, 0)
Data2Manufactuer$ypost5M <- ifelse(Data2Manufactuer$FitTest2_Factor_Overall >= 5, 1, 0)
ypost_cutoff5M_model <- lm(ypost5M ~ treatment + ypre5M, data = Data2Manufactuer)
summary(ypost_cutoff5M_model)
confint(ypost_cutoff5M_model)

###Model 1 Fit Factor > 10 Manufactuer####
Data2Manufactuer$ypre10M <- ifelse(Data2Manufactuer$FitTest1_Factor_Overall >= 10, 1, 0)
Data2Manufactuer$ypost10M <- ifelse(Data2Manufactuer$FitTest2_Factor_Overall >= 10, 1, 0)
ypost_cutoff10M_model <- lm(ypost10M ~ treatment + ypre10M, data = Data2Manufactuer)
summary(ypost_cutoff10M_model)
confint(ypost_cutoff10M_model)

###Model 1Fit Factor > 50 Manufactuer####
Data2Manufactuer$ypre50M <- ifelse(Data2Manufactuer$FitTest1_Factor_Overall >= 50, 1, 0)
Data2Manufactuer$ypost50M <- ifelse(Data2Manufactuer$FitTest2_Factor_Overall >= 50, 1, 0)
ypost_cutoff50M_model <- lm(ypost50M ~ treatment + ypre50M, data = Data2Manufactuer)
summary(ypost_cutoff50M_model)
confint(ypost_cutoff50M_model)

###Model 2 Fit Factor > 2 Manufactuer####
Data2Manufactuer$ypre2.2M <- ifelse(Data2Manufactuer$FitTest1_Factor_Overall >= 2, 1, 0)
Data2Manufactuer$ypost2.2M <- ifelse(Data2Manufactuer$FitTest3_Factor_Overall >= 2, 1, 0)
ypost_cutoff2.2M_model <- lm(ypost2.2M ~ treatment + ypre2.2M, data = Data2Manufactuer)
summary(ypost_cutoff2.2M_model)
confint(ypost_cutoff2.2M_model)

###Model 2 Fit Factor > 5 Manufactuer####
Data2Manufactuer$ypre2.5M <- ifelse(Data2Manufactuer$FitTest1_Factor_Overall >= 5, 1, 0)
Data2Manufactuer$ypost2.5M <- ifelse(Data2Manufactuer$FitTest3_Factor_Overall >= 5, 1, 0)
ypost_cutoff2.5M_model <- lm(ypost2.5M ~ treatment + ypre2.5M, data = Data2Manufactuer)
summary(ypost_cutoff2.5M_model)
confint(ypost_cutoff2.5M_model)

###Model 2 Fit Factor > 10 Manufactuer####
Data2Manufactuer$ypre2.10M <- ifelse(Data2Manufactuer$FitTest1_Factor_Overall >= 10, 1,
0)
Data2Manufactuer$ypost2.10M <- ifelse(Data2Manufactuer$FitTest3_Factor_Overall >= 10, 1,
0)
ypost_cutoff2.10M_model <- lm(ypost2.10M ~ treatment + ypre2.10M, data =
Data2Manufactuer)
summary(ypost_cutoff2.10M_model)
confint(ypost_cutoff2.10M_model)

###Model 2 Fit Factor > 50 Manufactuer####
Data2Manufactuer$ypre2.50M <- ifelse(Data2Manufactuer$FitTest1_Factor_Overall >= 50, 1,
0)
```

```
Data2Manufactuer$ypost2.50M <- ifelse(Data2Manufactuer$FitTest3_Factor_Overall >= 50, 1,
0)
ypost_cutoff2.50M_model <- lm(ypost2.50M ~ treatment + ypre2.50M, data =
Data2Manufactuer)
summary(ypost_cutoff2.50M_model)
confint(ypost_cutoff2.50M_model)

###Model 3 Fit Factor > 2 Manufactuer####
Data2Manufactuer$ypre3.2M <- ifelse(Data2Manufactuer$FitTest2_Factor_Overall >= 2, 1, 0)
Data2Manufactuer$ypost3.2M <- ifelse(Data2Manufactuer$FitTest3_Factor_Overall >= 2, 1, 0)
ypost_cutoff3.2M_model <- lm(ypost3.2M ~ treatment + ypre3.2M, data = Data2Manufactuer)
summary(ypost_cutoff3.2M_model)
confint(ypost_cutoff3.2M_model)

###Model 3 Fit Factor > 5 Manufactuer####
Data2Manufactuer$ypre3.5M <- ifelse(Data2Manufactuer$FitTest2_Factor_Overall >= 5, 1, 0)
Data2Manufactuer$ypost3.5M <- ifelse(Data2Manufactuer$FitTest3_Factor_Overall >= 5, 1, 0)
ypost_cutoff3.5M_model <- lm(ypost3.5M ~ treatment + ypre3.5M, data = Data2Manufactuer)
summary(ypost_cutoff3.5M_model)
confint(ypost_cutoff3.5M_model)

###Model 3 Fit Factor > 10 Manufactuer####
Data2Manufactuer$ypre3.10M <- ifelse(Data2Manufactuer$FitTest2_Factor_Overall >= 10, 1,
0)
Data2Manufactuer$ypost3.10M <- ifelse(Data2Manufactuer$FitTest3_Factor_Overall >= 10, 1,
0)
ypost_cutoff3.10M_model <- lm(ypost3.10M ~ treatment + ypre3.10M, data =
Data2Manufactuer)
summary(ypost_cutoff3.10M_model)
confint(ypost_cutoff3.10M_model)

###Model 3 Fit Factor > 50 Manufactuer####
Data2Manufactuer$ypre3.50M <- ifelse(Data2Manufactuer$FitTest2_Factor_Overall >= 50, 1,0)
Data2Manufactuer$ypost3.50M <- ifelse(Data2Manufactuer$FitTest3_Factor_Overall >= 50, 1,
0)
ypost_cutoff3.50M_model <- lm(ypost3.50M ~ treatment + ypre3.50M, data =
Data2Manufactuer)
summary(ypost_cutoff3.50M_model)
confint(ypost_cutoff3.50M_model)

###Model 1 Fit Factor > 2 Video####
Data2Video$ypre2M <- ifelse(Data2Video$FitTest1_Factor_Overall >= 2, 1, 0)
Data2Video$ypost2M <- ifelse(Data2Video$FitTest2_Factor_Overall >= 2, 1, 0)
ypost_cutoff2M_model <- lm(ypost2M ~ treatment + ypre2M, data = Data2Video)
summary(ypost_cutoff2M_model)
confint(ypost_cutoff2M_model)

###Model 1 Fit Factor > 5 Video####
```

```
Data2Video$ypre5M <- ifelse(Data2Video$FitTest1_Factor_Overall >= 5, 1, 0)
Data2Video$ypost5M <- ifelse(Data2Video$FitTest2_Factor_Overall >= 5, 1, 0)
ypost_cutoff5M_model <- lm(ypost5M ~ treatment + ypre5M, data = Data2Video)
summary(ypost_cutoff5M_model)
confint(ypost_cutoff5M_model)

###Model 1 Fit Factor > 10 Video####
Data2Video$ypre10M <- ifelse(Data2Video$FitTest1_Factor_Overall >= 10, 1, 0)
Data2Video$ypost10M <- ifelse(Data2Video$FitTest2_Factor_Overall >= 10, 1, 0)
ypost_cutoff10M_model <- lm(ypost10M ~ treatment + ypre10M, data = Data2Video)
summary(ypost_cutoff10M_model)
confint(ypost_cutoff10M_model)

###Model 2 Fit Factor > 2 Video####
Data2Video$ypre2.2M <- ifelse(Data2Video$FitTest1_Factor_Overall >= 2, 1, 0)
Data2Video$ypost2.2M <- ifelse(Data2Video$FitTest3_Factor_Overall >= 2, 1, 0)
ypost_cutoff2.2M_model <- lm(ypost2.2M ~ treatment + ypre2.2M, data = Data2Video)
summary(ypost_cutoff2.2M_model)
confint(ypost_cutoff2.2M_model)

###Model 2 Fit Factor > 5 Video####
Data2Video$ypre2.5M <- ifelse(Data2Video$FitTest1_Factor_Overall >= 5, 1, 0)
Data2Video$ypost2.5M <- ifelse(Data2Video$FitTest3_Factor_Overall >= 5, 1, 0)
ypost_cutoff2.5M_model <- lm(ypost2.5M ~ treatment + ypre2.5M, data = Data2Video)
summary(ypost_cutoff2.5M_model)
confint(ypost_cutoff2.5M_model)

###Model 2 Fit Factor > 10 Video####
Data2Video$ypre2.10M <- ifelse(Data2Video$FitTest1_Factor_Overall >= 10, 1, 0)
Data2Video$ypost2.10M <- ifelse(Data2Video$FitTest3_Factor_Overall >= 10, 1, 0)
ypost_cutoff2.10M_model <- lm(ypost2.10M ~ treatment + ypre2.10M, data = Data2Video)
summary(ypost_cutoff2.10M_model)
confint(ypost_cutoff2.10M_model)

###Model 3 Fit Factor > 2 Video####
Data2Video$ypre3.2M <- ifelse(Data2Video$FitTest2_Factor_Overall >= 2, 1, 0)
Data2Video$ypost3.2M <- ifelse(Data2Video$FitTest3_Factor_Overall >= 2, 1, 0)
ypost_cutoff3.2M_model <- lm(ypost3.2M ~ treatment + ypre3.2M, data = Data2Video)
summary(ypost_cutoff3.2M_model)
confint(ypost_cutoff3.2M_model)

###Model 3 Fit Factor > 5 Video####
Data2Video$ypre3.5M <- ifelse(Data2Video$FitTest2_Factor_Overall >= 5, 1, 0)
Data2Video$ypost3.5M <- ifelse(Data2Video$FitTest3_Factor_Overall >= 5, 1, 0)
ypost_cutoff3.5M_model <- lm(ypost3.5M ~ treatment + ypre3.5M, data = Data2Video)
summary(ypost_cutoff3.5M_model)
confint(ypost_cutoff3.5M_model)
```

```
###Model 3 Fit Factor > 10 Video####
Data2Video$ypre3.10M <- ifelse(Data2Video$FitTest2_Factor_Overall >= 10, 1, 0)
Data2Video$ypost3.10M <- ifelse(Data2Video$FitTest3_Factor_Overall >= 10, 1, 0)
ypost_cutoff3.10M_model <- lm(ypost3.10M ~ treatment + ypre3.10M, data = Data2Video)
summary(ypost_cutoff3.10M_model)
confint(ypost_cutoff3.10M_model)
```

Bar Plots of Achieving Fit Factor Thresholds (Figure 5)

```
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Aim #2")
library("readxl")
FFDataControl <- read_excel("FitFactor Proportion Figures.xlsx", sheet = "Control")
FFDataFactsheet <- read_excel("FitFactor Proportion Figures.xlsx", sheet = "Factsheet")
FFDataManufactuer <- read_excel("FitFactor Proportion Figures.xlsx", sheet = "Manufacturer")
FFDataVideo <- read_excel("FitFactor Proportion Figures.xlsx", sheet = "Video")

##Bar Plot Fit Factors - Control ##
FFplotcontrol <- ggplot(data=FFDataControl, aes(x=FitFactor, y=Participants, fill=Test)) +
geom_bar(stat="identity", position=position_dodge()) + ylab("Number of Participants") +
ggtitle("Control") + scale_fill_manual(name="Test", labels = c("Pre","Post","One"), values =
c("#CCCCCC", "#333333","#666666")) + theme_classic() + theme(plot.title =
element_text(hjust = 0.5))+ scale_y_continuous(limits =c(0,10), breaks=c(2,4,6,8,10)) +
scale_x_discrete(labels=c(">2",">5",">10",">50",">100"))
FFplotcontrol

##Bar Plot Fit Factors - Factsheet ##
FFplotfactsheet <- ggplot(data=FFDataFactsheet, aes(x=FitFactor, y=Participants, fill=Test)) +
geom_bar(stat="identity", position=position_dodge()) + ylab("Number of Participants") +
ggtitle("Factsheet") + scale_fill_manual(name="Test", labels = c("Pre","Post","One"), values =
c("#CCCCCC", "#333333","#666666")) + theme_classic() + theme(plot.title =
element_text(hjust = 0.5))+ scale_y_continuous(limits =c(0,10), breaks=c(2,4,6,8,10)) +
scale_x_discrete(labels=c(">2",">5",">10",">50",">100"))
FFplotfactsheet

##Bar Plot Fit Factors - Manufacturer ##
FFplotmanufacturer <- ggplot(data=FFDataManufactuer, aes(x=FitFactor, y=Participants,
fill=Test)) + geom_bar(stat="identity", position=position_dodge()) + ylab("Number of
Participants") + ggtitle("Manufacturer") + scale_fill_manual(name="Test", labels =
c("Pre","Post","One"), values = c("#CCCCCC", "#333333","#666666")) + theme_classic() +
theme(plot.title = element_text(hjust = 0.5))+ scale_y_continuous(limits =c(0,10),
breaks=c(2,4,6,8,10))+ scale_x_discrete(labels=c(">2",">5",">10",">50",">100"))
FFplotmanufacturer

##Bar Plot Fit Factors - Video ##
FFplotvideo<- ggplot(data=FFDataVideo, aes(x=FitFactor, y=Participants, fill=Test)) +
geom_bar(stat="identity", position=position_dodge()) + ylab("Number of Participants") +
ggtitle("Video") + scale_fill_manual(name="Test", labels = c("Pre","Post","One"), values =
c("#CCCCCC", "#333333","#666666")) + theme_classic() + theme(plot.title =
```

```
element_text(hjust = 0.5))+ scale_y_continuous(limits =c(0,10), breaks=c(2,4,6,8,10))+
scale_x_discrete(labels=c(">2",">5",">10",">50",">100"))
FFplotvideo

##Combined Fit Factor Bar Plot##
library(ggpubr)
ffplotall<-ggarrange(FFplotcontrol, FFplotfactsheet, FFplotmanufacturer, FFplotvideo,
                     common.legend=TRUE, legend="bottom", nrow=2, ncol=2)
ffplotall
annotate_figure(
  ffplotall,
  top=text_grob("Fit Factors Achieved", color="black", face="bold", size=12))
```

Descriptive Analysis of Survey Data (Table B5)

```
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data/Survey Data")
library("readxl")
SurveyDataNo6sControl <- read_excel("SurveyDataNo6s.xls", sheet = "Control")
SurveyDataNo6sFactsheet <- read_excel("SurveyDataNo6s.xls", sheet = "Factsheet")
SurveyDataNo6sManufactuer <- read_excel("SurveyDataNo6s.xls", sheet = "Manufactuer")
SurveyDataNo6sVideo <- read_excel("SurveyDataNo6s.xls", sheet = "Video")
library(knitr)
opts_chunk$set(results = 'asis',
          comment = NA,
          prompt = FALSE,
          cache = FALSE)
library(summarytools)
st_options(plain.ascii = FALSE,
          style = "rmarkdown",
         footnote = NA,
          subtitle.emphasis = FALSE)
st_css()
view(dfSummary(SurveyDataNo6sControl, style = 'grid', graph.magnif = 0.75, tmp.img.dir =
"/tmp"))
view(dfSummary(SurveyDataNo6sFactsheet, style = 'grid', graph.magnif = 0.75, tmp.img.dir =
"/tmp"))
view(dfSummary(SurveyDataNo6sManufactuer, style = 'grid', graph.magnif = 0.75, tmp.img.dir
= "/tmp"))
view(dfSummary(SurveyDataNo6sVideo, style = 'grid', graph.magnif = 0.75, tmp.img.dir =
"/tmp"))
```

Bar Plot of Survey Data (Figure B1)

```
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data/Survey Data")
library("readxl")
SurveyDataControl <- read_excel("Survey Figures.xlsx", sheet = "Control")
SurveyDataFactsheet <- read_excel("Survey Figures.xlsx", sheet = "Factsheet")
SurveyDataManufactuer <- read_excel("Survey Figures.xlsx", sheet = "Manufacturer")
SurveyDataVideo <- read_excel("Survey Figures.xlsx", sheet = "Video")
```

```
##Bar Plot Survey - Control ##
surveyplotcontrol <- ggplot(data=SurveyDataControl, aes(x=Question, y=Likert_Scale,
fill=Test)) + geom_bar(stat="identity", position=position_dodge()) + ylab("Likert Scale") +
ggtitle("Control") + scale_fill_manual(name="Test", labels = c("Pre","Post"), values =
c("#CCCCCC", "#333333")) + theme_classic() + theme(plot.title = element_text(hjust = 0.5)) +
scale_x_discrete(breaks=c("1","2","3","4","5","6","7","8","9","10","11","12","13","14","15","16
","17","18","19","20","21"),
labels=c("K1","A2","K3","K4","K5","K6","K7","K8","K9","K10","K11","K12","K13","K14","
K15","K16","A17","A18","P19","A20","P21")) +
xlim("1","2","3","4","5","6","7","8","9","10","11","12","13","14","15","16","17","18","19","20",
"21")
surveyplotcontrol

##Bar Plot Survey - Factsheet ##
surveyplotfactsheet <- ggplot(data=SurveyDataFactsheet, aes(x=Question, y=Likert_Scale,
fill=Test)) + geom_bar(stat="identity", position=position_dodge()) + ylab("Likert Scale") +
ggtitle("Factsheet") + scale_fill_manual(name="Test", labels = c("Pre","Post"), values =
c("#CCCCCC", "#333333")) + theme_classic() + theme(plot.title = element_text(hjust = 0.5)) +
scale_x_discrete(breaks=c("1","2","3","4","5","6","7","8","9","10","11","12","13","14","15","16
","17","18","19","20","21"),
labels=c("K1","A2","K3","K4","K5","K6","K7","K8","K9","K10","K11","K12","K13","K14","
K15","K16","A17","A18","P19","A20","P21")) +
xlim("1","2","3","4","5","6","7","8","9","10","11","12","13","14","15","16","17","18","19","20",
"21")
surveyplotfactsheet

##Bar Plot Survey - Manufacturer ##
surveyplotmanufacturer <- ggplot(data=SurveyDataManufactuer, aes(x=Question,
y=Likert_Scale, fill=Test)) + geom_bar(stat="identity", position=position_dodge()) +
ylab("Likert Scale") + ggtitle("Manufacturer") + scale_fill_manual(name="Test", labels =
c("Pre","Post"), values = c("#CCCCCC", "#333333")) + theme_classic() + theme(plot.title =
element_text(hjust = 0.5)) +
scale_x_discrete(breaks=c("1","2","3","4","5","6","7","8","9","10","11","12","13","14","15","16
","17","18","19","20","21"),
labels=c("K1","A2","K3","K4","K5","K6","K7","K8","K9","K10","K11","K12","K13","K14","
K15","K16","A17","A18","P19","A20","P21")) +
xlim("1","2","3","4","5","6","7","8","9","10","11","12","13","14","15","16","17","18","19","20",
"21")
surveyplotmanufacturer

##Bar Plot Survey - Video ##
surveyplotvideo<- ggplot(data=SurveyDataVideo, aes(x=Question, y=Likert_Scale, fill=Test)) +
geom_bar(stat="identity", position=position_dodge()) + ylab("Likert Scale") + ggtitle("Video")
+ scale_fill_manual(name="Test", labels = c("Pre","Post"), values = c("#CCCCCC",
```

```
"#333333")) + theme_classic() + theme(plot.title = element_text(hjust = 0.5)) +
scale_x_discrete(breaks=c("1","2","3","4","5","6","7","8","9","10","11","12","13","14","15","16
","17","18","19","20","21"),
labels=c("K1","A2","K3","K4","K5","K6","K7","K8","K9","K10","K11","K12","K13","K14","
K15","K16","A17","A18","P19","A20","P21")) +
xlim("1","2","3","4","5","6","7","8","9","10","11","12","13","14","15","16","17","18","19","20",
"21")
surveyplotvideo

##Combined Survey Bar Plot##
library(ggpubr)
surveyplotall<-ggarrange(surveyplotcontrol, surveyplotfactsheet, surveyplotmanufacturer,
surveyplotvideo,
            common.legend=TRUE, legend="bottom", nrow=2, ncol=2)

surveyplotall
annotate_figure(
  surveyplotall,
  top=text_grob("Survey Reponses", color="black", face="bold", size=12))
```

KAP Survey Analysis (Table 7)

```
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data/Survey Data")
library("readxl")
SurveyDataNo6sAllTraining<- read_excel("SurveyDataNo6s.xls", sheet = "All Training")
SurveyDataNo6sControl <- read_excel("SurveyDataNo6s.xls", sheet = "Control")
SurveyDataNo6sFactsheet <- read_excel("SurveyDataNo6s.xls", sheet = "Factsheet")
SurveyDataNo6sManufactuer <- read_excel("SurveyDataNo6s.xls", sheet = "Manufactuer")
SurveyDataNo6sVideo <- read_excel("SurveyDataNo6s.xls", sheet = "Video")

##Question 1###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q1,Post_Q1, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q1,Post_Q1, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q1,Post_Q1, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q1,Post_Q1, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q1,Post_Q1, paired = TRUE, alternative = "two.sided"))

##Question 2###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q2,Post_Q2, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q2,Post_Q2, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q2,Post_Q2, paired = TRUE, alternative =
"two.sided"))
```

with (SurveyDataNo6sManufactuer, t.test(Pre_Q2,Post_Q2, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q2,Post_Q2, paired = TRUE, alternative = "two.sided"))

##Question 3###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q3,Post_Q3, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q3,Post_Q3, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q3,Post_Q3, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q3,Post_Q3, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q3,Post_Q3, paired = TRUE, alternative = "two.sided"))

##Question 4###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q4,Post_Q4, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q4,Post_Q4, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q4,Post_Q4, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q4,Post_Q4, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q4,Post_Q4, paired = TRUE, alternative = "two.sided"))

##Question 5###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q5,Post_Q5, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q5,Post_Q5, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q5,Post_Q5, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q5,Post_Q5, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q5,Post_Q5, paired = TRUE, alternative = "two.sided"))

##Question 6###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q6,Post_Q6, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q6,Post_Q6, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q6,Post_Q6, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q6,Post_Q6, paired = TRUE, alternative = "two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q6,Post_Q6, paired = TRUE, alternative = "two.sided"))

```
##Question 7###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q7,Post_Q7, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q7,Post_Q7, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q7,Post_Q7, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q7,Post_Q7, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q7,Post_Q7, paired = TRUE, alternative = "two.sided"))

##Question 8###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q8,Post_Q8, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q8,Post_Q8, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q8,Post_Q8, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q8,Post_Q8, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q8,Post_Q8, paired = TRUE, alternative = "two.sided"))

##Question 9###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q9,Post_Q9, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q9,Post_Q9, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q9,Post_Q9, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q9,Post_Q9, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q9,Post_Q9, paired = TRUE, alternative = "two.sided"))

##Question 10###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q10,Post_Q10, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q10,Post_Q10, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q10,Post_Q10, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q10,Post_Q10, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q10,Post_Q10, paired = TRUE, alternative =
"two.sided"))

##Question 11###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q11,Post_Q11, paired = TRUE, alternative =
"two.sided"))
```

```
with (SurveyDataNo6sControl, t.test(Pre_Q11,Post_Q11, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q11,Post_Q11, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q11,Post_Q11, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q11,Post_Q11, paired = TRUE, alternative =
"two.sided"))

##Question 12###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q12,Post_Q12, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q12,Post_Q12, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q12,Post_Q12, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q12,Post_Q12, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q12,Post_Q12, paired = TRUE, alternative =
"two.sided"))

##Question 13###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q13,Post_Q13, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q13,Post_Q13, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q13,Post_Q13, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q13,Post_Q13, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q13,Post_Q13, paired = TRUE, alternative =
"two.sided"))

##Question 14###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q14,Post_Q14, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q14,Post_Q14, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q14,Post_Q14, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q14,Post_Q14, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q14,Post_Q14, paired = TRUE, alternative =
"two.sided"))

##Question 15###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q15,Post_Q15, paired = TRUE, alternative =
"two.sided"))
```

```
with (SurveyDataNo6sControl, t.test(Pre_Q15,Post_Q15, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q15,Post_Q15, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q15,Post_Q15, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q15,Post_Q15, paired = TRUE, alternative =
"two.sided"))

##Question 16###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q16,Post_Q16, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q16,Post_Q16, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q16,Post_Q16, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q16,Post_Q16, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q16,Post_Q16, paired = TRUE, alternative =
"two.sided"))

##Question 17###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q17,Post_Q17, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q17,Post_Q17, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q17,Post_Q17, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q17,Post_Q17, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q17,Post_Q17, paired = TRUE, alternative =
"two.sided"))

##Question 18###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q18,Post_Q18, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q18,Post_Q18, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q18,Post_Q18, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q18,Post_Q18, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q18,Post_Q18, paired = TRUE, alternative =
"two.sided"))

##Question 19###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q19,Post_Q19, paired = TRUE, alternative =
"two.sided"))
```

```
with (SurveyDataNo6sControl, t.test(Pre_Q19,Post_Q19, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q19,Post_Q19, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q19,Post_Q19, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q19,Post_Q19, paired = TRUE, alternative =
"two.sided"))

##Question 20###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q20,Post_Q20, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q20,Post_Q20, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q20,Post_Q20, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q20,Post_Q20, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q20,Post_Q20, paired = TRUE, alternative =
"two.sided"))

##Question 21###
with (SurveyDataNo6sAllTraining, t.test(Pre_Q21,Post_Q21, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sControl, t.test(Pre_Q21,Post_Q21, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sFactsheet, t.test(Pre_Q21,Post_Q21, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sManufactuer, t.test(Pre_Q21,Post_Q21, paired = TRUE, alternative =
"two.sided"))
with (SurveyDataNo6sVideo, t.test(Pre_Q121,Post_Q21, paired = TRUE, alternative =
"two.sided"))
```

Descriptive Analysis of Observations (Table B7)

```
##### Descriptive Analysis of Observations All Training ####
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data/Video Data")
video_alltraining <- read.csv("VideoDataAllTraining.csv")
library(knitr)
opts_chunk$set(results = 'asis',
        comment = NA,
        prompt = FALSE,
        cache = FALSE)
library(summarytools)
st_options(plain.ascii = FALSE,
        style = "rmarkdown",
        footnote = NA,
        subtitle.emphasis = FALSE)
```

```
st_css()
view(dfSummary(video_alltraining, style = 'grid', graph.magnif = 0.75, tmp.img.dir = "/tmp"))

##### Descriptive Analysis of Observations Control ####
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data/Video Data")
video_control <- read.csv("VideoDataControl.csv")
library(knitr)
opts_chunk$set(results = 'asis',
        comment = NA,
        prompt = FALSE,
        cache = FALSE)
library(summarytools)
st_options(plain.ascii = FALSE,
        style = "rmarkdown",
        footnote = NA,
        subtitle.emphasis = FALSE)
st_css()
view(dfSummary(video_control, style = 'grid', graph.magnif = 0.75, tmp.img.dir = "/tmp"))

##### Descriptive Analysis of Observations Factsheet ####
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data/Video Data")
video_factsheet <- read.csv("VideoDataFactsheet.csv")

library(knitr)
opts_chunk$set(results = 'asis',
        comment = NA,
        prompt = FALSE,
        cache = FALSE)
library(summarytools)
st_options(plain.ascii = FALSE,
        style = "rmarkdown",
        footnote = NA,
        subtitle.emphasis = FALSE)
st_css()
view(dfSummary(video_factsheet, style = 'grid', graph.magnif = 0.75, tmp.img.dir = "/tmp"))

##### Descriptive Analysis of Observations Manufacturer ####
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data/Video Data")
video_manufacturer <- read.csv("VideoDataManufacturer.csv")
library(knitr)
opts_chunk$set(results = 'asis',
        comment = NA,
        prompt = FALSE,
        cache = FALSE)
library(summarytools)
st_options(plain.ascii = FALSE,
        style = "rmarkdown",
        footnote = NA,
```

```
        subtitle.emphasis = FALSE)
st_css()
view(dfSummary(video_manufacturer, style = 'grid', graph.magnif = 0.75, tmp.img.dir =
"/tmp"))

##### Descriptive Analysis of Observations Video ####
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data/Video Data")
video_video <- read.csv("VideoDataVideo.csv")
library(knitr)
opts_chunk$set(results = 'asis',
        comment = NA,
        prompt = FALSE,
        cache = FALSE)
library(summarytools)
st_options(plain.ascii = FALSE,
        style = "rmarkdown",
           footnote = NA,
        subtitle.emphasis = FALSE)
st_css()
view(dfSummary(video_video, style = 'grid', graph.magnif = 0.75, tmp.img.dir = "/tmp"))
```

Bar Plot Observation Data (Figure 6)

```
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data/Video Data")
library("readxl")
ObservationDataControl <- read_excel("Observation Figures.xlsx", sheet = "Control")
ObservationDataFactsheet <- read_excel("Observation Figures.xlsx", sheet = "Factsheet")
ObservationDataManufactuer <- read_excel("Observation Figures.xlsx", sheet =
"Manufacturer")
ObservationDataVideo <- read_excel("Observation Figures.xlsx", sheet = "Video")

##Bar Plot Observations - Control ##
observationplotcontrol <- ggplot(data=ObservationDataControl, aes(x=Observations,
y=Participants, fill=Test)) + geom_bar(stat="identity", position=position_dodge()) +
ylab("Number of Participants") + ggtitle("Control") + scale_fill_manual(name="Test", labels =
c("Pre","Post"), values = c("#CCCCCC", "#333333")) + theme_classic() + theme(plot.title =
element_text(hjust = 0.5)) + theme(axis.text.x = element_text(angle=65, hjust = 1))+
scale_y_continuous(limits =c(0,10), breaks=c(2,4,6,8,10)) +
scale_x_discrete(labels=c("Donn_Inspect_Mask","Donn_Cuppped","Donn_Cuppped_Nose","Do
nn_Cuppped_Strap","Donn_Strap_Order","Donn_Strap_Position","Donn_Strap_Straight","Donn
_Position","Donn_Nosepiece","Donn_Molded_Nose","Seal_Check","Seal_Check_Hands","Seal
_Check_Positon","Seal_Check_Leak","Seal_Check_2","Donn_Movement","Donn_Movement_1
","Donn_Movement_2","Donn_Movement _3","Glasses","Glasses_Obstruction"))
observationplotcontrol

##Bar Plot Observations - Factsheet ##
observationplotfactsheet <- ggplot(data=ObservationDataFactsheet, aes(x=Observations,
y=Participants, fill=Test)) + geom_bar(stat="identity", position=position_dodge()) +
```

```
ylab("Number of Participants") + ggtitle("Factsheet") + scale_fill_manual(name="Test", labels =
c("Pre","Post"), values = c("#CCCCCC", "#333333")) + theme_classic() + theme(plot.title =
element_text(hjust = 0.5)) + theme(axis.text.x = element_text(angle=66, hjust = 1))+
scale_y_continuous(limits =c(0,10), breaks=c(2,4,6,8,10))+
scale_x_discrete(labels=c("Donn_Inspect_Mask","Donn_Cuppped","Donn_Cuppped_Nose","Do
nn_Cuppped_Strap","Donn_Strap_Order","Donn_Strap_Position","Donn_Strap_Straight","Donn
_Position","Donn_Nosepiece","Donn_Molded_Nose","Seal_Check","Seal_Check_Hands","Seal
_Check_Positon","Seal_Check_Leak","Seal_Check_2","Donn_Movement","Donn_Movement_1
","Donn_Movement_2","Donn_Movement _3","Glasses","Glasses_Obstruction"))
observationplotfactsheet

##Bar Plot Observations - Manufacturer ##
observationplotmanufacturer <- ggplot(data=ObservationDataManufactuer, aes(x=Observations,
y=Participants, fill=Test)) + geom_bar(stat="identity", position=position_dodge()) +
ylab("Number of Participants") + ggtitle("Manufacturer") + scale_fill_manual(name="Test",
labels = c("Pre","Post"), values = c("#CCCCCC", "#333333")) + theme_classic() +
theme(plot.title = element_text(hjust = 0.5)) + theme(axis.text.x = element_text(angle=65, hjust
= 1))+ scale_y_continuous(limits =c(0,10), breaks=c(2,4,6,8,10))+
scale_x_discrete(labels=c("Donn_Inspect_Mask","Donn_Cuppped","Donn_Cuppped_Nose","Do
nn_Cuppped_Strap","Donn_Strap_Order","Donn_Strap_Position","Donn_Strap_Straight","Donn
_Position","Donn_Nosepiece","Donn_Molded_Nose","Seal_Check","Seal_Check_Hands","Seal
_Check_Positon","Seal_Check_Leak","Seal_Check_2","Donn_Movement","Donn_Movement_1
","Donn_Movement_2","Donn_Movement _3","Glasses","Glasses_Obstruction"))
observationplotmanufacturer

##Bar Plot Observations - Video ##
observationplotvideo<- ggplot(data=ObservationDataVideo, aes(x=Observations, y=Participants,
fill=Test)) + geom_bar(stat="identity", position=position_dodge()) + ylab("Number of
Participants") + ggtitle("Video") + scale_fill_manual(name="Test", labels = c("Pre","Post"),
values = c("#CCCCCC", "#333333")) + theme_classic() + theme(plot.title = element_text(hjust
= 0.5)) + theme(axis.text.x = element_text(angle=65, hjust = 1))+ scale_y_continuous(limits
=c(0,10), breaks=c(2,4,6,8,10))+
scale_x_discrete(labels=c("Donn_Inspect_Mask","Donn_Cuppped","Donn_Cuppped_Nose","Do
nn_Cuppped_Strap","Donn_Strap_Order","Donn_Strap_Position","Donn_Strap_Straight","Donn
_Position","Donn_Nosepiece","Donn_Molded_Nose","Seal_Check","Seal_Check_Hands","Seal
_Check_Positon","Seal_Check_Leak","Seal_Check_2","Donn_Movement","Donn_Movement_1
","Donn_Movement_2","Donn_Movement _3","Glasses","Glasses_Obstruction"))
observationplotvideo

##Combined Observations Bar Plot##
library(ggpubr)
observationplotall<-ggarrange(observationplotcontrol, observationplotfactsheet,
observationplotmanufacturer, observationplotvideo, common.legend=TRUE, legend="bottom",
nrow=2, ncol=2, + labs(colour = NULL))
observationplotall
annotate_figure(
  observationplotall,
  top=text_grob("Actions Observed", color="black", face="bold", size=12))
```

Scatterplot of Fit Factors vs observations (Figure 7)

```
setwd("/Users/kaitlynkelly/Desktop/N95 Research/Participant Data/Video Data")
FFObsData <- read.csv("ObservationFigureData.csv")
FFObs <- ggplot(FFObsData, aes(x=Observation, y = Fit_Factor, group=Observed)) +
xlab("Actions") + ylab("Fit Factor") + ggtitle("Actions Taken vs. Fit Factor") +
geom_jitter(aes(color=Observed)) + scale_color_manual(labels = c("No", "Yes"),
values=c("#CCCCCC", "#333333")) + theme_classic() + theme(plot.title = element_text(hjust =
0.5))+ theme(axis.text.x = element_text(angle=45, hjust = 1))
FFObs
```

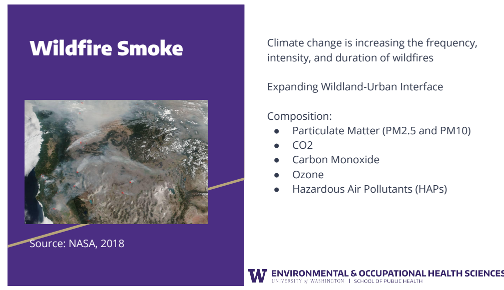
Air Quality Scatter Plot (Figure 8)

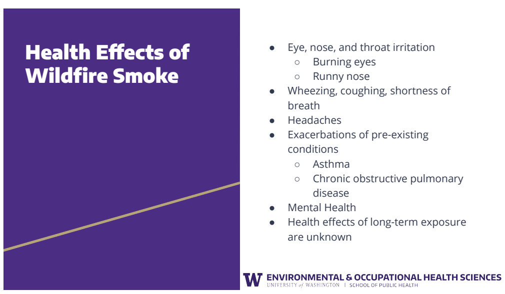
```
library(ggplot2)
theme_set(
  theme_bw() +
        theme(legend.position = "top"))

setwd("/Users/kaitlynkelly/Desktop/N95 Research")
AirQualityData <- read.csv("Air Quality Graph.csv")
AirQuality <- ggplot(AirQualityData, aes(x=Date, y = PM_2.5Concentration, group=Location))
+ geom_line()+ geom_point()+geom_line(aes(color=Location))+
  xlab("State Wide Smoke Event Dates") + ylab("PM 2.5 Concentration") +
  ggtitle("PM 2.5 Concentration Across WA During the August Statewide Smoke Event") +
geom_point(aes(shape=Location)) + geom_point(aes(color=Location))+ scale_color_grey() +
theme_classic()+ geom_hline(yintercept=12.1, linetype="dashed", color = "yellow") +
  geom_hline(yintercept=150.4, linetype="dashed", color = "#800000") +
  geom_hline(yintercept=80.5, linetype="dashed", color = "#4B0082") +
  geom_hline(yintercept=35.5, linetype="dashed", color = "red") +
  geom_hline(yintercept=20.5, linetype="dashed", color = "orange") +
  theme(plot.title = element_text(hjust = 0.5))+
  coord_cartesian(xlim=c(1,12), clip='off')+
  theme(plot.margin=unit(c(3,3,3,3), "lines"))
AirQuality
AirQualitylegend <- AirQuality + theme(legend.position="bottom")
AirQualitylegend
AirQualityLabeled <- AirQualitylegend + annotate(geom="text", label="Moderate", x=11,
y=15)+ annotate(geom="text", label="Unhealthy for SG's", x=11, y=25) +
annotate(geom="text", label="Unhealthy", x=11, y=40) + annotate(geom="text", label="Very
Unhealthy", x=11, y=85)+ annotate(geom="text", label="Hazardous", x=11, y=155)
AirQualityLabeled
```

Appendix U. Research Translation Materials

<u>3rd International Smoke Symposium PowerPoint Presentation</u>





General Public Use

Source: Huffpost, 2019

General public has started to use N95 respirators during wildfire smoke events

Available for purchase at hardware stores, pharmacies, and online

Affordable, $1-$3 per mask

In WA state:

- In 2017, 72,460 respirators distributed
- In 2018, 249,040 respirators distributed

The practice of medical clearance, proper training, and individual fit testing is not required for public use

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Their use is becoming a concern

Source: Houston Chronicle, 2019

International Society for Respiratory Protection (ISRP) America's Section held their technical meeting in October

- *Developing a Roadmap to Address Respirator Use by the General Public - Translating Occupational Safety and Health Knowledge to Guide Non-occupational Respirator Users*

Concerns:

- Inconsistent messaging
- Proper Training & Use
- Regulator Authority
- No standards
- Liability

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And research is limited

> Previous studies have shown the filtration efficiency of ambient particulate matter, but no studies describe their use during WFS events

> No existing studies that assess respirator effectiveness among the general public who do not undergo individual fit-testing

> A few studies have evaluated training materials, but their not focused on the general public

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Study Aims

1. Quantify the transference of knowledge from different training and communication mediums into N95 respirator fit in a convenience sample of untrained persons

2. Identify challenges and gaps in knowledge and actions for proper use of N95 respirators by the general public

3. Inform recommendations for training materials for the general public surrounding N95 respirator mask use

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Interventions

Source: WA DOH 2019

1. "Smoke From Fires: N95 Respirator Masks" video
2. "Wildfire Smoke and Face Masks" factsheet
3. Manufacturer Instructions
4. No training

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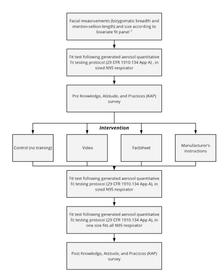
Study Design



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Study Methods: Fit Testing

Generated aerosol quantitative fit testing protocols
- TSI PortaCount Plus
  - N95 mask capacity
- 8 exercises, 7 minutes

Produces fit factor
- Ratio of ambient concentration to the concentration inside the respirator

Fit test before and after intervention

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Study Methods: Observational Analysis

Video record participants donning the N95 respirator

Analyze actions that are important to achieve proper fit

Checklist (Y/N) of pre-identified actions

Examples:
- Pulled top strap over head first
- Molded nose piece
- Straps straight
- Seal Check

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Study Methods: KAP Survey

Knowledge, Attitudes, and Practice Survey
- Determines participants opinion on statements
- Repeated before and after intervention
- Likert scale (1 = Strongly Disagree, 5 = Strongly Agree, 6 = I Don't know)

Example Statements:
- "I know how to properly wear an N95 respirator"
- "I think N95 respirators are easy to use"
- "I would wear an N95 respirator during a wildfire smoke event when the air quality is poor"

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Preliminary Results:

Study Population (n= 40)

- 73% female, 27% male
- 55% between the ages of 18-24
- 60% identified as white, 43% as Asian
- 56% graduated college
- 85% had no prior respirator use

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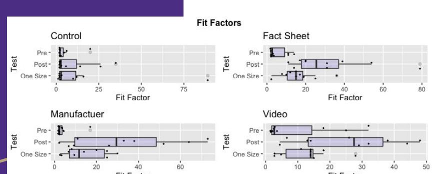
Preliminary Results:



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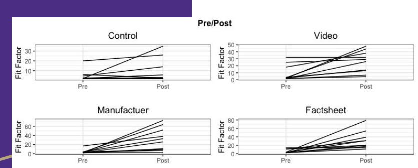
Preliminary Results:



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Preliminary Results:

# of participants above	No Training		Video		Manufacturer's Instructions		Factsheet	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Fit Factor > 2	8	8	7	10	7	10	9	10
Fit Factor > 5	2	4	3	9	1	9	3	10
Fit Factor > 10	1	3	3	8	1	7	3	10
Fit Factor > 50	0	0	0	0	0	3	0	2
Fit Factor > 100	0	0	0	0	0	0	0	0

Results:

# of participants above	No Training		Video		Manufacturer's Instructions		Factsheet	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Fit Factor > 2	8	8	7	10	7	10	9	10
Fit Factor > 5	2	4	3	9	1	9	3	10
Fit Factor > 10	1	3	3	8	1	7	3	10
Fit Factor > 50	0	0	0	0	0	3	0	2
Fit Factor > 100	0	0	0	0	0	0	0	0

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Discussion

Source: 3M

- Inconsistent information
- Fit testing for the general public unlikely
- Is it still better than nothing?
- What about false sense of security?
  - Advertised "air pollution" masks
- What from occupational use should be incorporated into public use and training?
- Training improves fit, but is it enough to achieve a fit factor that will protect public health

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Limitations

- Sizing
- One brand
- Study Population
- Fit factor may not represent real time protection

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Public Health Practice Implications

- Develop & improve upon communication materials in partnership with practice partners
  - Factsheets, videos, communication strategies
- Provide evidence to support decisions on their recommended use during WFS

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Graduate Student Research Day Poster

Informing recommendations for the use of N95 respirators and their relative training and communication mediums as a public health intervention for wildfire smoke

Kaitlyn Kelly[1] MPH$_C$; Marc Beaudreau[1], CIH, MS; Marissa Baker[1], PhD, MS; Tania Busch Isaksen[1], PhD, MPH
[1] Department of Environmental and Occupational Health Sciences

Introduction

Climate change is increasing the frequency, intensity, and duration of wildfires. To reduce personal exposure to wildfire smoke and resulting adverse health effects, N95 respirators have been used by the general public to filter out particulate matter present in smoke.

> In Washington state in 2017, a total of 72,460 respirators were distributed across several counties, and the number increased to 249,040 in 2018.

> The mandatory use of N95 respirators in an occupational setting requires medical clearance, proper training, and individual fit testing. This practice is not required for public distribution or use of respirators, and the description of information and/or training provided is incomplete.

> A need for better understanding of evidence-based intervention and risk communication strategies (specifically N95 respirators) during prolonged and extreme smoke events has been identified by the University of Washington and practice partners.

Objectives

> Quantify the transference of knowledge from different training and communication mediums into N95 respirator fit in a convenience sample of the lay public

> Identify challenges and gaps in knowledge and actions for proper use of N95 respirators by the lay public

> Inform recommendations for training materials for the lay public surrounding N95 respirator mask use

Preliminary Results

We expect data analysis and translation of results to be completed in spring 2020.

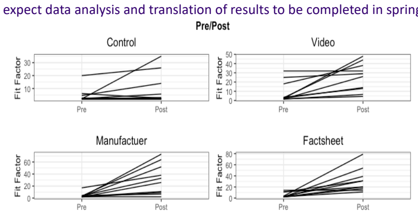


Figure 1. Change in fit factor before and after training, by intervention.

	No Training		Video		Manufacturer's Instructions		Factsheet	
# of participants above	Pre	Post	Pre	Post	Pre	Post	Pre	Post
Fit Factor > 2	8	8	7	10	7	10	9	10
Fit Factor > 5	2	4	3	9	1	9	3	10
Fit Factor > 10	1	3	3	8	1	7	3	10
Fit Factor > 50	0	0	0	0	0	3	0	2
Fit Factor > 100	0	0	0	0	0	0	0	0

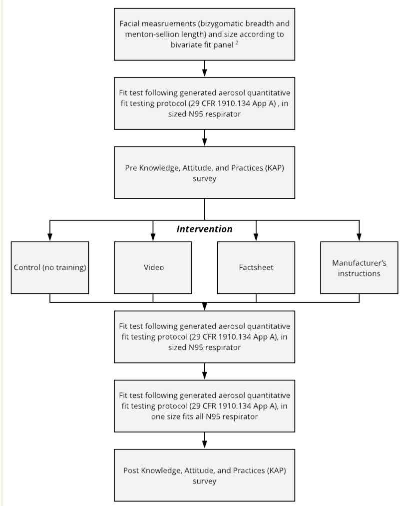
Figure 2. Change in the number of participants achieving fit factors of 2 ,5, 10, 50, and 100 before and after training, by intervention.

Discussion

Wildfires are an increasingly important issue in the Western United States as human populations live at the wildland-urban interface. Wildfire smoke exposure is associated with respiratory morbidity in the general population, as well as exacerbations for those with asthma and chronic obstructive pulmonary disease, and all-cause mortality.[1] This study will help evaluate the appropriateness of N95 respirators and training materials as an intervention to reduce wildfire smoke exposure. We expect our results to inform the communication and recommendation of use by practice partners.

Materials & Methods

> Sliding caliper, spreading caliper
> TSI PortaCount Plus
> HDX N95 Respirator Masks: H950S, H950, H950V
> "Smoke From Fires: N95 Respirator Masks" video, "Wildfire Smoke and Face Masks" factsheet, HDX User Instructions



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References:
1. *Cascio, W. E. Wildland fire smoke and human health. Sci. Total Environ. 624, 586–595 (2018).*
2. *Zhuang, Ziqing, Bradtmiller, Bruce and Shaffer, Ronald E. New Respirator Fit Test Panels Representing the Current U.S. Civilian Work Force. Journal of Occupational and Environmental Hygiene. 4: 9, 647-659 (2007).*

Acknowledgements:
This project was funded by the Pacific Northwest Agricultural Safety and Health (PNASH) Center through Grant Number #61-1999

<u>N95 Respirator & Masks Talking Points for Panel Hosted by WA DNR on Wildfire Smoke and Respiratory Protection during the COVID-19 Pandemic</u>

General Conversation about N95 Mask use for WFS:

- N95 respirators are not originally designed for general public use
- Prior to COVID-19, WA DOH did not N95 respirators were not recommended as the first way to reduce exposure. We generally have said that they are an option if you cannot leave a smoke area or find other ways to reduce your exposure.
- We recommend staying inside, clean air spaces, reduced physical activity outdoors, when possible, before use of face masks
- Their use in an occupational setting requires medical clearance, proper training, and fit testing per OSHA regulations—**we do not have this for the general public**
    - Fit testing evaluates the fit of a respirator on an individual—the notion being that particles that cannot pass through the N95 filter cartridge in the mask and thus all the detected particles are a result of poor fit
- Communicating their proper use to the general public is challenging
- No way to know they are fitting and providing without an individual fit test, and the general public does not usually have access to this
- No regulatory authority, inconsistent messaging, issues of liability
- Little is known about respirator effectiveness among the general public who do not undergo fit testing
- A few studies have evaluated training materials, but not focused for general public
- Previous studies have shown the filtration efficiency of ambient particulate matter, but no studies describe their use during WFS events
- They only achieve filter efficiency (e.g. 95%) if there is the correct seal—and this the inherent challenge for their use by the general public
- Now with COVID-19, N95 and other NIOSH approved respirators should be reserved for health care providers until further notice
    - Cloth masks are not generally considered protective for PM 2.5/WFS

What level of smoke protection does a person receive from manufactured masks that are not rated as a N95? What are the next-best options when N95 masks are unavailable?

- There is limited research on this
- No way to ensure filtration efficiency unless they are NIOSH approved & fit tested
    - Existing guidance around N95 use & WFS recommends NIOSH approved masks
- N95 should be used as a last step, there is no next-best option. They are at the bottom of hierarchy of controls. The best options are other interventions (staying inside, clean air spaces) then the next option is PPE, rather than the other way around

In the past few weeks, we have seen a lot of folks wearing masks in a variety of ways. Can one of you demonstrate the proper way to wear and put on a mask?

- Nuisances
    - Pinching the noise piece vs. molding it
    - Not every mask works for every face shape (and we don’t know this without fit testing)

- Need proper training to achieve fit & filter efficiency; however, occupational use and training is very different than that for the general public
- Communicating proper mask use and all the nuisances to the general public is challenging, and expect it to be more challenging with the increased familiarity and use for COVID-19
    - Cannot reduce the information to a simple and short message and still be effective—need enough details to get people to don it properly. This makes messaging to the general public difficult.
- Likely many of the general public aren't even doing any sort of training on how to wear one
- The other problem with N95s is that they don't work well for everyone. They are not recommended for use in children, they don't seal well if you have facial hair, and you should consult your physician before using if you have a cardiopulmonary condition. And additional not ever make and model fit every face shape

Recommendations for Updating Washington State Department of Health Factsheet

1. Add information on sizes and sizing
2. Add information on conducting a seal check on the factsheet instead of referring to manufacturer's instructions
3. Update photos
4. Add information about different fit between manufacturer's and models
5. Add information about every respirator fits differently for every face shape
6. Clarify and creating consistency on mask vs. respirator language
7. Take out that N95 respirators are not the cheapest and update to usually most available
8. Explain that the NIOSH certification will be on the mask
9. Change "pinch the metal part" to "metal nosepiece"
10. Add information on storage

Appendix V. Proposed Methods for Sensitivity Analysis

Background

The face-fitting characteristics of N95 respirators varies among the models available on the market. Several studies have evaluated the fitting characteristics of N95 respirators [1-3]. The first was done by NIOSH in 1996 [2-3], and another done by Coffeey et al. in 2004. The study conducted by NIOSH found that the performance level of N95 respirators varied among the 21 models tested. In the study done by Coffey et al., it was found that fit testing improved the level of protection of "poor-fitting respirators."

In our pilot study, only one brand of N95 respirators (HDX) was used to assess the impact of training on fit among participants. To address this limitation, we plan to conduct a sensitivity analysis to compare the fitting characteristics of the HDX N95 respirator model in our study to other N95 respirators available to the general public.

Aim

Compare the fitting characteristics of three N95 masks to enhance the robustness of our pilot study results.

- To test this, we will compare fit factors of participants wearing three different N95 mask models after receiving training.

Desired Outcome: Improved understanding of the impact of training on N95 respirator fit determined in our pilot study.

Recruitment

This proposed research will require IRB approval with the University of Washington prior to proceeding, although it is expected that this will be determined exempt similar to the pilot study. It will take about 30 minutes to complete the protocol. Participants will not be compensated for their time. Participants will be selected using convenience sampling. To be eligible, participants must meet the same inclusion and exclusion criteria as defined in our pilot study. The number of participants will be determined using a power calculation based on the effect size of the selected intervention from pilot study.

Materials

Materials needed will be similar to that of the pilot study, except for N95 respirators:

- HDX one size fits all masks (1 per participant)
- 3M air pollution masks (1 per participant)
- 3M 8210 standard mask (1 per participant)

Two of the three N95 respirator models have already been purchased. The only materials that would need to be purchased are 3M 8210 masks and additional mask probes, for which there is likely money available leftover from the PNASH grant for the pilot.

Methods

1. Receive informed consent
2. Administer selected intervention
    a) Participants will all be given the same intervention, so the difference in fit factor cannot be attributed to differences in training. Intervention will be selected based on the results of the pilot study. However, manufacturer's instructions cannot be used, due to using N95 respirators by three different manufacturers.
3. Conduct three fit tests with three different respirators using the ambient aerosol condensation nuclei counter quantitative fit test protocol with TSI PortaCount Plus in the N95 mask setting.

. The order will be randomized for each participant.

4. Measure participant's face and collect demographic information like that in the pilot study
5. Use statistical analysis to determine if there is a significant difference in fit factors among models

Limitations

Limitations are similar to that of the pilot study. (1) Subjects may not be representative of the general public. (2) Fit factors can vary with repeated donning, even when wearing the same mask. Thus, this can confound the difference of fit factors between N95 models, although we will attempt to address this by randomizing the order of masks when fit tested. (3) The fit factors produced during fit testing with a PortCount may overestimate exposure, when compared to working conditions.[4] (4) For this sensitivity analysis, we are using masks that are not marketed with sizes and our "one size fits all". We will still measure participants faces to determine expected size using the bivariate fit panel developed by Zhang et al. The fit factor may be confounded by poor fit due to improper size (e.g. mask is to big for those with smaller faces). However, the aim of this analysis to compare the fitting characteristics of the mask and participants will be fit tested with every model selected. (5) In the pilot we used three models of the HDX mask, two of which were sized (i.e. S and M/L). We are only using the "one size fits all" model in this analysis. Thus, we're assuming the fitting characteristics of the "one size fits all model" will be similar to that of the other models since they're the same manufacturer. (6) Three models are still only a select amount available on the market. However, it is out of our budget and resources to compare more.

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