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**Quantifying and Reducing Aerosol  
Generation in Dental Settings**

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## **A Introduction**

### ***A1 Study Abstract***

Greater than 100,000 Americans have died from COVID-19. Many of these have included healthcare providers caring for both symptomatic and asymptomatic COVID-19 patients. Dental healthcare professionals (DHCPs) are estimated to be among the highest risk professionals for acquiring COVID-19. This risk is thought to be a combination of prolonged contact with oral secretions and aerosolization of SARS-CoV-2 during dental procedures. However, to our knowledge, no studies have actually evaluated the size of particles generated during dental procedures. Particle size has direct implications on what personal protective equipment (PPE) should be worn and environmental engineering strategies to reduce/minimize particle aerosolization in dental settings. Furthermore, without such data, dentists are currently employing non-evidence-based strategies to minimize aerosol generation in dental settings.

### ***A2 Purpose of the Study Protocol***

The purpose of this proposal is to: 1) quantify baseline air particle data in a variety of common dental settings; 2) quantify aerosol generation for common dental procedures in restorative dentistry, endodontics, periodontics, orthodontics, and pediatric dentistry; and 3) evaluate the impact of current non-evidence-based strategies employed by dentists to reduce aerosol generation in dental clinics.

## **B Background**

### ***B1 Prior Literature and Studies***

We have limited data on what constitutes an aerosol generating procedure (AGP) in dental settings. The CDC states that dental handpieces, air/water syringes, and ultrasonic scalers may generate aerosols. Other sources also include air polishers, prophylaxis angles, lasers, electrosurgery units, and hand instruments. Lack of data has led the CDC to recommend that dentists wear either a N95 respirator or a standard surgical mask with a face shield. Clear evidence of what is considered an AGP in dental settings would allow the CDC to provide concrete recommendations regarding when dentists should wear an N95 respirator (aerosol/airborne precautions) or a surgical mask (droplet precautions). These recommendations will protect dentists, dental hygienists, and dental assistants from acquiring COVID-19 from infected patients. Dentists and dental professional societies recommend using anti-retraction handpieces, rubber dams, and high-speed suction to reduce the risk of spreading aerosols in dental clinics. However, these recommendations are based on limited and conflicting data. Furthermore, none of the data actually evaluated particle size, which is needed to understand what PPE is necessary to protect DHCPs.

### ***B2 Rationale for this Study***

Our research plan rapidly addresses the critical knowledge gaps regarding the spread of SARS-CoV-2 in the dental healthcare setting. By using a combination of wearable air particle sensor and stationary aerosol characterization instruments, we can evaluate aerosol generation during dental procedures in a pragmatic fashion. The wearable air particle sensor can quantify discrete particle sizes that DHCPs would be exposed to during routine dental care. Aerosol characterization instruments can be placed at various distances from the patient and DHCPs to better understand the spectrum of particle sizes generated in a dental operator and how long aerosols remain in the air. These instruments can be deployed in a variety of common dental clinic

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settings, small offices with closed doors, dental offices with semi-open rooms, dental offices with large open bays, and surgical operating rooms. In collaboration with the Dental Practice Based Research Network (DPBRN), we will obtain additional insight regarding study design and knowledge dissemination from local and national dental experts from a variety of dental specialties.

## **C Study Objectives**

### ***C1 Specific Aims***

1. Measure and quantify aerosol particle size, and the duration of aerosolization in dental clinics.
2. Evaluate and quantify the level of aerosol generation in common dental procedures.
3. Measure the impact of common barriers on the reduction of aerosol generation.

## **D Study Design**

### ***D1 Overview or Design Summary***

We propose to 1) evaluate baseline air quality in a variety of dental clinic settings, 2) quantify the risk of aerosol generation by dental procedure type, and 3) determine whether currently employed non-evidence-based strategies actually reduce aerosol burden in dental clinics.

### ***D2 Subject Selection and Withdrawal***

#### **2.a Inclusion Criteria**

We will include any DHCPs performing common dental procedures during our study period at the study sites. Participating DHCPs must agree to wear particle sensors and document what dental procedures were performed and when they started.

#### **2.a Exclusion Criteria**

We will exclude any DHCPs unwilling to participate or unable to provide de-identified schedules to our research team.

#### **2.b Subject Recruitment Plans and Consent Process**

Eligible DHCPs will be recruited from the 3 participating dental clinics:

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

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.

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## 2.c Risks and Benefits

There are no risks associated with the use of the aerosol equipment or the wearing of sensors.

The only potential risk 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. 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.

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 quantifying aerosol formation during common dental procedures and evaluate current nonevidence-based strategies employed in dental settings to reduce aerosolization in dental settings.

## 2.d Early Withdrawal of Subjects

Not applicable

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

Not applicable

# 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 regarding aerosol collection.

Aims 1: We will deploy real-time aerosol characterization instruments to dental care settings located at St. Louis Children's Hospital, Deer Creek Dental, and St. Louis University. Each dental clinic will be sampled in separate locations prior to any procedures and sampling will continue for a 24-hour period. This process will be repeated on at least 5 separate occasions per methods previously described. Our environmental sensor: AeroTrak Portable Particle Counter (TSI, Inc.) estimates particle surface area ( $\mu\text{m}^2/\text{cm}^3$ ) and identifies concentrations of particles (PM 10, PM 2.5, PM 1.0) capable of depositing in the alveolar region of the human lung.

Aim 2: We will use real-time aerosol characterization instruments to measure aerosols generated during pre-defined dental procedures in dental care settings located at St. Louis Children's Hospital, Deer Creek Dental, and St. Louis University. These procedures may include but are not limited to cleanings, filling cavities, performing root canals, dental scaling, and dental extractions. In addition to dental procedures, we will also explore the impact of conscious dental sedation interventions, such as nitrous oxide, on aerosol generation. This is because high flow nasal cannula can be considered an aerosol generating procedure in medical settings. Furthermore, we will explore the impact of lasers and electrosurgery, which can cause smoke plumes, which may contain human papillomavirus.

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**Aim 3:** We will evaluate the impact of just-in-time, non-evidence-based strategies to reduce aerosol burden during dental procedures on aerosol generation. We will create a list of high-risk dental procedures based on results from Aim 2. We will then gather a list of aerosol mitigation devices from a literature review, our clinical champions, and our dental content experts. We anticipate this will include rubber dams, high-speed suction (with and without adapters), and anti-retraction hand pieces. However, we will also explore incorporating existing tools in medical settings, such as portable high efficiency particulate air (HEPA) filters. After we collect the list of procedures and aerosol mitigation devices, we will evaluate the impact of each mitigation device on aerosol generation. We will use the same four cart-based aerosol characterization instruments, baseline data, and statistical comparison approach described in Aim 2 for our analysis.

## **F Statistical Plan**

### ***F1 Sample Size Determination and Power***

As no previous aerosol data exists in dental settings, it is not possible to perform standard power and sample size calculations. However, we anticipate collecting 5 samples for each procedure based on our previous experience. This would include roughly 30 collection periods for each clinic location or aim 1. For aims 2 and 3, we anticipate collecting data on at least 10 different procedures. This will likely be 50 collection periods for aim 2. For the impact of risk mitigation interventions, we expect to perform a similar number of collection periods, depending on the number of high-risk procedures and non-evidence-based risk mitigation devices tested.

### ***F2 Data Management***

Data will be recorded on standardized data collection forms and entered into a secure database to which only the select members of the study team will have access. Names will not be included on the paper data collection forms.

### ***F3 Statistical Methods***

For aim 1, we will calculate averages and standard deviations for all aerosol characterization data (particle counts, mass, size, lung deposited surface area). This statistical approach has been used by our team in previous CDC-funded projects. This will allow us to compare baseline data from each clinic type. Testing for statistical significance is generally not performed with this approach. However, if desired by the NIDCR or DPBRN, we will use paired statistical tests to evaluate differences between clinics. The ultimate test will depend on normality of the data. The results of Aim 1 will allow us to compare baseline air quality across several dental clinic layouts, each with different facilities engineering designs. This data will provide further insights into how infection prevention engineering controls currently promote safe indoor air quality in dental care settings during the COVID-19 pandemic and serve as baseline data for Aim 2.

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.

For aims 2 and 3, we anticipate using a paired testing approach, such as a t-test or Wilcoxon signed rank test to compare quantity and duration of particulate matter at baseline and during a procedure. We will also stratify our results by particle size; smaller particles likely to travel further and deposit in the alveolar region of the lung (PM 1 and 2.5 micron) pose the greatest risk to human health. Based on this information, our team will assign an aerosol risk assessment for each dental procedure. This risk assessment will be stratified into high, medium, and low risk procedures.

## **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. Durkin, and his 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 aerosol equipment used in this study.

### **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.

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7

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