Study Title: Product Testing of the FaceView Mask™: Usability Survey

Principal Investigator: Samuel R. Atcherson, Ph.D.
Department of Audiology and Speech Pathology
College of Health Professions
University of Arkansas for Medical Sciences
4301 W. Markham Street, Slot # 711
Little Rock, AR 72205
Telephone: 501.686.6860
Email: sratcherson@uams.edu

Study location: University of Arkansas for Medical Sciences
4301 W. Markham Street
Little Rock, AR 72205

Background and Rationale

Approximately 4% of people in the US are either deaf or hard of hearing[1], equating to more than 13 million people. Of these, approximately 12 million people over the age of 5 years have difficulty hearing normal conversation even when using a hearing aid[1]. Hearing difficulties affect all age groups and present significant challenges in daily life. These challenges are particularly acute in healthcare settings, where miscommunication results in suboptimal treatment and can lead to serious and potentially life-threatening outcomes for patients[2]. Errors in interpersonal communication are an important contributing factor in medical errors, and the wearing of surgical masks by healthcare personnel and patients increases the likelihood of miscommunication. The surgical mask is an essential item of personal protective equipment, preventing the transmission of infectious agents such as bacteria and viruses, but conventional surgical masks can muffle speech and prevent patients and healthcare workers with hearing difficulties from being able to lip read[3,4]. Lip reading is an important visual aid to communication for everyone but is particularly important for those who are deaf or hard of hearing[5-10]. Our goal is to complete the development of a transparent surgical N95 respirator mask that prevents infectious disease transmission and improves communication among healthcare personnel and patients with hearing impairment.

Objectives

The investigators will recruit adult participants to complete a usability survey on a transparent surgical N95 respirator (i.e., FaceView mask) designed to improve communication. The study aims to gather participants' perceptions of the novel transparent surgical N95 respirator vs. a conventional surgical N95 respirator. Following fitting of the masks (up to 30 minutes wear time each), the participants will complete a questionnaire to provide their perceptions of fit, comfort, ease of use, and benefit to communication.

Study Design and Procedures

For both objectives, participants will try on both the FaceView Mask™ and the conventional surgical N95 respirator in quasi-random order from participant to participant. The participants will be informed that both masks meet N95 standards. The participants will be fit tested for both masks to ensure that the appropriate size is used. Training for fit testing will be performed by trained FaceView Mask, LLC personnel using a standard fit testing kit (3M™ Qualitative Fit Test Kit, Sweet) and the PI (and hired graduate student) will apply this fitting technique to all participants. The participants will wear each mask for up to 30 minutes before completing the study survey. All surgical respirators will be immediately discarded after use. Important requirements before fit testing include:

- No participants with facial hair should be included in the fit testing study.
- All participants (test subjects and administrators) should view the video at http://multimedia.3m.com/mws/media/992396O/3m-respirator-fit-kit-test-video.mp4 before beginning the study.
- Test subjects must not eat, drink (other than plain water), smoke, or chew gum in the 15 minutes preceding the test.

Study Population

A goal of 200 participants is desired with a minimum of 125 to meet study targets. We will be contacting known persons (not cold contacts) with ability to share study brochure by e-mail:

1) across the UAMS campus (e.g., College Deans, Center Directors, Program Directors);

2) surrounding clinics;

3) American Sign Language interpreter education at the University of Arkansas at Little Rock (Program Director)

4) Arkansas School for the Deaf (Superintendent and/or Assistant to the Superintendent); and

5) Communications Plus+ Interpreter Services, Inc. (owner and operator)

In the event that recruitment numbers are low in Little Rock, AR, the PI has contacts in San Francisco, CA, Ann Arbor, MI, and Rochester, NY who belong to the healthcare community, Deaf and hard of hearing community, or both. If needed, recruiters at these three additional sites will be hired to recruit 25 participants per site. Approvals for IRB amendments will be sought, and if necessary, IRB approvals will be obtained at those additional sites.

Compensation

The participants will each receive a $25 gift card as compensation for their participation in the study. As the subjects' active participation in this study ends with the completion of the survey, there is no retention plan.

Inclusion Criteria

- Study participants must be at least 18 years old, have no health conditions that would prevent them from safely wearing an N95 respirator (e.g., severe asthma, chronic obstructive pulmonary disease), read in English and communicate in English or American Sign Language, and be able to provide or arrange their own transportation to the study location.
- The ages of the participants are expected to reflect the demographics of the healthcare workforce from which they will be recruited (typically 18-65 years).
- There will not be any exclusion of subjects based on racial/ethnic background. It is expected that the races and ethnicities represented in these studies will reflect the overall demographics of the workforce involved.

Exclusion Criteria

- Prospective participants with facial hair.
- Children are to be excluded from the proposed research project because the current FaceView Mask™ is designed for adults.
- Adults who are non-English communicators.
- Any adult with health conditions that would prevent them from safely wearing an N95 respirator (e.g., severe asthma, chronic obstructive pulmonary disease).

Risks and Benefits

When testing surgical mask that makes contact with the skin of the wearer, there is the potential for study participants to experience an allergic reaction to the mask material.

N95-grade surgical respirators are designed to filter the air breathed by the wearer, and there is the potential for study participants to experience some restricted airflow.

The information obtained from the participants will not jeopardize them in any way and will be deidentified.

The information obtained through this product testing study will inform the final design of a novel transparent surgical N95 respirator that will improve communication among healthcare workers and patients. Therefore, the participants are likely to benefit from the product that the proposed research supports.

There are no transparent surgical N95 respirators currently on the market. Successful testing of the FaceView Mask™ surgical N95 respirator will lead to commercialization of this novel product to improve communication between healthcare workers and deaf patients in situations requiring the use of N95-grade surgical respirators (e.g., when there is a risk of exposure to respiratory pathogens). Healthcare workers with hearing difficulties and those working in noisy environments may also benefit from this novel surgical N95 respirator. The FaceView Mask™ is designed to improve communication and reduce the risk of medical errors. The inclusion of an antimicrobial coating on the FaceView Mask™ will provide additional protection against respiratory pathogens and reduce fomite

transmission of these pathogens that may occur through handling of the mask by the wearer.

An understanding of the needs of healthcare workers with regard to this novel N95 respirator (e.g., size, shape, fit, and comfort) will improve the effectiveness of the design and lead to a significant advance in personal protective equipment (PPE).

Data Handling and Recordkeeping

We will collect all data using RedCap, and completed surveys will not collect personal identifying information or PHI. Therefore, the data are already de-identified/anonymized and untraced back to the participant.

The PI will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study.

At the conclusion of the study, the data will be retained and remain deidentified/anonymous, and later destroyed in accordance with institutional policy.

Data Analysis

As this is a product survey, and not a treatment or intervention project, all data will be reported using descriptive statistics in the aggregate.

Ethical Considerations

This study will be conducted in accordance with all applicable government regulations and University of Arkansas for Medical Sciences research policies and procedures. This protocol and any amendments will be submitted and approved by the UAMS Institutional Review Board (IRB) to conduct the study.

This is a minimal risk study and a waiver of documentation of consent is requested. The research involves no more than minimal risk to the subjects and the only record linking the subject and the study would be the consent document and the principal risk is the breach of confidentiality.

The study team will recruit *via* word of mouth and by emailing the study brochure to people known to the study team. The study will be fully explained to the participant prior to engaging in any activities. All participants will be given a copy of the study brochure for their records. Study participation will be taken as agreement to participate.

Dissemination of Data

Results of this study may be used for presentations, posters, or publications. The publications will not contain any identifiable information that could be linked to a participant.

References

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Appendices

See survey instrument in Documents.