




## Original research

# Effectiveness of an anti-fog polymer coating in protective eyewear: a blinded, randomised controlled cross-over trial with healthcare providers in an emergency department setting

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## ABSTRACT

**Background** Eye protection is a mandatory component of the personal protective equipment in healthcare settings, especially for suspected or confirmed cases of COVID-19 and during aerosolising procedures. Fogging of protective eyewear is a frequent problem experienced by providers. The hydrophilic property of a sulfonated polymer, BiaXam, may be able to decrease fogging through wicking moisture from the lens. In this study, we tested the anti-fogging properties of this polymer when applied to protective eyewear.

**Methods** An investigator-initiated prospective, randomised, single-blinded cross-over study was conducted in an emergency department in a large, tertiary care hospital. Participants were blinded and randomised first to either a pair of anti-fog coated or uncoated eyewear, and then to the alternative pair after 2 hours. Study participants completed an identical survey at the end of each 2-hour period.

**Results** 50 emergency medicine healthcare providers were enrolled and 48 completed the study. Results demonstrated a significant difference in fogging between the coated and uncoated eyewear, as 81% of the participants reported fogging of the uncoated lenses and only 55% of the participants reported fogging in the coated pair ( $p=0.0029$ ). Participants reported that the uncoated lenses fogged two times as frequently on a 10-point Likert scale ( $4.5\pm3.3$  vs  $2.1\pm2.5$ ;  $p<0.0001$ ). Subgroup analysis of participants who wore only a surgical mask demonstrated even more efficacious results with coated eyewear.

**Conclusion** Overall, sulfonated polymer-coated eyewear improved provider visualisation, user

## WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Several studies in the literature describe fogging of protective eyewear as a widespread problem, but few offer solutions. Although other anti-fog coated lenses do exist, we are not aware of any that have been effectively validated in clinical environments.

## WHAT THIS STUDY ADDS

⇒ Given the paucity of the literature validating effective anti-fog coating of polyethylene terephthalate or alternative measures, as well as the dearth of studies looking at the impact of fogging of eyewear in the clinical setting, this study demonstrates value through assessing the effectiveness of a novel anti-fog coating.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Since there is currently no other gold-standard, anti-fog coating for personal protective equipment eyewear, future studies may compare this polymer to other coatings on the market. Further studies are required to determine durability, longevity and effectiveness of this novel anti-fog coating after prolonged periods of wear in non-disposable eyewear.

experience and perceived mitigation of potential medical errors.

## BACKGROUND

Donning personal protective equipment (PPE) is mandatory while caring for patients during the COVID-19 pandemic

to prevent the spread of infection. In emergency departments (EDs) and other healthcare settings, PPE typically consists of protective masks, gloves, gowns and protective eyewear. Eye protection is essential to prevent the spread of viral particles through mucosal membranes and is now a mandatory component of the PPE used during patient encounters, notably for suspected or confirmed cases of COVID-19 and during aerosolising procedures.<sup>1</sup> This is recommended by leading health agencies such as the Centers for Disease Control and Prevention and the Occupational Safety and Health Administration.<sup>2,3</sup> In our experience working at a large tertiary-care hospital, fogging of protective eyewear is a frequent problem experienced by many front-line providers and may impact patient care, provider safety and experience, and adherence to proper wear and usage. Several studies in the literature describe this widespread problem too, but few offer solutions.<sup>4–7</sup> Fogging of protective eyewear is frequently produced through moisturised, expired air leaking around the contours of masks. Unfortunately, fog-resistant protective eyewear currently on the market make claims that are often unfounded and have not been properly tested in clinical environments.<sup>8,9</sup>

Although PPE eyewear is considered essential in preventing occupational risk to healthcare workers, practical considerations must be addressed to ensure there are not issues related to fogging that may impact patient and provider safety as well as user experience. A study by Jordan and Pritchard-Jones<sup>10</sup> found that a tightly sealed face mask, such as the N-95 mask, is effective in reducing fogging. Although this is a simple and effective method, N-95 masks are more expensive and relatively scarce compared with surgical masks. Also, these masks are less comfortable due to their tight-fitting design and have been associated with other side effects after prolonged use. A cross-sectional study by Ong *et al*<sup>11</sup> found that the combined usage of the N-95 mask with protective eyewear was independently associated with developing *de novo* PPE-associated headaches. Another reported method to prevent fogging is the application of an adhesive strip on the nasal bridge–mask junction to block some of the air leakage around the nasal ridge.<sup>12</sup> Application of a detergent-based surfactant (eg, soapy water) that is then dried with a cloth has also been shown to temporarily reduce fogging by creating lower surface tension on the lens, which causes the water molecules to spread out more thinly thereby decrease the scattering of light.<sup>7,8,13,14</sup> Anti-fogging sprays and gels, used widely by scuba divers,<sup>15</sup> have a similar mechanism of action to the application of a detergent based surfactant. However, these require frequent reapplication, can be cumulatively expensive and require more user diligence as compared with a durable anti-fog coating.<sup>7</sup> Hence, these alternative solutions offer only temporary, postmanufacturing fogging reductions. Although other anti-fog coated lenses do exist, we are not aware

of any that have been effectively validated in a clinical environment. Furthermore, the lack of standardisation in PPE eyewear may prevent clinicians from developing proficiency and adherence in its use. To enhance safety and usage of PPE eyewear, increased attention needs to be directed towards anti-fogging performance in clinical settings.

Researchers at North Carolina State University initially discovered that a sulfonated polymer, BiaXam, produced by Kraton Polymers LLC, has inherently self-sterilising properties.<sup>16</sup> It was subsequently determined that the polymer also has anti-fog properties.<sup>17</sup> The hydrophilic property of this BiaXam sulfonated polymer may be able to decrease fogging through wicking moisture from the lens. To ensure widespread and safe usage of protective eyewear, eye protection must permit sufficient vision without disruptive fogging. Furthermore, fogging may not only impact the user-experience, but also impede providers' ability to safely perform critical tasks. In addition, removal of protective eyewear, even temporarily, to wipe down and defog the lens may also put the user at risk of infection, either through direct touching of one's face or through respiratory aerosols or droplets. In this first of its kind clinical trial, we sought to test the anti-fogging properties of this polymer when applied to protective eyewear in a real-world clinical setting in a high-throughput ED. In addition to anti-fog properties, we wished to assess the relative user-experience and safety factors as compared with current-use protective eyewear.

## METHODS

We conducted an investigator-initiated prospective, randomised, single-blinded cross-over study to assess the experience and effectiveness of an anti-fog sulfonated polymer coating in protective eyewear in April and May 2021. The study was performed in a high-volume ED in a large, tertiary hospital in Boston, Massachusetts, USA. Study participants included healthcare providers (physicians, advanced practice providers including physician assistants and nurse practitioners, and registered nurses) who were working on shift and caring for patients in the ED. Healthcare providers who also wore corrective eyeglasses were excluded from the study as it was assumed it would interfere with their ability to properly assess and distinguish fogging on their corrective lenses from the protective eyewear provided. Study participants were verbally consented prior to enrolment by trained, ED research associates. The research associates were additionally responsible for the randomisation of participants on REDCap, a secure electronic platform. The ambient condition of the ED is maintained in a relative humidity and temperature range of 30%–60% and 21°C–24°C, respectively.

Study participants were blinded and randomised to wear either a pair of disposable anti-fog coated

polyethylene terephthalate (PET) eyewear (intervention) or disposable uncoated PET eyewear (control). Both types of disposable eyewear appeared the same and were otherwise indistinguishable to the user. After the participant wore the first pair of eyewear for 2 hours, they were then provided with the alternative pair to wear for an additional 2 hours. Participants wore the goggles during the course of their clinical duties with typical tasks including, for example, patient assessment, intravenous line placement, blood draws, reading of vitals signs and electronic medical record (EMR) data, administration of medications, and endotracheal intubation. Each study participant acted as their own control according to the crossover design of the study. The study participants completed an identical electronic survey on REDCap at the end of each 2-hour period. Statistical analysis was performed to evaluate for user-experience differences between uncoated and coated eyewear. A subgroup analysis was also performed to determine differences based on the type of mask worn by the user during the study. McNemar's test was performed to test for significance on paired survey questions with nominal responses and the Student's t-test was performed to test for significance on ordinal scale, interval data (Likert scale responses). A p value < 0.05 was considered statistically significant. SAS V.9.4 was used for statistical analysis.

## RESULTS

### Demographics

Overall, 50 emergency medicine healthcare providers were enrolled in the study. Two participants (0.04%) were eliminated from the study after not completing both surveys. Overall, 48 emergency medicine healthcare providers completed the study. Of the 48 participants who completed the study, there were 15 physicians, 18 advanced practice providers and 15 registered nurses. Overall, 30 (62.5%) of the participants were female and 18 (37.5%) were men with a reported mean age of 30–34 years with participants

ranging from 25 to 64. 29 (60%) of participants were first randomised to the anti-fog coated eyewear.

## SURVEY RESULTS

### Entire cohort

Survey results (table 1) demonstrate a significant difference in fogging between the coated and uncoated eyewear, as 39 (81%) of the participants reported any fogging of the uncoated eyewear and only 26 (55%) of the participants reported fogging in the coated pair (p=0.0029). Participants reported that the uncoated eyewear fogged two times as frequently on a 10-point Likert scale (4.5±3.3 vs 2.1±2.5; p<0.0001). Two times as many participants also reported that the uncoated eyewear had fogging that may have impacted the care of their patients and possibly led to safety concern(s) (35% vs 17%; p=0.0067). Similarly, participants reported that fogging of the uncoated eyewear limited their ability to perform patient-centric tasks more frequently than the coated eyewear (2.5±3.0 vs 1.4±2.5; p=0.0425). Fogging of the uncoated eyewear caused participants to touch their face nearly two times as frequently compared with the coated eyewear (3.4±3.3 vs 1.8±2.8; p=0.0181). Aside from fogging, there was no significant difference in distortion or limitation of one's vision between the two pairs of protective eyewear (p=0.2274).

### Subgroup analysis: surgical mask only

A subgroup analysis of the participants who wore only a surgical mask (n=15) during the entire duration of the study was performed (table 2). Overall, results demonstrate a significance in reduction of 'ever' fogging and 'frequency' of fogging, as well as improved safety while performing clinical duties while wearing the coated eyewear. The participants who wore only a surgical mask reported higher efficacy and improved experience relative to that of the entire cohort.

**Table 1** Entire cohort analysis (n=48)

Survey questions	Percentage of respondents who answered 'yes'		
	Uncoated (control)	Coated (intervention)	P value
Did the goggles you just wore ever fog while wearing them on today's shift?	39/48 (81%)	26/48 (55%)	0.0029
Were there any instances today that fogging of the goggles you have just worn may have impacted the care of your patient and possibly have led to a safety concern (eg, fogging while performing a procedure, difficulty with reading the patient monitor or labels, etc)?	17/48 (35%)	8/48 (17%)	0.0067
	Mean (0 (not at all) to 10 (very frequently))		
How often did the goggles fog?	4.5±3.3	2.1±2.5	<0.0001
How often did fogging of your goggles limit your ability to perform your tasks (eg, reading, communicating, performing procedures, etc)?	2.5±3.0	1.4±2.5	0.0425
Aside from fogging, did the goggles you wore limit or distort your vision?	1.5±2.4	2.0±2.6	0.2274
Approximately how often did fogging of the goggles you have just worn cause you to touch your face or head to either remove your goggles and/or face mask?	3.4±3.3	1.8±2.8	0.0181
Survey responses for nominal and Likert scaled questions.			

**Table 2** Subgroup analysis: surgical mask only (n=15)

Survey questions	Percentage of respondents who answered 'yes'		
	Uncoated (control)	Coated (intervention)	P value
Did the goggles you just wore ever fog while wearing them on today's shift?	13/15 (87%)	7/15 (47%)	0.0143
Were there any instances today that fogging of the goggles you have just worn may have impacted the care of your patient and possibly have led to a safety concern (eg, fogging while performing a procedure, difficulty with reading the patient monitor or labels, etc)?	6/15 (40%)	1/15 (7%)	0.0253
	Mean (0 (not at all) to 10 (very frequently))		
How often did the goggles fog?	5.5±3.7	2.2±2.7	0.0151
How often did fogging of your goggles limit your ability to perform your tasks (eg, reading, communicating, performing procedures, etc)?	3.7±3.7	1.1±2.1	0.0439
Aside from fogging, did the goggles you wore limit or distort your vision?	1.8±2.9	2.2±2.2	0.791
Approximately how often did fogging of the goggles you have just worn cause you to touch your face or head to either remove your goggles and/or face mask?	4.9±3.8	2.1±3.2	0.0313
Survey responses for nominal and Likert scaled questions.			

**Subgroup analysis: N-95 mask only**

A subgroup analysis of the participants who wore only an N-95 mask (n=9) during the entire duration of the study was performed (table 3). In this subgroup analysis, there was no significant difference to any of the survey questions, including the frequency of fogging, how frequently fogging may have impacted patient care and provider safety and experience.

**DISCUSSION**

Our study demonstrates the effectiveness and improved provider experience while wearing anti-fog coated PPE eyewear in clinical settings particularly while also wearing a surgical mask. We believe the application of an anti-fog material, such as the BiaXam sulfonated polymer, to protective eyewear should be considered as one solution in remedying the widespread problem of fogging. The coated eyewear demonstrated a significant reduction in fogging both 'ever' and with respect to the frequency of fogging in what appears a clinically meaningful way. Importantly, healthcare providers perceived that the uncoated eyewear would significantly impact

clinical care negatively at approximately double the rate compared with coated pair (35% vs 17%). In subgroup analysis, this difference was even more dramatic in people wearing only surgical masks (40% vs 7%). However, the difference in fogging or perceived negative care impacts was not seen when wearing only N-95 masks. Hence, our findings corroborate the study by Jordan and Pritchard-Jones<sup>10</sup> that found tightly sealed face masks, such as N-95's, are effective in reducing fogging. This is not an unexpected finding given that the design and seal of N-95 masks permits less moisturised expired air leaks than the more commonly worn surgical masks.

The barriers to increased or uniform usage of N-95 masks, the short-term nature and increased user diligence required for many alternative anti-fog measures, as well as the dearth of other studies looking at the impact of fogging of eyewear in the clinical setting have resulted in inadequate anti-fog eyewear solutions in healthcare. We believe this study demonstrates the effectiveness of this anti-fog eyewear coating while wearing a mask in a clinical setting.

**Table 3** Subgroup analysis: N-95 mask only (n=9)

Survey questions	Percentage of respondents who answered 'yes'		
	Uncoated (control)	Coated (intervention)	P value
Did the goggles you just wore ever fog while wearing them on today's shift?	5/9 (56%)	6/8 (75%)	0.3173
Were there any instances today that fogging of the goggles you have just worn may have impacted the care of your patient and possibly have led to a safety concern (eg, fogging while performing a procedure, difficulty with reading the patient monitor or labels, etc)?	0/9 (0%)	1/8 (13%)	p=N/A
	Mean (0 (not at all) to 10 (very frequently))		
How often did the goggles fog?	1.4±1.7	2.0±2.1	0.6875
How often did fogging of your goggles limit your ability to perform your tasks (eg, reading, communicating, performing procedures, etc)?	0.4±0.7	1.1±2.3	0.5
Aside from fogging, did the goggles you wore limit or distort your vision?	0.9±1.2	1.4±1.6	0.5
Approximately how often did fogging of the goggles you have just worn cause you to touch your face or head to either remove your goggles and/or face mask?	0.9±1.2	1.7±2.3	0.5
Survey responses for nominal and Likert scaled questions.			



A recent study by Herkert *et al*<sup>18</sup> at Duke's Nicholas School of the Environment found that anti-fogging sprays and cloths commonly used to prevent fogging on protective eyewear may contain high levels of polyfluorinated alkyl substances. Exposure to these substances has been associated with toxicological effects such as impaired immune function, cancer and thyroid disease. With this concern, the authors of this study requested safety information of BiaXam from the manufacturer and received a statement from the Kraton Polymers LLC Product Safety and Regulatory Team. 'BiaXam is considered a polymer of low concern to human and environmental health and meets the US EPA Polymer Exemption criteria (40 CFR 723.250). The BiaXam polymer is over 99% pure, with no known persistent, bioaccumulative or toxic substances intentionally added to the pure polymer. In addition, no known carcinogenic, mutagenic or reproductive substances are intentionally blended into the pure polymer. Results from independent laboratory studies performed to date report no detected adverse aquatic toxicity, dermal irritation, dermal toxicity or sensitisation effects, and continue to support the conclusion that BiaXam is a low risk to human health and the environment.'

Our study evaluated the effectiveness and experience after clinicians wore each type of PPE eyewear (coated and uncoated) for 2 hours. This is a reasonable duration given the short-term use, and disposable design of the eyewear used for this study. However, future studies are needed to evaluate the durability and longevity of this polymer in non-disposable eyewear. Also, given the hydrophilic nature of this polymer (and other, anti-fog polymers), further evaluation of anti-fog properties should be evaluated with longer uses as the anti-fog properties may have a saturation threshold and, hence, may become less effective over time. Lastly, our study compared the anti-fog properties of a sulfonated polymer against an uncoated pair in order to understand its effectiveness, as well as the importance of anti-fog lenses in the clinical setting. Since there is currently no other gold-standard, anti-fog coating for PPE eyewear, future studies may compare this polymer to other commonly used coatings on the market.

## CONCLUSION

Overall, BiaXam-coated protective eyewear greatly improved provider's visualisation due to its anti-fogging properties and was perceived to have significantly reduced potential negative care impacts and improved user's experiences for providers wearing a protective face mask. Due to the improved experience of wearing the coated eyewear, it is anticipated that the BiaXam coating would aid with improved eyewear-mandate compliance. Further study is required to determine durability and effectiveness of this novel anti-fog coating after prolonged periods of wear.

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**Contributors** YGK and KRO were responsible for the study's conceptualisation, design, implementation and are the guarantors of this study. JDM assisted in data collection. YGK, KRO and HZ performed the data analysis. YGK and KRO interpreted the results. YGK and KRO wrote the original draft of the manuscript. ASR and JDM provided edits and revisions to the manuscript.

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**Competing interests** YGK and KO received grant funding from Kraton Polymers LLC to sponsor the costs of this investigator-initiated study. No Kraton Polymers LLC personnel participated in the study design, implementation, interpretation of results or writing of the manuscript. The decision to submit the paper for publication was solely the decision of the investigators.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not applicable.

**Ethics approval** This study involves human participants and was approved by Mass General Brigham IRB, approved on 8 January 2021, protocol number 2020P003998. Participants gave informed consent to participate in the study before taking part.

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** Data are available upon reasonable request.

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**PARTNERS HUMAN RESEARCH COMMITTEE  
PROTOCOL SUMMARY**

**Answer all questions accurately and completely in order to provide the PHRC with the relevant information to assess the risk-benefit ratio for the study. Do not leave sections blank.**

**PRINCIPAL/OVERALL INVESTIGATOR**

Kristian Olson, MD, MPH (PI)  
Yonatan Keschner, MD (CO-I)  
Ali Raja, MD, MBA, MPH (CO-I)

**PROTOCOL TITLE**

Assessing the experience and effectiveness of a novel anti-fog polymer coating in protective eyewear.

**FUNDING**

Kraton Polymers LLC.

**VERSION DATE**

12.14.20

**SPECIFIC AIMS**

Concisely state the objectives of the study and the hypothesis being tested.

To conduct a randomized, cross-over study assessing the experience and effectiveness of a novel, sulfonated anti-fog polymer in protective eyewear.

**BACKGROUND AND SIGNIFICANCE**

Provide a brief paragraph summarizing prior experience important for understanding the proposed study and procedures.

Personal protective equipment (PPE) must be worn while caring for all patients during the current COVID-19 pandemic in order to prevent the contagious spread of infection. Eye protection is essential and is a mandatory component of the PPE that must be worn for all patient encounters. Current eyewear is problematic due to frequent fogging. This problem is greatly exacerbated due to healthcare providers need to wear face masks that directs humidified exhaled air upwards towards their eyewear. This problem is not only annoying to the wearer, but impacts their vision and can lead to safety issues. Additionally, it has been found that many providers do not comply with the eye protection mandate due to fogging. Furthermore, many providers have been purchasing their own, non-approved protective eyewear. Many brands purport to be anti-fog, which is often an inaccurate claim.

We have identified a novel, sulfonated polymer that appears to provide superior anti-fog properties to eyewear. This polymer is produced by Kraton Corporation, a polymer company. We will apply this novel polymer to the protective eyewear that is currently in use at MGH. Prototypes of this anti-fog coated eyewear have been produced, and pre-clinical feedback has demonstrated spectacular performance.

### **Demonstration of anti-fog coated vs non-coated goggle**

**Non-coated section**

**Anti-fog coated section**





## RESEARCH DESIGN AND METHODS

Briefly describe study design and anticipated enrollment, i.e., number of subjects to be enrolled by researchers study-wide and by Partners researchers. Provide a brief summary of the eligibility criteria (for example, age range, gender, medical condition). Include any local site restrictions, for example, "Enrollment at Partners will be limited to adults although the sponsor's protocol is open to both children and adults."

We will conduct a prospective, randomized, cross-over study of N=50 individuals. Study participants will involve healthcare providers in the MGH Emergency Department, including physicians, physician assistants, and registered nurses. The study will be a randomized, cross-over design, where the participant will be given either a standard goggle or anti-fog coated goggle, and then switch to the other pair after a set time. The participant will wear each goggle type for 2 hours. At the end of each 2-hour period, the study participant will complete a survey (see Appendix A). The survey will measure the participants experience wearing both types of goggles in order to determine if there is a significant difference between the two types of goggles. Specifically, we would like to measure the frequency of fogging, how fogging limited their ability to perform essential tasks, how it may have impacted their ability to care for patients, and their ability to comply with eye protection standards. All participants will be screened, consented and enrolled by trained ED research assistants (RAs). Survey data will be de-identified and collected through RedCAP.

### Inclusion criteria:

- Physicians (Attendings, Fellows, and Residents), Physician Assistants, and Registered Nurses.
- Providing care to patients in the MGH Emergency Department

### Exclusion criteria:

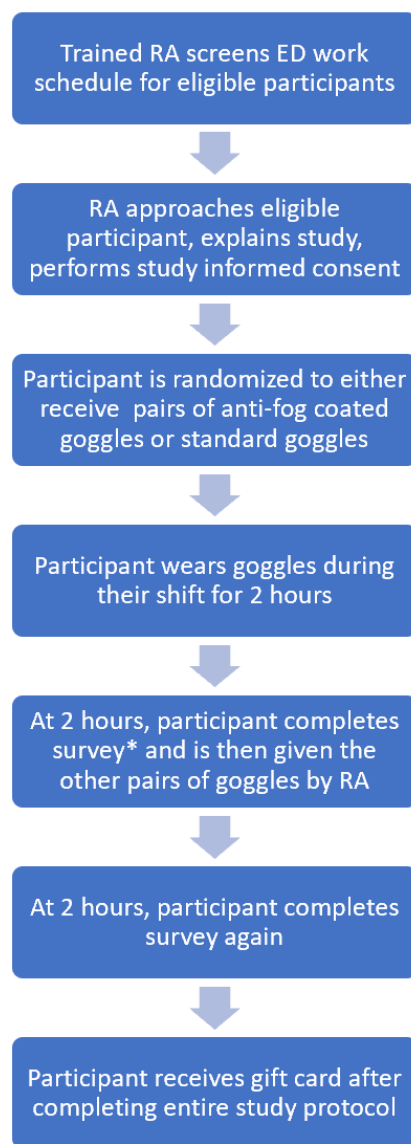
- Wear corrective eyeglasses
- Unable to wear protective eye goggles
- Prior participation in this study

After completing both surveys, participants will be compensated \$20 in a gift card to MGH Coffee Central.

The participant may elect to withdraw at any time during the study. Any withdrawals from the study will be tallied in anonymous fashion by the study personnel. Participation in this study does not preclude the subject from participating in any other research studies.

Briefly describe study procedures. Include any local site restrictions, for example, “Subjects enrolled at Partners will not participate in the pharmacokinetic portion of the study.” Describe study endpoints.

### Study Flow Diagram Overview:



\*Survey will be completed through RedCAP. Survey questions may be found in appendix.

### Detailed study procedures:

1. RA's identify eligible participants from daily ED work schedule.
2. RA's block-randomize, via computer based random number generator based on number in each list. Each list will contain eligible Physicians, Physician Assistants, and Registered Nurses, and approach eligible participants.

3. RA describes purpose of study and summary of protocol, requests participation, and performs informed consent.
4. RA uses computer randomizer to determine if an anti-fog goggles or standard (uncoated) goggles are distributed first.
5. RA provides new pair(s) of coated or uncoated goggle(s) to study participant per randomization.
6. Participant uses study protective goggles (eyewear is mandated per MGH PPE policy) for two hours.
7. After two hours, participant is approached (at a time that does not interfere with clinical duties). Survey is completed by study participant through RedCap.
8. First pair of study goggles are collected and stored for disposal in designated receptacle. Participant is then given other pair(s) of goggles.
9. Participant, again, uses study protective goggles (eyewear is mandated per MGH PPE policy) for two hours.
10. After two hours, participant is approached (at a time that does not interfere with clinical duties). Survey is completed by study participant through RedCap.
11. RA provides \$20 Coffee Central gift card to participant after completing the second survey.

Of note: If the participant ever requests a replacement pair(s) during the study period, the RA will be able to provide them with a replacement. If the study participant is unable to use the goggle or is dissatisfied with the study goggle (anti-fog), the study participant will be provided with the standard (not anti-fog) goggle and be asked to complete survey at this time. Study participants can withdraw from the study at any time.

For studies involving treatment or diagnosis, provide information about standard of care at Partners (e.g., BWH, MGH) and indicate how the study procedures differ from standard care. Provide information on available alternative treatments, procedures, or methods of diagnosis.

Not applicable.

Describe how risks to subjects are minimized, for example, by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk or by using procedures already being performed on the subject for diagnostic or treatment purposes.

We will minimize risks to potential participants by ensuring anonymity during the enrollment procedures. There will be no PHI collected for the purpose of this study. All study data (including survey data and participant information, such as role and gender) will be completed on a secure Partners tablet computers or desktop computers. Tablets and results will be secured using MobileIron and password protected.

Safety goggles utilized (coated and uncoated) are equivalent to the model that are in current use, and, as such, will provide equivalent protection.

In addition, RA will provide new, clean goggles to participants with gloved hands and will clean tablet surfaces (used for survey collection) by the standard hospital cleaning protocol before providing to participants.

Describe explicitly the methods for ensuring the safety of subjects. Provide objective criteria for removing a subject from the study, for example, objective criteria for worsening disease/lack of improvement and/or unacceptable adverse events. The inclusion of objective drop criteria is especially important in studies designed with placebo control groups.

Study participants will be able to leave the study at will, at any time. If study participants are having difficulty with the anti-fog coated protective eyewear (e.g. problem with fogging, distorted vision, etc), participant will immediately be given the standard eyewear (control) that is currently being used in the department. We will also be able to provide replacement eyewear to participants (e.g. participant misplaces or soils their given pair) at any time during the study.

#### **FORESEEABLE RISKS AND DISCOMFORTS**

Provide a brief description of any foreseeable risks and discomforts to subjects. Include those related to drugs/devices/procedures being studied and/or administered/performed solely for research purposes. In addition, include psychosocial risks, and risks related to privacy and confidentiality. When applicable, describe risks to a developing fetus or nursing infant.

There should not be any large risks or discomforts to the subjects. The study will be using the current standard protective eyewear distribute to healthcare providers in the ED. The only difference between the pairs, is that one will be coated with an anti-fog coating. The coating does not cause any safety or health concerns. This polymer has been used in consumer products for a long time, including diapers. The risk of harm due to the anti-fog coating is minimal. Please see Kraton Safety Data Sheet for more information.

#### **EXPECTED BENEFITS**

Describe both the expected benefits to individual subjects participating in the research and the importance of the knowledge that may reasonably be expected to result from the study. Provide a brief, realistic summary of potential benefits to subjects, for example, "It is hoped that the treatment will result in a partial reduction in tumor size in at least 25% of the enrolled subjects." Indicate how the results of the study will benefit future patients with the disease/condition being studied and/or society, e.g., through increased knowledge of human physiology or behavior, improved safety, or technological advances.



We anticipate that this study will demonstrate increased satisfaction and ability to safely perform clinical duties while wearing new, anti-fog coated eye protection. We expect these anti-fog coated goggles to be superior than what is currently being used in the hospital.

### **EQUITABLE SELECTION OF SUBJECTS**

The risks and benefits of the research must be fairly distributed among the populations that stand to benefit from it. No group of persons, for example, men, women, pregnant women, children, and minorities, should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.

We will never exclude individuals based on gender, ethnicity, religion, sex or race. We anticipate enrolling study participants that will mirror the demographics of the healthcare providers that work in our emergency department.

When people who do not speak English are excluded from participation in the research, provide the scientific rationale for doing so. Individuals who do not speak English should not be denied participation in research simply because it is inconvenient to translate the consent form in different languages and to have an interpreter present.

All healthcare providers (physicians, physician assistants, and nurses) who work at the MGH emergency department speak English.

For guidance, refer to the following Partners policy:

Obtaining and Documenting Informed Consent of Subjects who do not Speak English

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Non-English-Speaking-Subjects.pdf>

### **RECRUITMENT PROCEDURES**

Explain in detail the specific methodology that will be used to recruit subjects. Specifically address how, when, where and by whom subjects will be identified and approached about participation. Include any specific recruitment methods used to enhance recruitment of women and minorities.

1. RA's identify eligible participants at the beginning of each shift from staffing lists in the ED.
2. RA's block computer randomize eligible MDs, Physician Assistants, and RN's and approach at least one in sequential order of blocks until at their research shift capacity.

Provide details of remuneration, when applicable. Even when subjects may derive medical benefit from participation, it is often the case that extra hospital visits, meals at the hospital, parking fees or other inconveniences will result in additional out-of-pocket expenses related to study participation. Investigators may wish to consider providing reimbursement for such expenses when funding is available

A \$20 give card to Coffee Central will be provided to all participants after they complete the study.

For guidance, refer to the following Partners policies:

Recruitment of Research Subjects

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Recruitment-Of-Research-Subjects.pdf>

Guidelines for Advertisements for Recruiting Subjects

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Guidelines-for-Advertisements.pdf>

Remuneration for Research Subjects

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Remuneration-for-Research-Subjects.pdf>

## CONSENT PROCEDURES

Explain in detail how, when, where, and by whom consent is obtained, and the timing of consent (i.e., how long subjects will be given to consider participation). For most studies involving more than minimal risk and all studies involving investigational drugs/devices, a licensed physician investigator must obtain informed consent. When subjects are to be enrolled from among the investigators' own patients, describe how the potential for coercion will be avoided.

We plan on obtaining verbal for this study from study participants. Participants will be approached by a RA who will explain the study to them. If consenting, participants will provide a verbal consent. All consent procedures will take place in the emergency department.

NOTE: When subjects are unable to give consent due to age (minors) or impaired decision-making capacity, complete the forms for Research Involving Children as Subjects of Research and/or Research Involving Individuals with Impaired Decision-making Capacity, available on the New Submissions page on the PHRC website:

<https://partnershealthcare.sharepoint.com/sites/phrmApply/aieipa/irb>

For guidance, refer to the following Partners policy:

Informed Consent of Research Subjects:

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Informed-Consent-of-Research-Subjects.pdf>

## DATA AND SAFETY MONITORING

Describe the plan for monitoring the data to ensure the safety of subjects. The plan should include a brief description of (1) the safety and/or efficacy data that will be reviewed; (2) the planned frequency of review; and (3) who will be responsible for this review and for determining whether the research should be altered or stopped. Include a brief description of any stopping rules for the study, when appropriate. Depending upon the risk, size and complexity of the study, the investigator, an expert group, an independent Data and Safety Monitoring Board (DSMB) or others might be assigned primary responsibility for this monitoring activity.

NOTE: Regardless of data and safety monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for protecting the rights, safety, and welfare of subjects under his/her care.

The PIs will be available at all times by telephone or email to receive complaints or concerns from participants or would-be participants. We will also be available at any time to discuss any questions, events or concerns from the RAs. The PI will be responsible for determining whether the research should be altered or stopped based upon any adverse events reported by participants or by concerns raised by the RA's. All the adverse events will be monitored by the PI and will be reported in accordance with PHSRC policies. We do not plan to utilize a DSMB.

This project was reviewed and approved by MGH Infection Control. Notice of approval by MGH Infection Control sent by Meredith Fay ([mfahy1@partners.org](mailto:mfahy1@partners.org)) on 12/2/2020.

Describe the plan to be followed by the Principal Investigator/study staff for review of adverse events experienced by subjects under his/her care, and when applicable, for review of sponsor safety reports and DSMB reports. Describe the plan for reporting adverse events to the sponsor and the Partners' IRB and, when applicable, for submitting sponsor safety reports and DSMB reports to the Partners' IRBs. When the investigator is also the sponsor of the IND/IDE, include the plan for reporting of adverse events to the FDA and, when applicable, to investigators at other sites.

NOTE: In addition to the adverse event reporting requirements of the sponsor, the principal investigator must follow the Partners Human Research Committee guidelines for Adverse Event Reporting

We will follow all standard Partners IRB procedures for monitoring and reporting adverse events.

## MONITORING AND QUALITY ASSURANCE

Describe the plan to be followed by the principal investigator/study staff to monitor and assure the validity and integrity of the data and adherence to the IRB-approved protocol. Specify who will be responsible for monitoring, and the planned frequency of monitoring. For example, specify who will review the accuracy and completeness of case report form entries, source documents, and informed consent.

NOTE: Regardless of monitoring plans by the sponsor or others, the principal investigator is ultimately responsible for ensuring that the study is conducted at his/her investigative site in accordance with the IRB-approved protocol, and applicable regulations and requirements of the IRB.

We do not anticipate convening a DSMB for the study. The study PI and Co-I will conduct a data review with a random sample of the first 10 enrollees to determine that there are no issues with completion. All surveys will be monitored for completeness at the point of completion by study RAs. All discrepancies in data entry will be managed by the study PI and Co-I.

Prior to enrollment, all study RAs will be trained by the study PI/Co-I. We will conduct mock enrollments to ensure that RAs are adequately trained prior to enrollment of study participants.

We will continue to report all adverse events in compliance with PHRC reporting requirements.

For guidance, refer to the following Partners policies:

Data and Safety Monitoring Plans and Quality Assurance

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/DSMP-in-Human-Subjects-Research.pdf>

Reporting Unanticipated Problems (including Adverse Events)

<https://www.partners.org/Assets/Documents/Medical-Research/Clinical-Research/Reporting-Unanticipated-Problems-including-Adverse-Events.pdf>

## PRIVACY AND CONFIDENTIALITY

Describe methods used to protect the privacy of subjects and maintain confidentiality of data collected. This typically includes such practices as substituting codes for names and/or medical record numbers; removing face sheets or other identifiers from completed surveys/questionnaires; proper disposal of printed computer data; limited access to study data; use of password-protected computer databases; training for research staff on the importance of confidentiality of data, and storing research records in a secure location.



NOTE: Additional measures, such as obtaining a Certificate of Confidentiality, should be considered and are strongly encouraged when the research involves the collection of sensitive data, such as sexual, criminal or illegal behaviors.

A confidential register of participants will be maintained on password protected device in order to ensure that already completed participants are not re-approached. This list will not be linked to responses nor will it be shared and it will be destroyed at the completion of the trial. In addition, data will be anonymized and analyzed as such after completion of the RedCap Surveys.

#### **SENDING SPECIMENS/DATA TO RESEARCH COLLABORATORS OUTSIDE PARTNERS**

Specimens or data collected by Partners investigators will be sent to research collaborators outside Partners, indicate to whom specimens/data will be sent, what information will be sent, and whether the specimens/data will contain identifiers that could be used by the outside collaborators to link the specimens/data to individual subjects.

Not applicable.

Specifically address whether specimens/data will be stored at collaborating sites outside Partners for future use not described in the protocol. Include whether subjects can withdraw their specimens/data, and how they would do so. When appropriate, submit documentation of IRB approval from the recipient institution.

Not applicable.

#### **RECEIVING SPECIMENS/DATA FROM RESEARCH COLLABORATORS OUTSIDE PARTNERS**

When specimens or data collected by research collaborators outside Partners will be sent to Partners investigators, indicate from where the specimens/data will be obtained and whether the specimens/data will contain identifiers that could be used by Partners investigators to link the specimens/data to individual subjects. When appropriate, submit documentation of IRB approval and a copy of the IRB-approved consent form from the institution where the specimens/data were collected.

Not applicable.