Assess an innovative mDentistry eHygiene strategy amid the COVID-19 pandemic

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STATEMENT OF COMPLIANCE

The study will be conducted in accordance with the International Council for Harmonisation guidelines for Good Clinical Practice (ICH E6), the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and the NIDCR Clinical Terms of Award. All personnel involved in the conduct of this study have completed human subjects protection training.

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments and provides the necessary assurances that this study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

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LIST OF ABBREVIATIONS

AE	Adverse Event/Adverse Experience
CFR	Code of Federal Regulations
COVID	Coronavirus Disease
CRF	Case Report Form
CROMS	Clinical Research Operations and Management Support
CSI	Clinical Site Investigator
DCC	Data Coordinating Center
DHCP	Dental Health Care Personnel
DHHS	Department of Health and Human Services
FFR	Federal Financial Report
FWA	Federalwide Assurance
GCP	Good Clinical Practice
GD	General Dentist
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Council for Harmonisation
ICMJE	International Committee of Medical Journal Editors
IRB	Institutional Review Board
mDent	mDentistry
MOP	Manual of Procedures
N	Number (typically refers to participants)
NIDCR	National Institute of Dental and Craniofacial Research, NIH, DHHS
NIH	National Institutes of Health
OCTOM	Office of Clinical Trials Operations and Management, NIDCR, NIH
OHRP	Office for Human Research Protections
OHSR	Office of Human Subjects Research
PD	Protocol Deviation
PI	Principal Investigator
PO	Program Official, NIDCR, NIH
PPE	Personal protective equipment
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience

SOP	Standard Operating Procedure
UP	Unanticipated Problem
US	United States

PROTOCOL SUMMARY

Title: Assess an innovative mDentistry eHygiene strategy amid the COVID-19 pandemic

Précis: Amid the COVID-19 outbreak, dentistry urgently needs modified dental examination regimens that render quality care and ensure the safety of patients and dental health care personnel (DHCP). This mDentistry (mDent) eHygiene project aims to assess the acceptance of virtual dental examinations by patients and DHCP, and the potential of empowering patients with mhealth tools to engage in oral health care. We will conduct a two-stage implementation study to assess two critical components of the mDent model, a virtual hygiene exam (eHygiene) and patient self-taken intraoral photos (SELFIE) among 144 patients and 24 DHCP (dentists and hygienists) within the National Dental Practice-Based Research Network.

Objectives and Outcome Measures:

Primary Objective 1: assess the acceptance and barriers of mDent eHygiene among patients and DHCP

Primary Outcome Measures 1: Patients' and DHCP's acceptance of eHygiene model compared to the current hygiene examination model, measured by the following parameters:

1) Quantitative data (System Usability Scale (SUS) of eHygiene model and Dentist-Patient communication (DPC) score of current hygiene model and eHygiene model)
2) Qualitative data on the acceptance and barriers of eHygiene perceived by patients and DHCP, measured by individual interviews and thematic analysis.

Secondary Objective 1: assess the economic impact of mDent eHygiene

Secondary Outcome Measures 1: economic difference between eHygiene and the current hygiene examination model, measured by the following parameters:

1) Office operation cost related to eHygiene
2) Office operation difference between eHygiene and traditional hygiene exams

Secondary Objective 2: assess patient's capability of generating intraoral photos using mHealth tools (SELFIE).

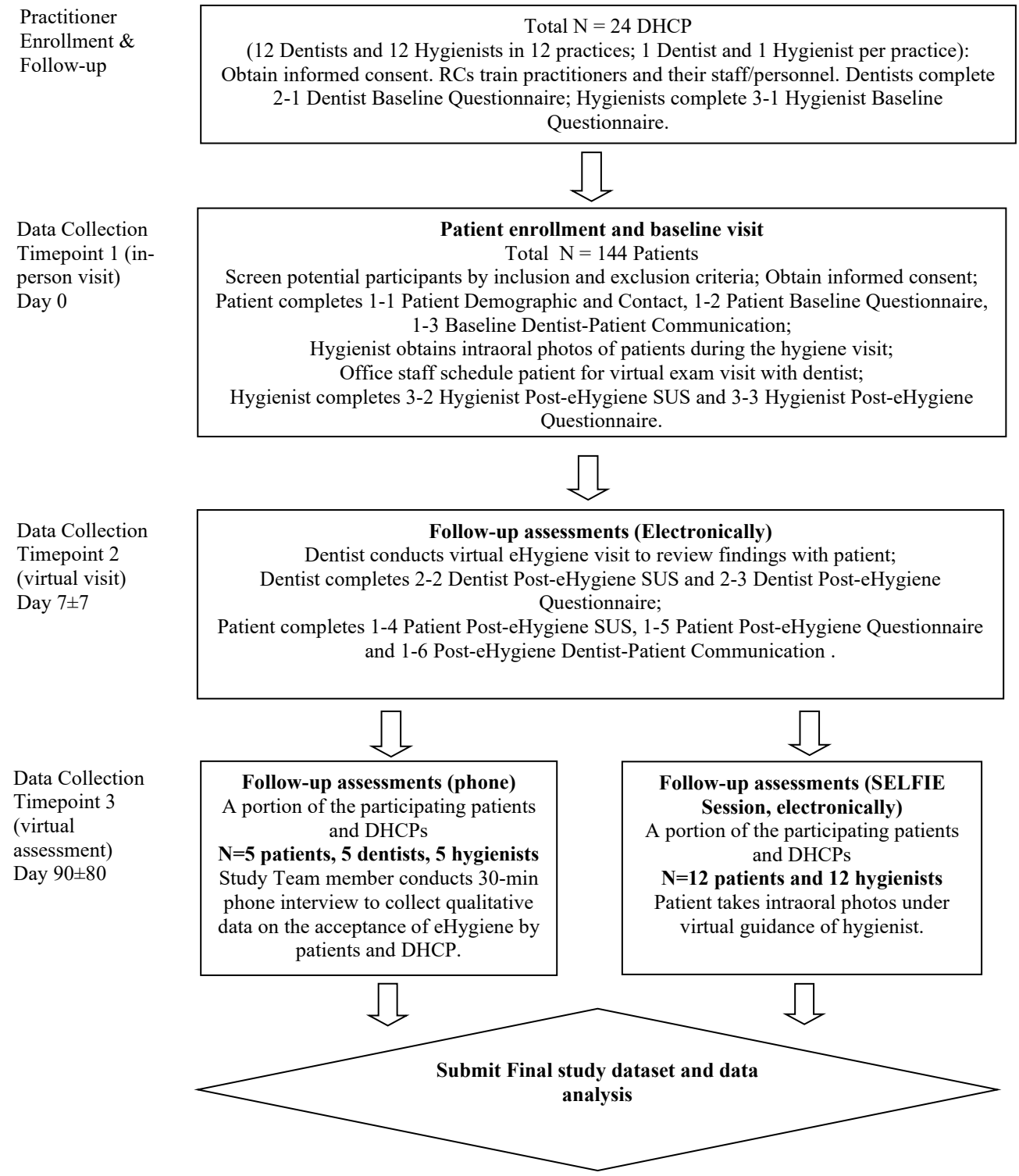
Secondary Outcome Measures 2:

1) Quantity and quality of intraoral photos generated by patients

2) Common themes of challenges encountered by patients via recorded video sessions

Population:	Patients = 144 adult patients age ≥ 18 years who are scheduled to undergo routine oral hygiene care within 12 practices in the National Dental Practice Based Research Network (National Dental PBRN). Practitioners = 12 dentists and 12 hygienists working in the same dental office.
Number of Sites:	Approximately 12 National Dental PBRN practices
Study Duration:	Approximately 12 months
Subject Participation Duration:	Approximately 1-2 weeks
Estimated Time to Complete Enrollment:	Practitioner Enrollment = approximately 2 months Patient Enrollment = each practitioner will have approximately 6 months to enroll patients Overall study Enrollment = approximately 8 months

Schematic of Study Design:



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2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

Amid the COVID-19 outbreak, Dental Health Care Personnel (DHCP) are at great risk of contracting SARS-CoV-2 virus due to their close physical proximity to their patients, as well as the enhanced potential for transmission of airborne viruses in the dental setting. When delivering dental services, DHCP consume enhanced levels of personal protective equipment (PPE), equivalent to the ones used by health care providers who provide care to COVID-19 positive patients. These PPEs include N95 respirators, goggles, gowns, head covers and face shields. Although dentistry has practiced for years utilizing person-to-person visual-tactile examinations, now, more than ever, utilizing a wide variety of technologies and approaches to deliver virtual dental services would have significant utility.

Aggressively converting traditional dental examinations (e.g., comprehensive, limited and hygiene recall examinations) to virtual examinations could significantly reduce the exposure risk for patients and DHCP, and preserve a large volume of PPEs essential to the medical/dental community. According to the American Dental Association, as of 2019, 200,419 dentists are practicing dentistry in the US, with 158,331 (79%) general dentists (GD) providing a range of examination visits on a daily basis[1]. The GDs in the US are delivering 564 million patient visits per year (an average of 3,566 patient visits per GD)[2]. Importantly, 316 million (56%) of these 564 million patient visits are examination visits. These visits comprise 67 million (21%) new patient examinations, 40 million (13%) limited examinations, and 209 million (66%) hygiene recall examinations, which often do not lead to definite treatment delivery at the same visit. If these 316 million examinations were all (or partially) converted to virtual visits serving as remote triage of patient' needs, 316 million person-to-person contacts would be avoided, preserving at least 1 billion PPEs per year.

In the current dental examination model, patients often need to have one examination visit and one hygiene visit before they get to a definite treatment visit. A new patient examination visit includes reviewing x-ray records and is conducted by one dentist and one dental assistant, with a consumption of 2 PPEs. A hygiene check visit usually includes x-rays completed by the hygienist and then an examination completed by the dentist. In a regular dental office, the dentists usually are conducting hygiene examinations in between treating their chairside patients. In the current COVID-19 environment and for the foreseeable future, the dentist needs to change PPEs between seeing his/her chairside patient and the hygiene patient, and change to another PPE when completing the hygiene check and returning to the original chairside patient. A single hygiene check examination consumes 2 PPEs for the dentist alone and increases the challenge of infection control due to frequent switching of PPEs and dentist running between dental operatories. Moreover, with added time from changing PPEs, extended waiting will add more frustration to that already reported by patients and hygienists while waiting for dentists during traditional hygiene examinations[3]. In reality, US dental practitioners have already recognized the infection control challenges and high demand for PPEs required to perform traditional hygiene examinations since the COVID-19 outbreak. Although several states in the US have lifted the ban on performing routine dental services, anecdotally, according to several dentists in the reopened states, dentists choose not to resume routine hygiene examinations due to the

challenges described above. Consequently, patients could be receiving compromised dental care. Dentistry urgently needs changes in dental examination regimens, especially hygiene visits, that render quality care and ensure the safety of patients and the DHCP.

2.2 Rationale

Our long-term goal is to develop a mobile Dentistry model (mDent). The mDent model refers to the practice of dentistry supported by mobile devices such as mobile phones, tablets, personal digital assistants, and a wireless infrastructure. The mDent combines virtual dental visits with the use of digital mHealth tools, such as intraoral cameras, to complete oral health screening, treatment planning, virtual hygiene examinations and interactive oral health education on a broad population basis. In the mDent model, before patients arrive at the dental office, they would have a virtual visit with a dental assistant or staff member to take a series of intraoral photos at home. Capable patients could do this independently, by watching a photo-taking tutorial video, minimizing DHCP instruction time in a virtual visit. With the intraoral photos, the DHCP would have a preliminary idea of the patients' oral health. The second visit could be an in-office hygiene visit conducted by the hygienist to complete intraoral x-ray records, soft and hard tissue examination, and additional intraoral photos, if needed. Patients will then have a virtual dental visit with the dentist to review findings and treatment plans before they proceed with an in-office visit to confirm the examinations and receive definite dental treatment plan and dental treatment as appropriate. This mDent model will fully engage relevant stakeholders (patients, hygienists, and dentists) to conduct interactive oral health practice. The mDent model will also utilize a patient-driven mobile device to increase the accessibility of dental care. Moreover, in an era of COVID-19 risk, this remote virtual dental service model will lead to well-planned dental services, better infection control, and reduced PPE consumption. To facilitate the ultimate testing and implementation of mDent, acceptance of patients and DHCP of this model and patients' capability of generating intraoral photos using mhealth tools are necessary. In this X01 project, our immediate objective is to use the virtual hygiene examination model (mDent eHygiene), including the assessment of these two essential components, in an implementation study in the National Dental PBRN, as a first and important step in the broader vision.

Impact on clinical practice: Successful completion of this X01 pilot study will provide data on the acceptance and economic impact of virtual dental examination during eHygiene, which will be a test vehicle for the future mDent model. The results will inform immediate modification of the dental service system that provides better safety and preserves PPEs amid COVID-19 and other infectious disease outbreaks.

2.3 Potential Risks and Benefits

Research participants will not receive dental care as a study procedure; rather, patients will receive routine clinical care, including radiographs and intraoral and extraoral clinical examinations, as patients of participating practitioners. Risks of dental treatment provided as a part of routine dental care are not considered to be study associated.

2.3.1 Potential Risks

The primary potential risk to practitioners and patients is the possibility of breach of confidentiality. Appropriate precautions will be taken and procedures will be followed to maintain confidentiality. These include the use of unique study codes for participants, encryption

of electronic data for transmission to the National Coordinating Center (NCC), and password-protected computers for data storage. Compliance with all IRB regulations concerning data collection, data analysis, data storage, and data destruction will be strictly observed. Another risk of participating in this study for patients is the potential for psychological discomfort when answering some of the questions that are sensitive in nature. To reduce this risk, the patient will be allowed to skip any question that makes them feel uncomfortable. All questionnaires will be administered electronically with data sent directly to the study researchers, and the practitioner will not have access to patient responses.

2.3.2 Potential Benefits

Participation in the study will provide no direct benefit to patients. The potential benefits of this study are that the results may contribute to the evidence about utilizing intraoral images to assist virtual oral disease diagnosis and treatment planning.

3 OBJECTIVES AND OUTCOME MEASURES

3.1 Primary

Objective	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
To assess the acceptance and barriers of mDent eHygiene among patients and DHCP	The SUS instrument will be used to assess the acceptance of the mDent eHygiene approach. The SUS instrument[4-6] is widely adopted in business and technology industries and mHealth fields to measure and quantify the perception of product and service usability. A SUS score above 68 indicates above-average usability; a score above 80.3 indicates excellent usability of the mDent model. The SUS score of all patients, dentists, and hygienists will be calculated. The DPC component will be used to assesses how well the patients understand the planned treatment and the quality of the communication between the patients and dentists using eHygiene. We will use a modified questionnaire from a validated Doctor-Patient Communication questionnaire[7] and a Functional Assessment of Chronic Illness Therapy Scale[8] often used in the medical field. Qualitative analysis will be conducted among 15 individuals (5 patients, 5 dentists, 5 hygienists) via 30-min virtual individual interviews. The questions during the interview will address the feedback, perceived challenges, and suggestions for improvement of the mDent eHygiene model. The interviews will be standardized using interview guides, audio-recorded, transcribed and analyzed for thematic content.	• System Usability Scale (SUS) • Dentist-Patient Communication (DPC) • Theme of acceptance and barriers analyzed from individual qualitative interviews with the HDCP	• The SUS data will be collected from hygienists at Data Collection Timepoint 1 and from patients and dentists at Data Collection Timepoint 2. • DPC data will be collected from patients at Data Collection Timepoints 1 and 2. • Qualitative interviews to assess theme of acceptance and barriers will be conducted at Data Collection Timepoint 3.

3.2 Secondary

Objective	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
To assess the economic impact of mDent eHygiene.	In addition to confirming the accuracy of virtual dental consultation in treatment planning, studies from other groups have shown improved cost-effectiveness using virtual dental visits[9,10]. Now facing the PPE shortage amid the COVID-19 outbreak, the economic benefits of mDent eHygiene are promising. The magnitude, however, must be carefully evaluated, which will be assessed using the outcome measured listed in this objective via role-specific baseline and post-eHygiene questionnaires.	• PPE Consumption and Estimated Cost • eHygiene Chair-Time per patient • eHygiene Virtual Visit Time per patient • DHCP (dentist and hygienist) personnel cost related to eHygiene	• Secondary outcomes related to economic impact will be obtained via role-specific questionnaires to be completed by hygienists at Data Collection Timepoint 1 and by patients and dentists at Data Collection Timepoint 2.

3.3 Tertiary/Exploratory

Objective	Brief Description/Justification of Outcome Measure	Outcome Measured By	Time Frame
To assess patient's capability of generating intraoral photos using mHealth tools (SELFIE).	This objective will provide preliminary data on patient engagement in using mhealth tools which is essential to empower patients in the complete mDent model.	• Quantity and Quality of intraoral photos taken by patients, assessed by one dentist in study team who will be trained for photo assessment. • Themes of challenges encountered by patients during intraoral photos taken by themselves, via analyzing the video recordings of the SELFIE session.	• Outcomes related to this objective will be obtained at Data Collection Timepoint 3.

4 STUDY DESIGN

- This study will use a two-stage implementation study to assess the acceptance of two components (eHygiene and SELFIE) of mDent eHygiene model among patients and DHCP (dentists and hygienists) within the National Dental PBRN.

- The mDent eHygiene study will be conducted in the Northeast (NE) Node of the National Dental PBRN.

- This mDent eHygiene study will enroll approximately 144 patients and 24 DHCP from approximately 12 practices. Each practice will enroll approximately 12 patients, 1 dentist and 1 hygienist. Approximately 144 patients and 24 DHCP will conduct the eHygiene session (1st stage) of the study, which includes 2 data collection timepoints. Among enrolled patients and DHCPs, 5 patients, 5 dentists and 5 hygienists will be invited for a 30-min phone interview for qualitative session of the eHygiene study (3rd data collection timepoint). In addition, 12 patients will be invited to conduct a SELFIE (2nd stage, 3rd data collection timepoint) study to evaluate their capability of taking intraoral photos by themselves, with guidance from the dental hygienist.

- The mDent eHygiene study involves 2 data collection timepoints (1 in-person visit, 1 virtual visit) for all participating patients and DHCP and a third data collection timepoint (virtual) for a portion of the participating patients and DHCP. We expect the enrollment for DHCP to be completed within 2 months and the enrollment for patients to be completed within 6 months. We expect the participating patients in eHygiene session to complete the study within approximately 1-2 weeks. For those who participate the qualitative interview of the eHygiene and SELFIE session, only 1 data collection timepoint (virtual phone interview) is expected, to be completed in approximately 30-60 minutes.

- This mDent eHygiene study will use mixed-methods (quantitative and qualitative data) to collect outcome measures and conduct data analysis. Role-specific questionnaires will be completed by the patients and DHCP at the baseline and the last study visits (electronically). Interviews will be conducted by phone. SELFIE session will be conducted electronically, with intraoral photos obtained electronically and reviewed by one study evaluator (dentist) to compare the quantity and quality of intraoral photos taken by patients comparing to those taken by hygienists.

5 STUDY POPULATION

5.1 Participant Inclusion Criteria

Practitioners (Dentist): To be eligible to participate in this study and recruit patient participants, a practitioner must be deemed study ready by their Regional Administrative Site (RAS) and meet the following criteria:

- Be a practicing dentist and willing to work with a hygienist in his/her office for the study
- Be willing to perform virtual (remote) hygiene examination results review;
- Have the ability to receive emails and access online questionnaires

Practitioners (Hygienist): To be eligible to participate in this study and recruit patient participants, a practitioner must be deemed study ready by their Regional Administrative Site (RAS) and meet the following criteria:

- Be a practicing dental hygienist and willing to work with a dentist in his/her office for the study;
- Be willing to participate in study procedures;
- Be able to obtain intraoral digital images
- Have the ability to receive emails and access online questionnaires

Patients: To be eligible to participate in this study, a patient must meet all of the following eligibility criteria:

- Age ≥ 18 years;
- Be willing to provide consent according to regionally approved procedures;
- Be scheduled for a routine hygiene visit at an office with a participating dentist and hygienist;
- Anticipate being available for a 30-min virtual visit with the dentist;
- Access to a smartphone, tablet or computer with a webcam and internet connection to participate in a virtual visit;
- Be able to provide contact information for one other person with a different phone number who will know the patient's whereabouts in the event the patient cannot be reached;
- Have the ability to receive emails and access online questionnaires;
- Be willing to be contacted by each of these entities: the practice, regional Node coordinators, and the National Coordinating Center (NCC).

5.2 Participant Exclusion Criteria

Patients: An individual who meets any of the following criteria will be excluded from participation in this study:

- Unable to tolerate intraoral imaging;
- Previously enrolled in the study;
- Obvious cognitive impairments that preclude participation in the informed consent process or ability to complete study activities (*e.g.*, previous stroke with communication deficits, dementia)
- Inability to understand study procedures or provide consent in English.

5.3 Strategies for Recruitment and Retention

5.3.1 Practitioner Recruitment:

Practitioners will be recruited in the NE Node of the National Dental PBRN and led by the study team in collaboration with NE Node staff and interested professional organizations. Practitioner recruitment emails will be developed and tailored by the NE Node. The network practitioner database will be used to identify general dentists for email recruitment and follow-up.

eHygiene session participating hygienists will receive $40 remuneration for each enrolled patient when the Hygienist completes 3-2 Hygienist Post-eHygiene SUS and 3-3 Hygienist Post-eHygiene Questionnaire for a patient. Each hygienist will also be allowed to keep a study-purchased tablet computer (approximately $300 each) that will be used for data collection in the clinic. The remuneration for the first 4 patients ($160) will be compensated with value of the tablet included as part of the total remuneration.

eHygiene session participating dentists will receive $40 remuneration for each enrolled patient when the Dentist completes 2-2 Dentist Post-eHygiene SUS and 2-3 Dentist Post-eHygiene Questionnaire for a patient. Each dentist will also be allowed to keep a study-purchased intraoral camera (approximately $300 each) that will be used for data collection in the clinic. The remuneration for the first 4 patients ($160) will be compensated with value of the Mouthwatch intraoral camera included as part of the total remuneration.

Hygienists and Dentists participating in qualitative interviews will receive additional $40 remuneration. Hygienists participating in SELFIE session will also receive an additional $50 remuneration.

5.3.2. Patient Recruitment:

Approximately 144 patients who undergo oral hygiene procedures will be recruited over a study recruitment period of 4-6 months. Following protocol training, each practitioner will be asked to enroll a target of approximately 12 patients.

The participating hygienists will be asked to use a consecutive enrollment strategy. Each participating hygienist will establish a regular recruitment period (days and/or times) that fits the

practice and is sufficient to meet enrollment targets. A screening criteria log will be used to record potential patient refusal/non-enrollment and, where allowed, reasons for non-enrollment during established recruiting periods. Practitioners' recruitment schedules may be adjusted at any time with the consultation of the NE Principal Node Coordinator.

The overall study recruitment period, and practitioner-specific recruitment numbers and time periods, will provide sufficient flexibility for the study to meet its enrollment target.

5.3.3. Patient Retention:

Patient retention is important to this study and all follow-up data will be collected independent of a clinic visit. Patients will be remunerated with a total of $50, $25 for completing questionnaires at the baseline visit (Data Collection Timepoint 1) and $25 for completing questionnaires following the virtual eHygiene session (Data Collection Timepoint 2).

Patients participating in qualitative interviews will receive an additional $40 remuneration. Patients participating in the SELFIE session will also receive an additional $50 remuneration.

The NE Principal Node Coordinator will use email, telephone and/or text messages to follow-up with non-responders prior to the close of the data collection window to encourage them to complete questionnaires. When contacted, patients will be given the option to complete the questionnaires by telephone with the NE Principal Node Coordinator.

5.3.4. Practitioner Retention:

Practitioner retention is important to this study. The study leadership and NE Principal Node Coordinator will maintain efforts to engage practitioners throughout the duration of the study, including addressing practitioner questions and concerns and informing them about study results after data analysis has been completed.

5.4 Participant Withdrawal

Practitioners and patients are free to withdraw from participation in the study at any time upon request.

5.4.1 Reasons for Participant Withdrawal

Participants are free to withdraw from participation in the study at any time upon request.

An investigator may withdraw a participant from the study if:

- Any medical condition, event or situation occurs such that continued participation in the study would not be in the best interest of the subject.
- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

5.4.2 Handling of Participant Withdrawals

In the case of patient withdrawal from the study, the study will only attempt continued follow-up data collection for patients who are withdrawn due to an unanticipated problem (UP) or other safety concerns. In those cases, only data related to the completion of reporting requirements for the UP or safety event will be recorded. Patients withdrawn from the study for any other reason will have the date and reason for withdrawal recorded, but no additional study data will be collected. Patients withdrawn from the study may continue to receive normal clinical care as patients of the participating dentists. Patients withdrawn will not be replaced by another participant.

5.5 Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. The Principal Investigator is responsible for promptly notifying all parties and providing the reason(s) for the termination or suspension.

Circumstances that may warrant termination include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to subjects.
- Insufficient adherence to protocol requirements.
- Data that are not sufficiently complete and/or evaluable.
- Determination of futility.

6 STUDY SCHEDULE

This study will include two study components – eHygiene and SELFIE- that will be conducted within 3 study visits (1 baseline and 2 follow up visits). The baseline visit will be conducted in the dental office as an in-person visit. The 2 follow up visits will be virtual visits that will be conducted remotely.

6.1 Practitioner Enrollment/Baseline

- Verify practitioner inclusion/exclusion criteria
- Practitioners (dentist and hygienist) and eligible staff participate in study training with a Node Coordinator
- Practitioners (dentist and hygienist) complete baseline role-specific questionnaires. Dentists complete 2-1 Dentist Baseline Questionnaire; Hygienists complete 3-1 Hygienist Baseline Questionnaire.

6.2 Patient Screening/Enrollment (Day 0)

Prospective patients may be recruited prior to or during their routine hygiene visit in a participating practitioner's office. The hygienist will review the study procedures and inclusion and exclusion criteria with the patient. If eligible and interested in the study, the patient will undergo the consenting process via the tablet, pursuant to overseeing IRB requirements. If an eligible patient wishes to decline participation in the study, this occurrence will be noted in the screening log, and the informed consent process will not be completed.

Together, patient and the hygienist will:

- Verify patient inclusion/exclusion criteria
- Obtain and document consent from potential participant
- Obtain and document HIPAA according to regional IRB requirements

6.3 Patient Baseline (In-Person Visit, Data Collection Timepoint 1, Day 0)

- Patient completes 1-1 Patient Demographic and Contact, 1-2 Patient Baseline Questionnaire and 1-3 Baseline Dentist-Patient Communication.
- Hygienist obtains intraoral photos
- Hygienist or office staff will schedule Patient for Virtual Data Collection Visit 2 with the participating dentist.
- Hygienist provides participating patient with instructions needed to prepare for Visit 2
- Hygienist completes 3-2 Hygienist Post-eHygiene SUS and 3-3 Hygienist Post-eHygiene Questionnaire

6.4 Intermediate Visits

Virtual Visit, Data Collection Timepoint 2 (Day 7 ± 7)

- Dentist reviews eHygiene findings with participating patient
- Dentist completes 2-2 Dentist Post-eHygiene SUS and 2-3 Dentist Post-eHygiene Questionnaire
- Patient completes 1-4 Patient Post-eHygiene SUS, 1-5 Patient Post-eHygiene Questionnaire, and 1-6 Post-eHygiene Dentist Patient Communication.

Virtual Visit, Data Collection Timepoint 3 (Day 90 ± 80)

Activity 1: Qualitative interview (5 patients, 5 dentists, 5 hygienists)

- Study team member conducts one-on-one 30-min phone interview with Participants (Patient, dentist and hygienist). Study team will use 1-7 Patient Qualitative Interview Guide with patients, 3-5 Hygienist Qualitative Interview Guide with hygienists, and 2-4 Dentist Qualitative Interview Guide with dentists.
- Study team member completes 4-1 Qualitative Interview Completion Record for each participant who completed an interview.

Activity 2: SELFIE session (12 patients and 12 hygienists)

- Participating patient takes intraoral photos under virtual guidance of participating hygienist
- Participating hygienist ensures images are properly saved electronically before completion of the visit. Hygienist completes 3-4 SELFIE Completion Record.

6.5 Participant Withdrawal

If a patient withdraws from the study, the study team will attempt to document the withdrawal date and reason for withdrawal on 4-4 Patient Withdrawal Form

Consistent with Section 5.4.2, the only evaluations and data collection authorized will be information needed to address an UP or other safety issue that may have led to his/her withdrawal from the study

7 STUDY PROCEDURES/EVALUATIONS

All baseline and follow-up data will be collected electronically.

7.1 Procedures

7.1.1 eHygiene intraoral photo taking by hygienist

The *hygienist* will complete a routine hygiene visit, update x-rays and perform a hard and soft tissue exam as part of routine clinical care. Intraoral photos of patients will be taken for research purposes. Intraoral photo taking will follow a template in the Mouthwatch Teledent (cloud based) software. A series of intraoral photos include a front view photo taken by the tablet camera and approximately 10-15 other anterior and posterior teeth photos taken by an intra-oral camera that is connected with a tablet. Examples of intraoral photos are shown in Fig 1. The hygienist will record the time spent taking intraoral photos in the role-specific questionnaire.

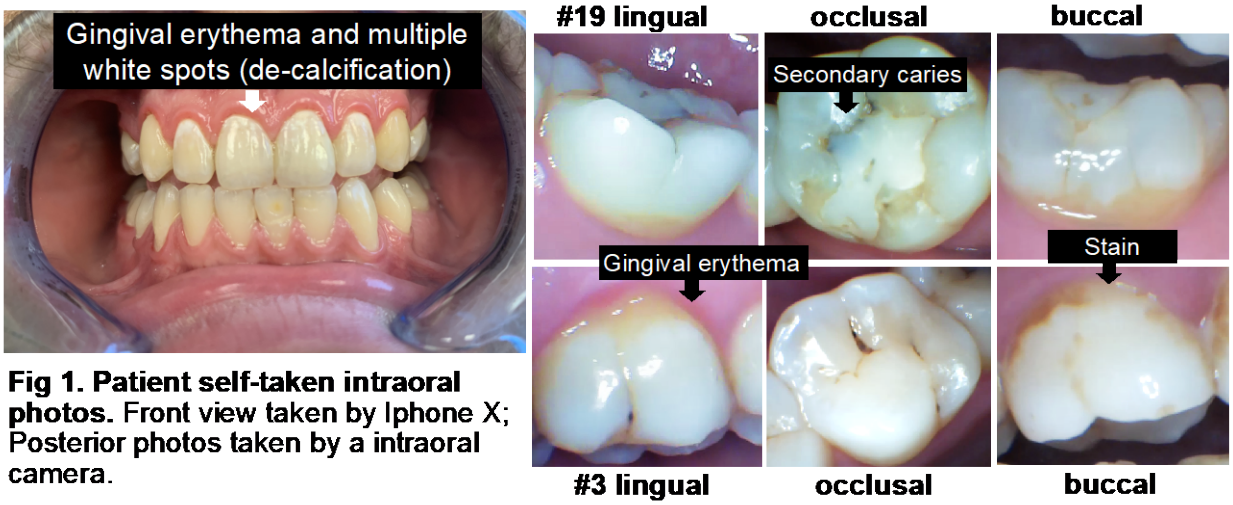

Fig 1. Patient self-taken intraoral photos. Front view taken by Iphone X; Posterior photos taken by a intraoral camera.

7.1.2 eHygiene virtual visit between patients and dentist

The *dentist* will then conduct a virtual visit with the patient, at a later and suitable time within 14 days of the study visit 1 (eHygiene intraoral photo visit in the dental office with the hygienist), to review eHygiene findings and treatment plan, in approximately 30 minutes or less. The dentist will record the time spent on virtual visits in the role-specific questionnaire.

7.1.3 SELFIE session

12 of the 144 study patients who completed the eHygiene session will pilot self-taking intraoral photos (SELFIE session) under remote supervision by trained hygienists. Each practice will invite one of the participants who completed eHygiene session to participate in the SELFIE session. The intraoral camera and instructional video will be given to the patient based on an agreed choice between the patient and practicing office, which includes the following scenarios: when the patient leaves the hygiene visit; the intraoral camera and tablet will be shipped to the participating patient or be picked up by the patient in the dental office; or other scenarios that are suitable for the patient and the practice.

During a virtual visit with the hygienist, the patient will use the Mouthwatch Teledent software while being supervised by the hygienist to take a series of intraoral photos of the front and posterior teeth. This virtual visit session will be recorded within the Mouthwatch Teledent. The patient will be encouraged to *Think-aloud*[11] about their feelings and difficulties encountered while taking photos. The think-aloud process asks users to verbalize their thoughts as they complete various tasks, allowing investigators to gain insight on participants' thought processes in relation to the technology products. Prior to the commencement of the photo-taking session, the trained hygienist will briefly demonstrate how to Think-aloud. Upon the completion of SELFIE session, the patient will complete the intraoral photo taking. The intraoral photos taken by the patients will simultaneously store in the Mouthwatch Teledent cloud-based software. The study team will log into the Teledent to download intraoral photos to a password-protected computer located at the University of Rochester to evaluate the quality and quantity of photos taken.

7.2.1 Study questionnaires

Each participating patient, dentist and hygienist will complete a baseline and post-eHygiene role-specific questionnaire following study schedule detailed in 6.3 and 6.4. The questionnaires include the following components:

- System Usability Scale (SUS): The SUS instrument will be used to assess the acceptance of the mDent eHygiene approach. The SUS instrument [4-6] is widely adopted in business and technology industries and mHealth fields to measure and quantify the perception of product and service usability. A SUS score above 68 indicates above-average usability; a score above 80.3 indicates excellent usability of the mDent model. The SUS data will be collected using the following three instruments:
    - 2-2 Dentist Post-eHygiene SUS
    - 3-2 Hygienist Post-eHygiene SUS
    - 1-4 Patient Post-eHygiene SUS
- Dentist-Patient Communication (DPC) Score: The DPC component will be used to assess how well patients understand the planned treatment and the quality of the communication between the patients and dentists who participate in eHygiene. We will use a modified questionnaire from a validated Doctor-Patient Communication questionnaire[7], which replaced the word "Doctor" with "Dentist" in the DPC form, and a Functional Assessment of Chronic Illness Therapy Scale[8] often used in the medical field. The DPC data will be collected using the following two instruments:
    - 1-3 Baseline Dentist-Patient Communication
    - 1-6 Post-eHygiene Dentist-Patient Communication
- Office operations: a) PPE Consumption/Estimated Cost and its comparison between eHygiene and traditional hygiene exam model; b) eHygiene Chair-Time per study patient; c) eHygiene Virtual Visit Time; d) DHCP (dentist and hygienist) personnel cost

related to eHygiene in-office and virtual visits comparing to traditional hygiene exam visits. The office operations data will be collected using the following three instruments:

- 1-5 Patient Post-eHygiene Questionnaire
- 2-3 Dentist Post-eHygiene Questionnaire
- 3-3 Hygienist Post-eHygiene Questionnaire

Note: For patients, the following questionnaires will be completed in the dental office during baseline visit: 1-1 Patient Demographic and Contact; 1-2 Patient Baseline Questionnaire; and 1-3 Baseline Dentist-Patient Communication. The following questionnaires will be sent to the patient electronically by sending an email with a link to the questionnaire, after the virtual eHygiene visit: 1-4 Patient Post-eHygiene SUS; 1-5 Patient Post-eHygiene Questionnaire; and 1-6 Post-eHygiene Dentist-Patient Communication.

7.2.2 Qualitative interviews

After receiving the SUS and DPC score from all patients and DHCP, the study team will randomly select 15 individuals (5 patients, 5 dentists, 5 hygienists) for approximately 30-minute virtual individual interviews. These 15 individuals will include those who rated above and below the average SUS score. The questions during the interview will address feedback/recommendations, perceived challenges, and suggestions for improvement of the mDent eHygiene model. The interviews will be standardized using an interview guide, and interviews will be audio-recorded. The Audio recordings will be transcribed by the Temi (USA) transcription service, and further verified by two trained research personnel. Transcribed data will be analyzed using MAXQDA software (VERBI GmbH, Berlin, Germany). The data will be coded by two trained coders with predetermined open codes using a codebook with description of the coding tree. Thematic content will be further analyzed using categorizing and contextualizing strategies to understand the factors associated with acceptance and barriers of eHygiene among patients and DHCP. The interview guides that will be used to facilitate the discussions are:

- 1-7 Patient Qualitative Interview Guide
- 2-4 Dentist Qualitative Interview Guide
- 3-5 Hygienist Qualitative Interview Guide

7.2.3 SELFIE session photos

Parameters to be evaluated include time spent on photo taking (based on Mouthwatch Teledent video), number of photos and readable photos [determined by a study evaluator (a dentist)], and their comparison to photos taken by hygienists. The photo evaluation data will be recorded on 4-2 SELFIE Session Intraoral Images Assessment form.

7.2.4 SELFIE session recorded videos qualitative assessment

The recorded "Think-aloud" videos during SELFIE session will be reviewed by the study evaluator to analyze common themes of challenges patients encounter. The video evaluation data will be recorded on 4-3 SELFIE Session Video Assessment form.

8 ASSESSMENT OF SAFETY

8.1 Definitions of Safety Parameters

8.1.1 Adverse Events

An adverse event (AE) is any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research.

8.1.1.1 Serious Adverse Event

A serious adverse event (SAE) is one that meets one or more of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- Results in inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability or incapacity
- Results in a congenital anomaly or birth defect
- Based upon appropriate medical judgment, the event may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

8.1.2 Unanticipated Problems

The Office for Human Research Protections (OHRP) considers unanticipated problems (UP) involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets all of the following criteria:

- unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

8.2 Specification of Safety Parameters

Safety monitoring for this study will focus on unanticipated problems involving risks to participants, including unanticipated problems that meet the definition of a serious adverse event.

8.3 Reporting Procedures

Incidents or events that meet the OHRP criteria for unanticipated problems require the creation and completion of an UP-report form. OHRP recommends that investigators include the following information when reporting an adverse event, or any other incident, experience, or outcome as an unanticipated problem to the sIRB and local institution IRB:

- appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;
- a detailed description of the adverse event, incident, experience, or outcome;
- an explanation of the basis for determining that the adverse event, incident, experience, or outcome represents an UP;
- a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, unanticipated problems will be reported using the following timeline:

UP that are SAE(s) will be reported to the IRB and to NIDCR within 5 days of the investigator becoming aware of the event.

Any other UP will be reported to the IRB and to NIDCR within 10 days of the investigator becoming aware of the problem.

All UP should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one month of the IRB's receipt of the report of the problem from the investigator.

All UP will be reported to NIDCR's centralized reporting system via Rho Product Safety:

Product Safety Fax Line (US): 1-888-746-3293

Product Safety Fax Line (International): 919-287-3998

Product Safety Email: rho_productsafety@rhoworld.com

General questions about SAE reporting can be directed to the Rho Product Safety Help Line (available 8:00AM – 5:00PM Eastern Time):

US: 1-888-746-7231

International: 919-595-6486

9 STUDY OVERSIGHT

The PIs (Dr. Xiao and Dr. Kopycka-Kedzierawski) will be responsible for study oversight, including monitoring safety, ensuring that the study is conducted according to the protocol and ensuring data integrity. The PIs will review the data for safety concerns and data trends at regular intervals, and will promptly submit reportable events to the IRB and NIDCR that arise during the conduct of the study.

10 CLINICAL SITE MONITORING

No outside clinical site monitoring will be employed for this study. The Principal Investigator(s) and staff will closely monitor the subjects as they progress through the study. They will monitor and evaluate study processes and documentation based on the International Council for Harmonisation (ICH), E6: Good Clinical Practice guidelines (GCP), and internal quality management plans. The NIDCR reserves the right to conduct independent clinical site monitoring as necessary.

11 STATISTICAL CONSIDERATIONS

11.1 Study Hypotheses

This pilot study is designed to test the following hypotheses:

- The patient-evaluated System Usability Scale (SUS) for the eHygiene examination model is comparable to the SUS score assessed for other published mHealth tools.

- The eHygiene examination model is associated with higher Dentist-Patient Communication (DPC) score evaluated by the patients, compared to the traditional hygiene examination model.

In addition, intraoral photos obtained by patients and the qualitative data collected from this study will serve the hypotheses generation purpose for future studies.

11.2 Sample Size Considerations

We plan to sample 12 practices within the NE Node to obtain diverse views from patients and DHCP on the acceptance of eHygiene model and inform the suggestion for process optimization.

11.2.1 Sample size calculation for primary outcome (eHygiene - SUS): We calculated the adjusted sample size based on the primary outcome SUS score from patients. Various studies[4,12,13] have used the SUS scale to assess the usability of medical service or mHealth tool report SUS score with the mean (47.5 to 81.2) and the standard deviation (SD: 9.9 to 21.1). Using a cluster randomized design calculation, assuming the SUS score difference between the patient-evaluated eHygiene model and other published mHealth tools, has a mean of 8 and an SD of 10, a sample size of 72 patients from 12 practices (6 per practice) will achieve 90% power, with an alpha=0.05. Considering the potential dropout rate, a sample size of 144 patients will well satisfy the statistical power of the primary outcome.

For dentists and hygienists, assuming the SUS score difference between $SUS_{\text{eHygiene model of the first patient}}$ and $SUS_{\text{eHygiene model of the last patient}}$ has a mean of 30 with a SD of 20, using paired T-test, a sample of 7 dentist/hygienist will achieve 90% power, with an alpha=0.05. Considering a potential dropout, recruiting 12 dentists and 12 hygienists will achieve satisfactory statistical power for this aim.

11.2.2 Sample size consideration for primary outcome (DPC): Using a cluster randomized design calculation, assuming patient-evaluated DPC score difference between the current hygiene model and to-be-tested eHygiene model has a mean of 8 and an SD of 10, a sample size of 48 patients from 12 practices (4 per practice) will achieve 85% power, with an alpha=0.05. A sample size of 144 patients will satisfy the statistical power of the DPC outcome, with the consideration of potential dropout.

11.2.3 Sample size consideration for tertiary outcome (SELFIE): We expect to reach data saturation[14] (no new themes are identified) after conducting 12 individual tests. The sample size is determined based on previously published studies, where between 6 to 11 usability tests were conducted to assess technology products, for instance, smartphone app usability[15,16].

11.3 Final Analysis Plan

11.3.1 Analyses for Primary Objective

The primary objective is to access the acceptance and barriers of mDent eHygiene among patients and DHCP via SUS and DPC scoring.

SUS score: We will calculate SUS scores for the eHygiene model (Post-eHygiene SUS) rated by patients, dentists and hygienists. The SUS score of patients and DHCP between practices will be compared. A linear mixed-effects model will be used to examine factors that influence the SUS score perceived by patients, including patient factors (demographic, socioeconomic, education, profession, and experience of using a digital device and mHealth tools) and DHCP factors (demographic and dental practicing experience), while considering the clustering effects within practices and providers. The eHygiene SUS score rated by dentists and hygienists from treating the 1st patient through the last study patient will be compared to assess whether SUS score by DHCP is associated with a learning curve.

DPC score: We will calculate the DPC score rated by patients, which assesses how well the patients understand the planned treatment and the quality of the communication between the patients and dentists who participate in eHygiene. We will use a linear mixed-effects model to examine factors that influence the DPC score perceived by patients, including patient factors (demographic, socioeconomic, education, profession, and experience of using a digital device and mHealth tools), DHCP factors (demographic and dental practicing experience), and time spent on the eHygiene visit, while controlling the clustering effects within practices and providers.

Qualitative data: The interviews will be standardized using interview guides, audio-recorded, transcribed, coded, and analyzed for thematic content**.**

11.3.2 Analyses for Secondary Objective

The Secondary Objective 1 is to assess the economic impact of mDent eHygiene.

Health economic impact: We will conduct analysis for the following parameters: a) PPE Consumption/Estimated Cost and its comparison between eHygiene and traditional hygiene exam model for each practice; b) eHygiene Chair-Time per study patient, learning curve related chair-time fluctuation per practice, and its comparison between practices; c) eHygiene Virtual Visit Time and its comparison between practices; and d) DHCP (dentist and hygienist) personnel cost related to eHygiene in-office and virtual visits comparing to traditional hygiene exam visits.

The Secondary Objective 2 is to assess patient's capability of generating intraoral photos using mHealth tools (SELFIE).

Patient-taken Intraoral photos: Evaluating parameters include time spent on photo taking (based on recorded video), number of photos and readable photos (determined by evaluator), and their comparison to photos taken by hygienists. Factors including patient demographic, education, experience of using a digital device and mHealth tools that potentially relate to patient capability will be further assessed.

Themes of challenges patients encountered during intra-oral photos taken will be analyzed. The key tasks connecting cameras with tablet, locating photo-taking module in Teledent software, using a cheek retractor, taking front-view and posterior teeth photos, and ensure photos stored in the TeleDent software. User performance for key tasks will be ranked as *critical* (requiring assistance to proceed), *severe* (major delay and/or frustration), or *cosmetic* (minor) and annotated to the specific task. Based on rankings, the team will suggest changes in the instructional video and clinic procedures for future implementation.

12 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

Study staff will maintain appropriate dental and research records for this study, in compliance with ICH E6, Section 4.9 and regulatory and institutional requirements for the protection of confidentiality of subjects. Study staff will permit authorized representatives of NIDCR and regulatory agencies to examine (and when required by applicable law, to copy) research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress and data validity.

The source documents for this study will be electronic, including the following:

- 1-1 Patient Demographic and Contact
- 1-2 Patient Baseline Questionnaire
- 1-3 Baseline Dentist-Patient Communication
- 1-4 Patient Post-eHygiene SUS
- 1-5 Patient Post-eHygiene Questionnaire
- 1-6 Post-eHygiene Dentist-Patient Communication
- 2-1 Dentist Baseline Questionnaire
- 2-2 Dentist Post-eHygiene SUS
- 2-3 Dentist Post-eHygiene Questionnaire
- 3-1 Hygienist Baseline Questionnaire
- 3-2 Hygienist Post-eHygiene SUS
- 3-3 Hygienist Post-eHygiene Questionnaire
- Intraoral Photos (Taken by Hygienists and Patients)
- Interview Recording
- Video Recording
- Intraoral Photos Quality Evaluation Form

13 QUALITY CONTROL AND QUALITY ASSURANCE

For the quality management activities associated with data collection and processing, the NCC will develop a data management plan which will detail quality management procedures including the development of data quality checks in the database system and the processes related to the manual review of data, discrepancy management, delinquent data handling, data updates, data verification and approval, and database audit.

The online questionnaires are designed with data validation checks. If out of range values are entered by the patient or provider, the individual will be alerted and asked to provide a value that is in range. Patients who undergo telephone follow-up will interact with the NE Principal Node Coordinator. Study personnel will complete the interview, and questionnaire responses will be entered directly into the electronic system. Data will be entered in real-time and will be subject to the same quality checks as the study participant interface. If the patient refuses to answer a question, this is noted in the online system by the interviewer. A subset of patient telephone interviews will be monitored by NCC supervisory staff. Although no interim analysis is planned, if interim data analysis is needed during the study period, the Data Manager will coordinate the activities with the Statistician. The datasets will be provided to the Statistician via secure data transfer method.

To ensure the quality of Hygienist training, both written and video training materials will be developed by the study team before study launch. The NE Principal Node Coordinator will send the materials to the participating hygienist electronically. The NE Principal Node Coordinator will schedule virtual meetings with enrolled hygienists to conduct training for hygienists. Towards the end of the virtual training, the participating hygienist will be asked to do a test run of using Teledent software and intraoral cameras to take pictures (with small objectives available in the dental office, e.g. paper clip, etc.). The NE Principal Node Coordinator will determine the readiness of the hygienist and decide whether additional sessions are needed.

14 ETHICS/PROTECTION OF HUMAN SUBJECTS

14.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6.

14.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials and all participant materials will be submitted to the University of Alabama at Birmingham single IRB (sIRB) for review and approval. Approval of both the protocol and the consent form will be obtained before any participant is enrolled. Any amendment to the protocol will be reviewed and approved by the sIRB before the changes are implemented in the study.

The protocol, informed consent form(s), recruitment materials and all participant materials will be submitted to the study institution IRB (University of Rochester) for content review, by study PIs. Study Pis will provide the sIRB with the appropriate approved IRB documents.

14.3 Informed Consent Process

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Discussion of risks and possible benefits of study participation will be provided to participants. An electronic consent form describing in detail the study procedures and risks will be provided to the participant. Consent forms will be IRB-approved, and the participant is required to read and review the document or have the document read to him or her. The investigator or designee will explain the research study to the participant and answer any questions that may arise. The participant will sign the informed consent document prior to initiating any study-related assessments or procedures. Participants will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the signed informed consent document will be given to participants for their records. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study.

The consent process will be documented in the clinical or research record.

14.4 Exclusion of Women, Minorities, and Specific Age Groups

Inclusion of women: We anticipate approximately 50% of the study population to be female, based on a review of the National Dental Practice-Based Research Network (PBRN) dental practitioner base and participating patients. No persons will be excluded from the study based on gender.

Inclusion of minorities: Consistent with the Belmont Report, there are no exclusions based on race or ethnicity in this study. Individuals of any gender or racial/ethnic group may participate. Racial and ethnic minorities invited to participate in the study will be at least proportional to the composition in the National Dental PBRN dental practitioner membership. Existing patients of the practices participating the National Dental PBRN and individuals of any gender or racial/ethnic group may participate.
Inclusion of children: This project will not recruit persons aged less than 18 years.

Justification of not including children: There are two groups of participants in this study: DHCP (dentists and hygienists) and patients. The DHCP are adults working the dental field, who are older than 18 years of age. The patient participant group will be conducting surveys through emails and taking intraoral photos under supervision of a hygienist during a virtual meeting. Considering some children (younger than 18 years of age) do not have emails or have restrictions related to receiving an account for a virtual meeting platform, we will not include children patients in the study.

14.5 Participant Confidentiality

Participant confidentiality is strictly held in trust by the investigators, study staff, and the study sponsor(s) and their agents. This confidentiality is extended to cover testing of biological samples and genetic tests in addition to any study information relating to participants.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the study sponsor.

The study monitor or other authorized representatives of the NIDCR may inspect all study documents and records required to be maintained by the investigator, including but not limited to, dental and medical records (office, clinic, or hospital) for the study participants. The clinical study sites will permit access to such records.

Certificate of Confidentiality

To further protect the privacy of study participants, the Secretary, Health and Human Services (HHS), has issued a Certificate of Confidentiality (CoC) to all researchers engaged in biomedical, behavioral, clinical, or other human subjects research funded wholly or in part by the federal government. Recipients of NIH funding for human subjects research are required to protect identifiable research information from forced disclosure per the terms of the NIH Policy (https://humansubjects.nih.gov/coc/index). As set forth in 45 CFR Part 75.303(a) and NIHGPS Chapter 8.3, recipients conducting NIH-supported research covered by this Policy are required to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal statutes, regulations, and the terms and conditions of award. It is the NIH policy that investigators and others who have access to research records will not disclose identifying information except when the participant consents or in certain instances when federal, state, or local law or regulation requires

disclosure. NIH expects investigators to inform research participants of the protections and the limits to protections provided by a Certificate issued by this Policy.

Confidentiality of Data Sharing

As described in section 16, it is NIH policy that the results and accomplishments of the activities that it funds should be made available to the public (see https://grants.nih.gov/policy/sharing.htm). Pis and funding recipient institutions will ensure that all mechanisms used to share data include proper plans and safeguards to protect the rights and privacy of individuals who participate in NIH-sponsored research.

14.6 Future Use of Stored Specimens and Other Identifiable Data

The only identifiable data will be video recording of the SELFIE session. The video will be transcribed and coded for thematic analysis. The original video will be destroyed after the completion of transcribing. The transcript will be stored in a database developed by NCC of the National Dental PBRN.

15 DATA HANDLING AND RECORD KEEPING

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data. The investigators will maintain adequate case histories of study participants, including accurate case report forms (CRFs), and source documentation.

15.1 Data Management Responsibilities

Data collection and accurate documentation are the responsibility of the study staff under the supervision of the Principal Investigator. All source documents must be reviewed by the study team, who will ensure that they are accurate and complete. Unanticipated problems must be reviewed by the Principal Investigator or designee.

Practitioners will be trained on the electronic data capture (EDC) system by Principal Node Coordinator prior to patient enrollment. Practitioners will provide questionnaire responses directly into the EDC system on a study-issued tablet and/or personal computer or smart-phone. Patients will be enrolled into the system at the point of care, will provide consent and will provide data directly into the EDC system. For patients who do not complete follow-up eHygiene study data, the NE Principal Node Coordinator will contact participants via phone to complete post-eHygiene questionnaire and will enter data directly into the EDC system. The Principal Node Coordinator will ensure that discrepancies generated by the system are resolved in a timely manner. The NE Node staff will work with practitioners and/or patients to clarify any data issues and maintain a tracking log for the data changes.

15.2 Data Capture Methods

Study specific case report forms (CRFs) will be developed to include fields for all data elements required for participant assessments. The CRFs are programmed into a secure EDC system, which will be used to obtain data from participating practitioners and patients electronically at baseline and follow-up. The EDC system will also allow for upload of digital intraoral photos. An electronic (internet-based) data collection system will assist in ensuring that all required data are collected in the study database. As most fields will require a categorical response and some fields will ask for a numeric response, the data fields in the database will be programmed to allow only certain values and ranges so that data entered from the electronic system can be validated and data errors can be corrected. For patients who undergo telephone follow-up, the NE Principal Node Coordinator will enter data into the EDC system and will respond to data queries generated by the EDC system. Reports and tools will be developed to help monitor the data activities.

Patients will be requested to complete 1-4 Patient Post-eHygiene SUS, 1-5 Patient Post-eHygiene Questionnaire and1-6 Post-eHygiene Dentist-Patient Communication within the study assessment windows. Reminders and other tools will be used to encourage timely submission of these assessments; however, it is expected that some patients will not comply. Follow-up assessments received outside of the study specified windows will be accepted; though this data may not be included in the analysis, it would still be of interest to the study team.

15.3 Schedule and Content of Reports

Reports to monitor enrollment will be produced monthly during the participant enrollment period, until enrollment targets are attained and enrollment is closed and will be provided to the PI, study team and NIDCR. These reports will contain accrual information in aggregate.

Reports to assess study retention will be produced monthly until data collection is complete and will be provided to the PI, study team and NIDCR. These reports will provide ongoing monitoring of participant retention.

The procedure for locking the database prior to final analysis will be detailed in the study Data Quality Management Plan developed by the Data Manager at the NCC. Briefly, the data will be locked and final datasets will be generated at the end of the study. Prior to locking the database, the NCC Data Manager or designee will ensure all data are complete and clean and will obtain approval from the PI to proceed with the data lock.

15.4 Study Records Retention

The file connecting participants' names with their unique identification number will be kept in a password-protected file maintained by the NCC. Study records and code file (linking participant name with study identification number) will be maintained for at least three years from the date that the grant federal financial report (FFR) is submitted to the NIH. After that date, and as outlined by IRB regulations, data will be destroyed in an appropriate and safe way with concurrence from the Administrative and Resource Center PI, the NCC PI, and the grant PI.

15.5 Protocol Deviations

A protocol deviation is any change, divergence, or departure from the study procedures described in the IRB-approved clinical study protocol. The deviation may be on the part of the participant, the investigator, or study staff.

Consistent with the investigator obligations in the ICH E6 Guideline for Good Clinical Practice, the PI will document in study source documents and explain any deviation from the IRB-approved protocol. The PI will report to the IRB any deviations or changes made to eliminate immediate hazards to participants and any changes that increase risk to participants and/or significantly affect the conduct of the study.

Protocol deviations will be assessed for their impact on safety, study operations, and data integrity. Appropriate corrective and preventive actions will be implemented if warranted.

16 PUBLICATION/DATA SHARING POLICY

This study will comply with all applicable NIH Data Sharing Policies. See https://grants.nih.gov/policy/sharing.htm for policies and resources.

NIH Public Access Policy

The NIH *Public Access Policy* requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to *PubMed Central* immediately upon acceptance for publication. This ensures that the public has access to the published results of NIH funded research.

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APPENDIX A: Schedule of Events

Procedures	**DHCP enrollment (Day -60, 0)**	**Patient enrollment (Day 0)**	**Data Collection Timepoint 1 (in-patient visit) (Day 0)**	**Data Collection Timepoint 2 (virtual visit) (Day 7 ± 7)**	**Data Collection Timepoint 3 (virtual visit) (Day 90 ± 80)**	**Premature Discontinuation**
Assessment of Eligibility Criteria (DHCP)	X					
Signed Consent Form (DHCP)	X					
2-1 Dentist Baseline Questionnaire (Dentist) 3-1 Hygienist Baseline Questionnaire (Hygienist)	X					
Assessment of Eligibility Criteria (Hygienist & Patient)		X				
Signed Consent Form (Patient)		X				
1-1 Patient Demographic and Contact (Patient) 1-2 Patient Baseline Questionnaire (Patient) 1-3 Baseline Dentist-Patient Communication (Patient, In-office)		X				
Intraoral photos taken by Hygienist			X			
3-2 Hygienist Post-eHygiene SUS (Hygienist) 3-3 Hygienist Post-eHygiene Questionnaire (Hygienist)			X			
eHygiene virtual visit (Dentist and Patient)				X		
2-2 Dentist Post-eHygiene SUS (Dentist) 2-3 Dentist Post-eHygiene Questionnaire (Dentist)				X		
1-4 Patient Post-eHygiene SUS (Patient) 1-5 Patient Post-eHygiene Questionnaire (Patient) 1-6 Post-eHygiene Dentist Patient Communication (Patient)				X		
Phone Interview (Patient, Hygienist, Dentist) 1-7 Patient Qualitative Interview Guide (Patient)					X	

2-4 Dentist Qualitative Interview Guide (Dentist) 3-5 Hygienist Qualitative Interview Guide (Hygienist) 4-1 Qualitative Interview Completion Record (Study Staff)						
SELFIE session (Patient, Hygienist) 3-4 SELFIE Completion Record (Hygienist) 4-2 SELFIE Session Intraoral Images Assessment (Study Staff) 4-3 SELFIE Session Video Assessment (Study Staff)					X	
Document withdrawal in EDC by NE Principal Node Coordinator 4-1 Patient Withdrawal Form (Study Staff)						X