
**Assessment of Personal Protective Equipment for Dental Healthcare
Professionals (PPE for DHCPs)**

Principal Investigator:

Jennie H. Kwon, DO, MSCI

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A Introduction

A1 Study Abstract

Coronavirus Disease 2019 (COVID-19) is one of the greatest global public health threats that the world has encountered in the 21st century. The Occupational Health and Safety Administration (OSHA) places dental healthcare providers (DHCP) in the very high exposure risk category for being exposed to SARS-CoV-2, the virus that causes COVID-19. However, data regarding the transmission dynamics of infectious agents in dental settings is limited, and studies evaluating methods to prevent organism transmission in dentistry are urgently needed. HCPs regularly interact with patient saliva, which have high viral loads of SARS-CoV-2 in infected patients. Although it is discouraged to perform procedures on individuals with active COVID-19, epidemiologic data indicates that there are individuals who asymptotically carry SARS-CoV-2, and it is unclear if these individuals can then transmit the virus to others. This is further complicated by the lack of SARS-CoV-2 testing availability, especially to asymptomatic individuals. Thus, appropriate personal protective equipment (PPE) is necessary to protect DHCPs from SARS-CoV-2. However, data regarding the transmission of infectious agents when utilizing PPE in the dental setting is limited. Most transmission dynamics studies regarding PPE use is in hospital workers, however DHCPs have different and specific needs than that of a hospital HCP.

A2 Purpose of the Study Protocol

The purpose of this proposal is to identify whether there are gaps in PPE donning and doffing by DHCPs, and pilot an educational video to improve PPE donning and doffing techniques.

The findings from these studies will be immediately shared with the National Dental Practice-Based Research Network and American Dental Association for rapid dissemination to the DHCPs and the public, and to improve methods to protect DHCPs from COVID-19.

B Background

B1 Prior Literature and Studies

Few data exist on interventions to improve PPE donning/doffing among DHCPs; however, data have been published on PPE use among hospital HCPs. In a previous study at WUSM (PI: Kwon), two surrogate markers, a fluorescence and the bacteriophage MS2, were used to assess for protocol deviations while donning and doffing the two types of PPE. Overall, when donning full PPE, 27% of HCPs had at least one protocol deviation; 50% had at least one protocol deviation when donning contact precautions PPE. When doffing full PPE, 100% of HCPs had at least one protocol deviation, vs. 67% of HCPs doffing contact precautions PPE. Fluorescence was detected on 44% of HCWs, mostly commonly on hands.¹

In a similar study, fluorescent powder and MS2 were applied to high-touch surfaces in patient rooms at BJH and HCPs were observed entering and exiting the patient room, and PPE use and hand hygiene were

recorded. The fluorescent powder was detected on 34% of HCPs upon exiting the room, indicating self-contamination during patient care and/or when doffing PPE.²

Together, these studies suggest that fluorescent powder can be a valuable educational tool to help HCPs understand how and when self-contamination may occur during PPE donning and doffing.

B2 Rationale for this Study

Educational interventions have been shown to be effective to improve PPE use in hospital HCPs, but this has not been fully explored with DHCPs. These educational resources may be useful to the National Institute of Dental and Craniofacial Research's (NIDCR) Dental Practice Based Research Network (DBPRN) to fulfill the need to provide resources and evidence for DHCPs on the policies and procedures necessary to utilize PPE properly in dental settings and provide DHCP specific PPE guidance. To our knowledge, no similar studies or educational materials exist for DHCPs. Therefore, this work will fulfill a critical and timely need in the setting of the COVID-19 pandemic.

C Study Objectives

C1 Specific Aims

1. Identify and quantify the type and number of protocol deviations when DHCPs don and doff PPE.
2. Characterize and quantify DHCP self-contamination while donning and doffing PPE utilizing fluorescent markers as a surrogate for infectious agents.
3. Develop and educational video focused on training DHCP on PPE donning and doffing techniques.

D Study Design

D1 Overview or Design Summary

This will be a cohort study with up to 120 DHCPs enrolled (60 in aims 1 and 2 and 60 in aim 3; some DHCPs may participate in all aims).

D2 Subject Selection and Withdrawal

2.a Inclusion Criteria

DHCPs will be eligible for enrollment if they provide written informed consent and are currently active in a dental care. DHCPs will include dentists and dental hygienists.

2.a Exclusion Criteria

None.

2.b Subject Recruitment Plans and Consent Process

Eligible DHCPs will be recruited from dental clinics in the St. Louis metropolitan area.

The study team has identified “dental champions” as collaborators at each site. These dental champions will introduce the study at each site, and will identify DHCPs interested in participating. This information will be shared with the study team, and these DHCPs will be contacted regarding enrollment in the study.

2.c Risks and Benefits

Fluorescent markers are commonly used in healthcare and restaurant/food environments as an educational tool for assessing hand hygiene with no risks to human health.

One potential risk to subjects is eye damage from exposure to UV/black light. Eye protection will be provided.

The other potential risk to subjects is a breach of confidentiality. As with any research, there is a potential risk of loss of privacy and inadvertent release of protected health information, and this can lead to psychological, social, or legal distress. The study team will protect against this risk by storing paper forms in locked file cabinets in locked offices. Electronic data will be stored in password-protected databases on secure network servers to which only select members of the study team have access. Videos and photos will be uploaded onto password-protected computers on secure network servers and deleted from the camera’s SD card or hard drive. Materials from this study, such as the camera and paper forms, will be carried in a locked case when transporting them between sites. Data will be stripped of all identifiers before being shared with the NIH or National Dental Practice-Based Research Network. Any manuscripts that result from this study will be written in such a way that individual participants cannot be identified. Data on DHCP contamination will be collected for study purposes only, and will not be shared with supervisors or effect employment.

There are no direct benefits to participants as a result of this study; however, we hope that the results of this study will help protect DHCPs from diseases such as COVID-19 in the future by providing data on the optimal strategies for dental PPE donning and doffing.

2.d Early Withdrawal of Subjects

Because donning and doffing will occur during the same study visit as enrollment, we do not expect any loss to follow-up during Aims 1 and 2. DHCPs who wish to withdraw before Aim 3 may do so by contacting the study team at the phone number listed on the consent document.

2.e Data Collection and Follow-up for Withdrawn Subjects

No further contact will occur with DHCPs that choose to withdraw from the study.

E Study Procedures

The study team will visit each participating facility on a day(s) convenient for the DHCPs at that facility. Study team members will introduce the study to DHCPs, answer any questions the DHCPs may have, and will obtain written, informed consent from DHCPs interested in participating.

Aims 1 and 2: DHCPs that choose to participate will be interviewed regarding demographics (age, gender, race), handedness (right or left), years in dental practice, level of PPE training, and type of DHCP (dentist vs.

hygienist vs. orthodontist, etc). DHCPs will be scanned with a blacklight for baseline fluorescence. Each subject will be instructed to don a gown, gloves, and surgical mask per their standard practice. The subjects will also be instructed to don any other appropriate equipment that they use during routine care, such as loops. The order and technique used to don PPE will be videotaped, observed, and recorded.

After donning PPE, DHCPs will be blindfolded and their PPE will be contaminated with a liquid fluorescent marker. To ensure the DHCPs are unaware of the locations of the fluorescent marker, the study team will also perform dummy applications with water.

DHCPs will then be instructed to doff PPE per their standard practices, and this will be videotaped and observed. After doffing, the study team will use an ultraviolet light to identify areas of fluorescent contamination. Areas of fluorescence will be photographed with a digital camera. The study team will then perform qualitative semi-structured interviews with DHCPs in order to ascertain comfort level with donning and doffing PPE, baseline knowledge of donning and doffing PPE, and interest level for educational materials related to donning and doffing PPE.

The study team will watch the videos and record protocol deviations on a standard data collection tool. The total number of protocol deviations per DHCP will be recorded for both donning and doffing.

Aim 3: Using the qualitative and quantitative data collected in Aims 1 and 2, the study team will develop an educational video specific to DHCPs on how to don and doff PPE. This video will include the specific order in which PPE should be donned and doffed and tips for common issues with self-contamination. This video will be shared with the dental champions and revised based on their comments. The study team will then return to the study sites and identify DHCPs interested in participating in this aim of the study. Written, informed consent will be obtained from interested DHCPs. Baseline data will be collected as described in Aims 1 and 2. DHCPs will be used to provide brief (<10 minute) feedback about the video using semi-structured interviews, focusing on acceptability, effectiveness, and potential for use in the clinic setting. The final video will be shared with the National Dental Practice-Based Research Network.

F Statistical Plan

F1 Sample Size Determination and Power

Based on prior PPE donning/doffing studies performed at WUSM/BJH, we anticipate 50% of individuals will have at least 1 protocol deviation. After an educational intervention, we anticipate that this protocol deviation rate will decrease to 25%. Based on an alpha of 0.05 and and beta of 0.80, we anticipate having to enroll 58 participants in Aims 1 and 2 and 58 patients in Aim 3.

F2 Data Management

Data will be recorded on standardized data collection forms and entered into a secure REDCap database to which only the select members of the study team will have access. Names of DHCPs who have consented to participate will be kept in a separate screening log from the REDCap database, and names will not be included on the paper data collection forms.

F3 Statistical Methods

Aims 1 and 2: The study team will evaluate correlation between protocol deviations, and quantity and location of PPE fluorescent contamination, with other covariates. Chi-square or univariate logistic regression will be used for categorical variables, and Mann-Whitney U will be used for continuous variables. Qualitative data will be transcribed and coded using a deductive approach from a code book developed by the research team.

Aim 3: The interviews will be assessed for feasibility and utility of the video in the clinic setting. A Likert-type scale will be utilized to assess these measures. Data analyses will be descriptive.

G Data Handling and Record Keeping

G1 Confidentiality and Security

To protect against loss of confidentiality, all electronic data will be stored in a password-protected electronic database on the password-protected, HIPAA-compliant server maintained and operated by Washington University Information Technology (WUIT). Data access in REDCap will be restricted to key study personnel. Participant name will be kept in a separate file from the remainder of the study data and will be linked by a unique identification number. Study data will never be transferred electronically via e-mail or protocols. Shredders will be used on any printed material containing PHI. Individually identifiable or deducible data will not be transmitted by unsecured telecommunications, which include the Internet, e-mail, texting, and electronic FTP. PHI will be available only to the PI, Dr. Kwon, and her direct research team. Only aggregate data will be reported in any abstracts or publications that result from this study.

G2 Training

Study personnel will receive training in how to operate the video camera used in this study, as well as proper techniques for applying the fluorescent marker.

G3 Case Report Forms and Source Documents

Case report forms and source documents will be stored in locked file cabinets in locked offices to which only select members of the study team have access.

G4 Records Retention

Records will be retained for 7 years after the closure of the study IRB.

H Study Administration

H1 Organization and Participating Centers

The lead site for this study is Washington University School of Medicine. The participating sites include:

1. St. Louis Children's Hospital pediatric dentistry
2. Deer Creek Dental (and other Heartland Dental office practices): restorative dentistry and orthodontics
3. St. Louis University Center for Advanced Dental Education: endodontics, orthodontics, periodontics, and pediatric dentistry

H2 Funding Source and Conflicts of Interest

This study is funded by the National Institutes of Health: National Institute of Dental and Craniofacial Research.

H3 Subject Stipends or Payments

Subjects will not receive any stipends or payments for participation in this study.

I References

1. Kwon JH, Burnham CD, Reske KA, et al. Assessment of Healthcare Worker Protocol Deviations and Self-Contamination During Personal Protective Equipment Donning and Doffing. *Infect Control Hosp Epidemiol.* 2017;38(9):1077-1083.
2. Kwon JH, Reske K, O'Neil CA, et al. Assessment of antibiotic-resistant organism transmission among rooms of hospitalized patients, healthcare personnel, and the hospital environment utilizing surrogate markers and selective bacterial cultures. *Infect Control Hosp Epidemiol.* 2020;41(5):539-546.