

## STUDY PROTOCOL

# Feasibility and acceptability of an oral pathology asynchronous tele-mentoring intervention: A protocol

Mary E. Northridge,<sup>1</sup> Tina Littlejohn,<sup>1</sup> Nathalie Mohadjeri-Franck,<sup>1</sup> Steven Gargano,<sup>1</sup> Andrea B. Troxel,<sup>2</sup> Yinxiang Wu,<sup>2</sup> Robert B. Bowe,<sup>1</sup> Paul A. Testa<sup>3</sup>

<sup>1</sup>Hansjörg Wyss Department of Plastic Surgery, Division of Dental Medicine, New York University (NYU Grossman School of Medicine, Brooklyn, NY

<sup>2</sup>Department of Population Health, Division of Biostatistics, NYU Grossman School of Medicine, New York, NY

<sup>3</sup>Ronald O. Perelman Department of Emergency Medicine, NYU Grossman School of Medicine, New York, NY, USA

## Abstract

**Introduction:** Oral cancer remains prevalent, despite being largely preventable. The widespread use of technology at chairside, combined with advances in electronic health record (EHR) capabilities, present opportunities to improve oral cancer screening by dentists, especially for disadvantaged patients with severe health needs.

**Design and methods:** Using a mixed-methods approach, we will evaluate the feasibility and acceptability of integrating a tele-mentoring component into the identification of oral lesions using the following 3 methods: 1) administering provider surveys that consist of a checklist of 10 key components of the intervention based on process, and asking the dental provider subjects if each one was covered; 2) conducting semi-structured interviews informed by the Consolidated Framework for Implementation Research and the Implementation Outcomes Framework with dental resident subjects to assess specific barriers to sustaining the intervention and strategies for addressing these barriers to facilitate integration of the intervention into the routine workflow of the dental clinics; and 3) administering brief exit interviews with patient subjects regarding the acceptability of the intervention to assess satisfaction with the use of intra-oral cameras at chairside to screen for and refer patients with oral lesions and identification of these oral lesions via EHR and secure e-mail tele-mentoring with an oral pathology expert.

**Expected impact of the study for public health:** If successful, then later clinical trials will maximize the external validity of the intervention and facilitate the widespread implementation and dissemination of the model for the teaching of dentists and residents, with the ultimate goal of improving patient care.

## Introduction

### Oral cancer risks in low-income, racial/ethnic minority, and immigrant communities

In 2020, an estimated 53,260 people in the United States will be diagnosed with oral cavity and oropharyngeal cancer, and an estimated 10,750 people will die of these cancers.<sup>1</sup> The primary risk factors for oral cavity cancer are tobacco and alcohol use,<sup>1,2</sup> whereas the primary risk factor for oropharyngeal cancer is human papillomavirus (HPV) infection, particularly types 16 and 18.<sup>1,3</sup> Oral cancer risks are compounded in low-income, racial/ethnic minority, and immigrant communities by difficulties in accessing health care services and multiple linguistic, cultural, economic, and social barriers.<sup>4</sup> Immigrants who have lived in the United States for longer periods of time and possess higher degrees of acculturation may have different cancer risks (e.g., consumption of tobacco and/or alcohol, sexual behaviors) than immigrants who report fewer years of US residence or lesser degrees of acculturation.<sup>5,6</sup> For all population groups, cultural beliefs influence both health care choices and service use. For instance, among certain Asian subgroups, a strong sense of group collectivism exists, and individuality is submerged in the interest of group welfare.<sup>7</sup> Friends, neighbors, and family members are often accessed and consulted before turning to formal health care services,<sup>7</sup> which may delay the identification and diagnosis of cancer, including oral cancer, especially in rural and other remote communities where pathology expertise may be absent.<sup>8,9</sup>

Cancer incidence rates for sites within the oral cavity have generally shown a downward trend over recent decades in the United States, while incidence rates for oropharyngeal cancer have

### Significance for public health

*This protocol demonstrates how to utilize implementation science methods to conduct a feasibility and acceptability study designed to integrate a tele-mentoring component into the identification of oral lesions at the 6 dental clinics of a Federally Qualified Health Center in Brooklyn, NY. It provides a model for embedded implementation research in a low-resource setting that may be adapted for diverse community health centers throughout the United States and the Caribbean. The study will evaluate whether or not the use of intra-oral cameras and a tele-mentoring component that facilitates consultation with an oral pathology expert aids in the detection and identification of oral lesions during routine dental visits.*

increased during this same time period.<sup>10,11</sup> One evidence-based strategy for reducing or preventing cancers at oral cavity sites is to attenuate or eliminate exposures to oral cancer risk factors through education, behavior change, and HPV vaccination, while a second evidence-based strategy is the identification of oral lesions suspicious for pre-malignancy or malignancy by dentists as part of preventive dental visits.<sup>12</sup> Suspicious lesions ought to undergo biopsy, whereas any other identified lesions ought to be reevaluated within 7-14 days and possibly undergo cytologic evaluation.<sup>13</sup>

### Promise of tele-dentistry

Dental provider shortages, remoteness, funding challenges, and decreased costs, coupled with advances in technology and the ongoing coronavirus virus 19 (COVID-19) pandemic, have increased interest in the use of tele-medicine applications.<sup>14,15</sup> In recent years, the field of dentistry has benefitted from myriad technological innovations, as is the case with medicine and other health care sectors. Among the most important of these advances in dentistry are the use of computers, tele-communications technology, digital diagnostic imaging services, and specialized hardware and software for patient screening and follow-up.<sup>16</sup> Technological capabilities that were considered implausible only a few decades ago are now possible in dental care, but implementing and evaluating them in diverse, low-resource dental settings requires the active engagement of key organizational stakeholders and clinical, technological, and scientific experts.<sup>17</sup> By leveraging advanced information technologies, the field of dentistry has unprecedented potential to progress far more in the next decade than it has since its professionalization in the United States in the mid-nineteenth century.<sup>18</sup> New information technologies have not only improved the quality of dental patient management, but have also made it possible to achieve partial or complete management remotely, even at distances of thousands of miles from community health center training sites or dental experts. Networking, the sharing of digital dentistry information, and distant consultations, workups, and analyses are handled by a specific branch of dentistry-related tele-medicine known as tele-dentistry.<sup>19,20</sup>

### Use of diagnostic-imaging multiformat cameras for identification of oral lesions

Routine screening of the entire oral mucosa, together with risk status assessment, should be recorded in the patient's chart at every dental visit (both negative and positive findings).<sup>21</sup> Low-cost intra-oral cameras may facilitate the identification of previously hidden and often overlooked defects in teeth and other parts of the oral cavity.<sup>22</sup> Previous reports have documented their use in recording carious lesion appearance in the patient record, and they may also be of significant benefit in monitoring early lesions over time following their detection.<sup>23,24</sup> This benefit extends not only to dentists but also to patients, for whom it may be a useful educational and motivational tool.<sup>23</sup> To the best of our knowledge, there are no prior findings in the extant literature regarding the use, accuracy, and cost-effectiveness of intra-oral cameras to screen for oral cancer during preventive dental visits. Hence, the proposed study and other research involving tele-dentistry applications are needed to assess the feasibility and acceptability of intra-oral cameras in the detection of non-malignant, pre-malignant, and malignant oral lesions during routine screening by dentists at chairside.<sup>24</sup>

### Rationale for study design

Dental practitioners have been called "the primary vanguards against oral cancer"<sup>13</sup> and are in a unique position to opportunistically examine the oral cavity and, to a lesser extent, the oropharynx

during routine dental visits.<sup>12</sup> Moreover, their educational background includes knowledge of the normal and pathological presentation of oral subsites,<sup>12</sup> which is further enhanced during dental residency training. Nonetheless, the detection and identification of lesions is hampered by difficulties in visualizing lesions intra-orally and lack of expertise among general dentists in oral cancer detection. We hypothesize that the oral pathology asynchronous tele-mentoring intervention will be both feasible to implement in the dental clinic setting and acceptable to dental patients who visit dental clinics for routine visits.

### Trial registration

ClinicalTrials.gov, NCT04166214, registered 15 November 2019, available at: <https://clinicaltrials.gov/ct2/show/NCT04166214?term=NCT04166214&draw=2&rank=1>

## Materials and Methods

The aim of the proposed study is to evaluate the feasibility and acceptability of integrating a tele-mentoring component into the identification of oral lesions at the 6 dental clinics of Family Health Centers at NYU Langone, a Federally Qualified Health Center in Brooklyn, NY. The primary objective of this study is to assess the feasibility of the oral pathology asynchronous tele-mentoring intervention in the dental clinic setting. The secondary objective of this study is to assess the acceptability of the asynchronous tele-mentoring pilot intervention to adult dental patients in the dental clinic setting.

### Approach of study

Using a mixed-methods approach, we will evaluate the feasibility and acceptability of integrating a tele-mentoring component into the identification of oral lesions at the following 6 dental clinics of Family Health Centers at NYU Langone in Brooklyn, NY. This will be achieved through the following 3 methods: 1) administering provider surveys (n=12) that consist of a checklist of 10 key components of the intervention based on process, and asking the dental provider subjects at each of the 6 Family Health Centers at NYU Langone dental sites if each one was covered; 2) conducting semi-structured interviews (n=6) with dental resident subjects at each of the 6 Family Health Centers at NYU Langone sites to assess specific barriers to sustaining the intervention and strategies for addressing these barriers to facilitate integration of the intervention into the routine workflow of the dental clinics—the interviews will be informed by the Consolidated Framework for Implementation Research<sup>25</sup> (CFIR) and the Implementation Outcomes Framework<sup>26</sup> (IOF); and 3) administering brief exit interviews (n=30) with patient subjects at each of the 6 Family Health Centers at NYU Langone dental sites regarding the acceptability of the intervention (the survey will assess patient satisfaction with the use of intra-oral cameras at chairside to screen for and refer patients with oral lesions and identification of these oral lesions via tele-mentoring with an oral pathology expert).

### Impact of study

If this pilot study proves successful, NYU Langone Health is equipped with both clinical and organizational expertise in faculty development activities, as well as the existing NYU Langone Dental Medicine national network of video-teleconferencing and web-based educational technology, to scale up the proposed oral pathology asynchronous tele-mentoring intervention for the teaching of dental educators and residents, with the ultimate goal of improving patient care.

## Assessment of primary study endpoints

Feasibility will be assessed using provider surveys, semi-structured interviews, and EHR data. We developed a checklist of 10 key components of the intervention based on process and will ask the participating dentists and residents at the 6 Family Health Centers at NYU Langone dental clinics if each was covered (see Appendix 1). This will be completed only once at the end of the implementation phase for each consented dental provider subject, and refer to the intervention experience with a specific consented patient subject. Endorsement of 8 of the 10 checklist items (80%) by the dental provider subjects will be considered as the feasibility criterion. Moreover, we will allow for open-ended collection of feedback on the feasibility of using the intra-oral cameras for identification of oral lesions as part of the tele-mentoring intervention.

Semi-structured interviews will also be conducted with dental resident subjects (see Appendix 2). We anticipate conducting 6 interviews before obtaining data saturation. The questions will be informed by the CFR<sup>25</sup> and IOF<sup>26</sup> constructs and will assess specific barriers to implementing and sustaining the intervention and strategies for addressing those barriers to facilitate integration of the intervention into the routine workflow of the Family Health Centers at NYU Langone dental clinics.

## Assessment of secondary study endpoints

Acceptability will be assessed using patient exit interviews<sup>27</sup> (PEIs) conducted immediately after the dental visit is completed. Specifically, research staff will conduct a brief exit interview with 5 patients at each of the 6 Family Health Centers at NYU Langone dental clinics with language interpretation services available regarding the acceptability of the intervention. We developed 5 statements on patient satisfaction with the intra-oral cameras and the overall tele-mentoring intervention that will constitute the PEI (see Appendix 3). Patients will be asked the extent to which they agree with each statement (e.g., Dentists should discuss with me ways to prevent and screen for oral cancer: strongly agree, agree, disagree, or strongly disagree). The acceptability criterion of the intervention will be that 80% or more of patients rate all 5 administered acceptability questions as “strongly agree” or “agree.”

## Study device

Below we describe the SOPROCARE<sup>®</sup> intra-oral camera to be used in this study (a full description is available from: <https://www.acteongroup.com/us/products/imaging/diagnostic-cameras/soprocure>). The SOPROCARE<sup>®</sup> intra-oral camera is available via commercial vendors to health care providers and is intended for the practice of general dentistry to aid in the diagnosis of pit and fissure caries, visualize anatomical details that are invisible to the naked eye or with a mirror, and highlight dental plaque and gingival inflammation. With regard to oral lesions, the magnification capability of SOPROCARE<sup>®</sup> helps to improve detection and identification. Images can be captured and stored in any imaging software, including the Dexis program within the Dentrax EHR, providing the necessary technological tools to practice minimally invasive dentistry.

## Procedures for training interventionalists and monitoring intervention fidelity

The PI will train and supervise the dental providers, who will implement the study. Since the training and practice of the attending dentists and the residents they supervise tends to vary across sites and is a key factor in whether educational interventions work, close attention will be paid to implementation fidelity. The PI has extensive experience in training dental providers to deliver inter-

ventions with fidelity, and the NYU Langone Dental Medicine Postdoctoral Residency Program emphasizes both quality clinical care and advanced research training.

Specifically, the tele-mentoring intervention involves training dental faculty members and residents to use intra-oral cameras to take photographs of oral lesions and place them in the Dentrax EHR, along with descriptions of the lesions. This information will then be sent via Dentrax EHR to the Director of Oral Pathology, and an initial dummy code entry will be placed in the Dentrax EHR. For each patient with a detected lesion, the Director of Oral Pathology will then review the Dentrax EHR chart and the uploaded photograph(s) of the lesion(s) found and place his observations in the Dentrax EHR. Next, the Director of Oral Pathology will discuss his findings with the involved dental faculty member / dental resident via secure NYU Langone Health e-mail. The dental provider will then enter an apt comment in the Dentrax EHR, using the following template: “Reviewed entry and contacted patient. Follow-up appointment needed / not needed (along with the date of patient contact) for an appointment on (date).” A second dummy code entry will then be placed in the patient record in the Dentrax EHR. Once a week, the Director of Oral Pathology will receive a Dentrax EHR report with the 2 affiliated dummy codes for the tele-mentoring pilot study, and assure that entries for both codes are completed, thus closing the loop on the process.

## Study procedures and schedule

The protocol for the tele-mentoring study was designed by the PI and the Director of Oral Pathology, and is summarized in Figure 1. This workflow will be refined based upon the results of the planned feasibility and acceptability testing. All study activities will take place in the 6 Family Health Centers at NYU Langone dental clinics and private offices of NYU Langone Dental Medicine in Brooklyn, NY. The PEIs with patient subjects and the feasibility checklists with provider subjects will take 10-15 minutes to complete. The semi-structures interviews with dental resident subjects will take 30-45 minutes to complete, and will be digitally recorded and transcribed. The transcriptions will be stored in a secure Research Electronic Data Capture (REDCap) database. The digital files will be deleted once they are transcribed. No identifying information will be recorded.

## Statistical considerations and quantitative analyses

A sample size calculation is not indicated for this feasibility and acceptability study. All quantitative analyses will be conducted by the data analyst under the direction of the biostatistician.

*Provider survey.* The feasibility criterion of the intervention will be the endorsement of 8 of the 10 checklist items (80%) by the dental provider subjects.

*Patient exit survey.* The acceptability criterion of the intervention will be that 80% or more of patients rate all 5 administered acceptability questions as “strongly agree” or “agree” on a Likert Scale.

## Semi-structured interviews and qualitative analyses

*Provider semi-structured interview.* All interviews will be transcribed by a transcription company and coded by 2 research team members. The research team members will code individually and then meet to discuss and agree upon the final codes. The analysis of the qualitative data will utilize the techniques of narrative analysis and be guided by the constant comparison analytic approach to identify themes.

## Informed consent process

A consent form and a key study information form specific to the category of subject enrolled (dental patient or dental provider) that describe in detail the study device, study procedures, and risks and possible benefits will be given to each subject and written documentation of informed consent will be required prior to beginning the study. The following consent materials were submitted with this protocol and approved by the IRB, and are available upon request from the authors:

- Consent Forms (dental patient and dental provider); and
- Research Subject Key Study Information Forms (dental patient and dental provider).

## Patient data

All data entered into the research database (in REDCap) will be protected by confidential entry codes. Locked file cabinets will be used to store materials with identifying information (e.g., consent forms). Unique identifiers will always replace patient names in all research databases. All computer systems are protected from possible external access. No Internet access is possible with the research systems to be used for this study. In addition, computer records will be maintained in such a way that the patient's name or other obvious identifying information is not accessible in the same file or by using the same code.

The digitally recorded interviews will be transcribed. The transcriptions will be kept in a password-protected computer. The files will be deleted once they are transcribed. No identifying information will be recorded.

## Discussion

Tele-dentistry has been reported to be comparable to face-to-face examination for oral screening in a systematic review that used the Quality Assessment of Studies of Diagnostic Accuracy tool to assess the methodologic quality of studies: sensitivity (25-100%), specificity (68-100%), positive predictive value (57-

100%), and negative predictive value (50-100%).<sup>15</sup> The potential of our oral pathology asynchronous tele-mentoring intervention to aid in the detection of oral lesions holds promise for reaching patients in rural areas and communities with limited access to care, especially given the COVID-19 pandemic.<sup>15</sup> If the results of this feasibility and acceptability study indicate that further testing of the model is indicated, we plan to partner with clinical trial experts at the Perlmutter Cancer Center at NYU Langone Health to conduct a real-world efficacy trial at training sites that are part of the NYU Langone Dental Medicine network.

The study design includes several limitations. First, the dental clinics at Family Health Centers at NYU Langone and the Dentrix EHR protocol may not be generalizable to dental clinics at geographically diverse community health centers or other EHRs in use at these sites. Hence, adaptations to the tele-mentoring intervention, including security safeguards, may be needed in future trials. Second, while most general dentists elect to opportunistically screen their patients for oral cancer, false positive findings can manifest as unnecessary patient anxiety, and can also incur monetary costs, discomfort, and possible side-effects of subsequent biopsies.<sup>12</sup> To reduce the potential for false-positive screening results for seemingly innocuous lesions, dentists should follow up with patients in 7-14 days to confirm persistence of the lesion after removing any possible cause.<sup>13</sup> Conversely, false negative findings can give rise to a false sense of security and result in patients failing to pursue care should symptoms later arise.<sup>12</sup> Thus, use of an intra-oral camera may improve the ability of general dentists to detect lesions in the oral cavity that otherwise may have been missed and merit follow-up.

Notwithstanding these limitations, this feasibility and acceptability study provides an important first step in implementing a tele-mentoring intervention that has the potential to identify and diagnosis non-malignant, pre-malignant, and malignant oral lesions and improve patient care. If successful, then later trials will maximize the external validity of the tele-mentoring model and facilitate the widespread implementation, dissemination, and sustained utilization of evidence-based oral cancer screening, referral, and care coordination guidelines.

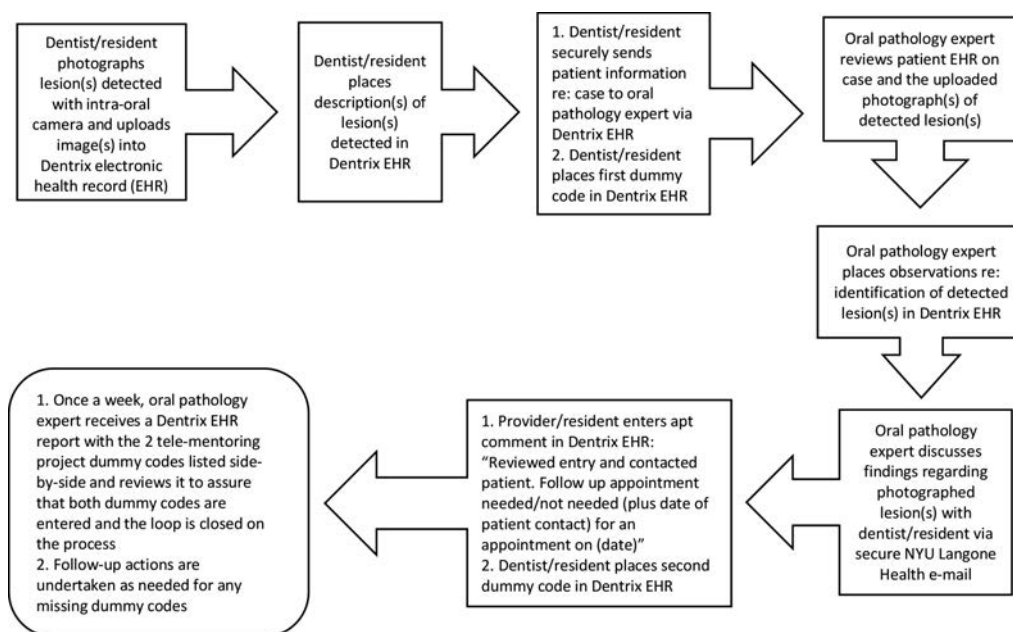


Figure 1. Workflow for the tele-mentoring pilot study to detect and identify oral lesions at chairside by dental faculty and residents.

**Correspondence:** Mary E. Northridge, 5800 Third Avenue, Room 344, Brooklyn, New York, NY 11220, USA. Tel. +1.347.377-4342. E-mail: Mary.Northridge@nyulangone.org

**Key words:** Tele-dentistry, dental clinics, oral cancer screening, oral health care, intra-oral cameras.

**Contributions:** MEN designed the research component of the study and drafted the text of the protocol and other study documents. TL led the regulatory compliance process for the study and ensured that all investigators and staff completed the necessary research ethics training and disclosure of potential conflict of interest (COI) documents. NMF devised the clinical protocol for the study and gained the buy-in of all 6 dental clinic directors. SG conceived of the Dentris / Dentrix electronic health record (EHR) process for the study, advised on the intra-oral cameras to purchase, and installed all of the hardware and software for use in the study in the 6 dental clinic sites. ABT drafted the analysis section of the protocol and contributed biostatistical expertise. YW drafted Figure 1 and contributed biostatistical expertise. RBB contributed to the conception and design of the study and provided oral cancer expertise. PAT contributed to the conception and design of the study and provided security safeguard expertise and assurance. All authors contributed to the writing of this paper and approved it for publication.

**Conflict of interest:** The authors declare no potential conflict of interest.

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**Ethics approval and consent to participate:** This research will be performed in accordance with the Declaration of Helsinki. The NYU Grossman School of Medicine Institutional Review Board (IRB) reviewed and approved all study procedures on October 30, 2019 (protocol s19-01268). This approval includes all 6 dental clinics where the research will take place. All Health Insurance Portability and Accountability Act (HIPAA) safeguards will be followed. Written consent will be obtained from each subject in accordance with the informed consent procedure included in this protocol.

**Availability of data and materials:** De-identified raw data and materials described in the manuscript are freely available from the corresponding author upon reasonable request.

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