Implementing a Participatory, Multi-level Intervention to Improve Asian American Health

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STATEMENT OF COMPLIANCE

The study will be conducted in accordance with the International Council on 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.

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LIST OF ABBREVIATIONS

AAFE	Asian Americans for Equality
ABM	Agent-Based Modeling
AE	Adverse Event/Adverse Experience
AHRQ	Agency for Healthcare Research and Quality
CBPR	Community-Based Participatory Research
CAB	Community Advisory Board
CFIR	Consolidated Framework for Implementation Research
CFR	Code of Federal Regulations
CHW	Community Health Worker
Co-I	Co-Investigator
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form
CPC	Chinese-American Planning Council
CTSI	Clinical and Translational Science Institute
DHHS	Department of Health and Human Services
EHR	Electronic Health Record
EPIC	Expert Recommendations for Implementing Change
FDA	Food and Drug Administration
FFR	Federal Financial Report
FWA	Federal-Wide Assurance
GCP	Good Clinical Practice
GIS	Geographic Information System
H+H	Health and Hospitals Corporation
HIPAA	Health Insurance Portability and Accountability Act
HMH	Hamilton-Madison House
ICH	International Conference on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IOF	Implementation Outcomes Framework
IRB	Institutional Review Board
MedDRA®	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
MPI	Multiple Principal Investigators

N	Number (typically refers to subjects)
NIDCR	National Institute of Dental and Craniofacial Research, NIH, DHHS
NIH	National Institutes of Health
NYU	New York University
NYU Dentistry	New York University College of Dentistry
OCTOM	Office of Clinical Trials Operations and Management, NIDCR, NIH
OHRP	Office for Human Research Protections
PHI	Protected Health Information
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event/Serious Adverse Experience
SD	System Dynamics
SOP	Standard Operating Procedure
TBN	To Be Named
UB Geography	University at Buffalo Department of Geography
UP	Unanticipated Problem
US	United States
WHO	World Health Organization

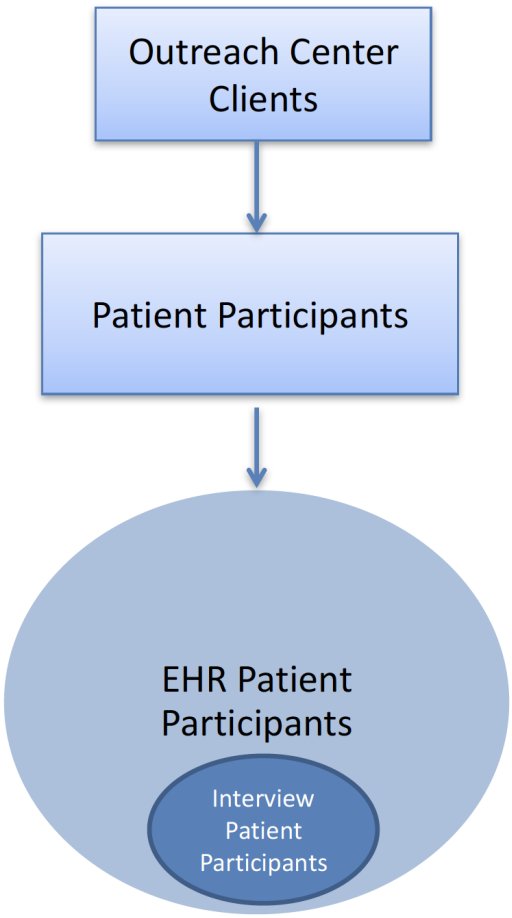
SPECIAL TERMS

Partnered Intervention

The partnered intervention consists of the following 4 evidence-based strategies: (1) written agreements of collaboration for dental screening at the site level; (2) culturally-tailored and language-specific adaptation of materials at the community and site levels; (3) demonstrations with role-playing of proper brushing with fluoride toothpaste and flossing techniques at the site and provider levels; and (4) community health worker (CHW) follow-up with patients about oral health care receipt and dental hygiene behaviors at the family and patient levels.

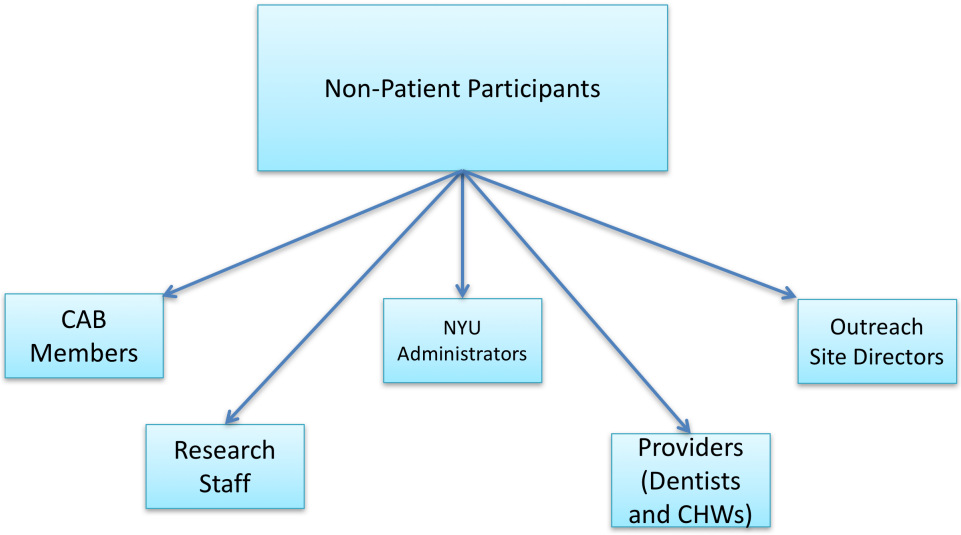
Patient Participants

Patient participants refer to study participants who are also patients screened at the urban outreach centers. Patient participants are first enrolled as EHR patient participants as part of the feasibility and acceptability study of this form of patient tracking. A subset of the EHR patient participants also complete exit interviews after the intervention at urban outreach centers and are referred to as interview patient participants.



Non-Patient Participants

Non-patient participants refer to all other study participants who are not patients screened at the urban outreach centers, including community advisory board (CAB) members, research staff, New York University (NYU) administrators, providers (dentists and CHWs), and outreach site directors.



PROTOCOL SUMMARY

Title: Implementing a Participatory, Multi-level Intervention to Improve Asian American Health

Abstract: This feasibility and acceptability study will be conducted at 3 community outreach centers serving an urban, low-income Chinese population. The study will evaluate the feasibility and acceptability of implementing a partnered intervention to improve the oral and general health of low-income, urban Chinese American adults and of using remote data entry into an electronic health record (EHR). The research staff will survey a sample of Chinese American patients screened at each center about their satisfaction with the partnered intervention and about their oral health behaviors. An additional sample selected from providers [dentists and community health workers (CHW)], research staff, New York University (NYU) administrators, site directors, and community advisory board (CAB) members will participate in structured interviews about the partnered intervention. The remote EHR evaluation will include group adaptation sessions and workflow analyses via multiple recorded sessions with research staff, NYU administrators, outreach site directors, and providers (dentists and CHWs). The study will also model knowledge held by these non-patient participants (including CAB members) to evaluate and enhance the partnered intervention during and/or after the feasibility and acceptability study for use in future implementations.

Objectives: The ultimate goal of this study is to provide information for the design and implementation of a larger, randomized, controlled trial of a participatory, multi-level, partnered intervention to improve the oral and general health of low-income Chinese American adults. Toward this end, this study has 3 objectives:

Primary:

- To evaluate and enhance the feasibility and acceptability of a partnered intervention designed to improve oral health for low-income, urban Chinese American adults at 3 community sites

Secondary:

- To evaluate and enhance the feasibility and acceptability of using remote data entry features of electronic health record (EHR) software at the New York University College of Dentistry (NYU Dentistry) to enter patient information at 3 Chinese American community sites

- To model knowledge held by non-patient participants about factors that influence access to oral health care and care-seeking behaviors among low-income, urban Chinese American adults, in order to enhance the intervention during and/or after the study for use in future implementations

Population: For the entire study, we plan to enroll a total of 182 human subjects: 150 patient participants and 32 non-patient participants.

As we are utilizing a community-based participatory research (CBPR) approach, several different populations/units of analysis are included in this feasibility and acceptability (F & A) study.

In accordance with CBPR principles, we will establish a community advisory board (CAB) comprised of 8 members to guide all aspects of the study.

The research staff (n = 10) is comprised of the 3 Multiple Principal Investigators (MPIs) (Drs. Northridge, Trinh-Shevrin, and Metcalf), the 3 Co-Investigators (Co-Is) at the New York University School of Medicine (NYU Medicine) (Drs. Troxel, Islam, and Yi), 2 Project Coordinators (TBN), and 2 modelers (Ms. Zhang and TBN).

The NYU administrators (n = 3) include both Co-Is at NYU Dentistry (Drs. Schenkel and Wolff) and an IT Specialist (Dr. Perelman).

The providers (n = 8) include faculty dentists at NYU Dentistry who participate in local community outreach events (n = 6) and bilingual (English and Mandarin Chinese) CHWs (n = 2).

Outreach site directors at each of 3 participating community outreach centers (n = 3) serving low-income Chinese American populations in New York, NY.

EHR patient participants. At least 50 low-income Chinese American adult patients will undergo a dental screening at each of 3 community outreach centers (n = 150) and have their data remotely entered into the NYU Dentistry EHR.

Interview patient participants. Approximately 30 Chinese American patients screened at each of 3 community outreach centers will be enrolled in the study as participants (n = 90) to complete interviews about their satisfaction with the partnered intervention and their use of dental services and evidence-based oral health behaviors.

Phase: Not applicable

Study Sites: The 2 study sites are New York University (intervention site) and the

State University of New York at Buffalo (modeling site).

Outreach Sites:

A total of 3 Chinese American community outreach centers will be selected by the research staff and the CAB members. As per the Office of Human Research Protections (OHRP) of the US Department of Health and Human Services, these sites whose employees or agents perform commercial or other services for the study investigators are not engaged in human subjects research since all of the following conditions are met:

(a) the services performed do not merit professional recognition or publication privileges;
(b) the services performed are typically performed by those institutions for non-research purposes; and
(c) the institution's employees or agents do not administer any study intervention being tested or evaluated under the protocol.

The following organizations provided letters of support, which will form the basis for selecting 3 community outreach centers and 8 CAB members for this F & A study:

- Asian Americans for Equality (AAFE)
- Chinatown YMCA, a branch of the YMCA of Greater New York
- Chinese-American Planning Council (CPC)
- Coalition for Asian American Children and Families (CACF)
- Hamilton-Madison House (HMH)

Moreover, 2 NYU centers provided letters of support for this feasibility and acceptability study.

- Integrating Special Populations Unit, New York University Health and Hospitals Corporation (NYU-H+H) Clinical and Translational Science Institute (CTSI)
- NYU-H+H CTSI

Description of Intervention:

The aspects of the partnering package of evidence-based intervention strategies are: (1) written agreements of collaboration for dental screening, health promotion, and incentives; (2) culturally-tailored and language-specific adaptation of materials; (3) demonstrations with role-playing of proper brushing with fluoride toothpaste and flossing techniques; and (4) CHW follow-up with patients of oral health care receipt and dental hygiene behaviors.

Additionally, bilingual (English and Mandarin Chinese) CHWs will

receive additional training in oral health promotion demonstration, oral health services and programs available at local clinics and hospitals, information about dental and health insurance, and evidence-based oral health behaviors.

Study Duration: 1 year

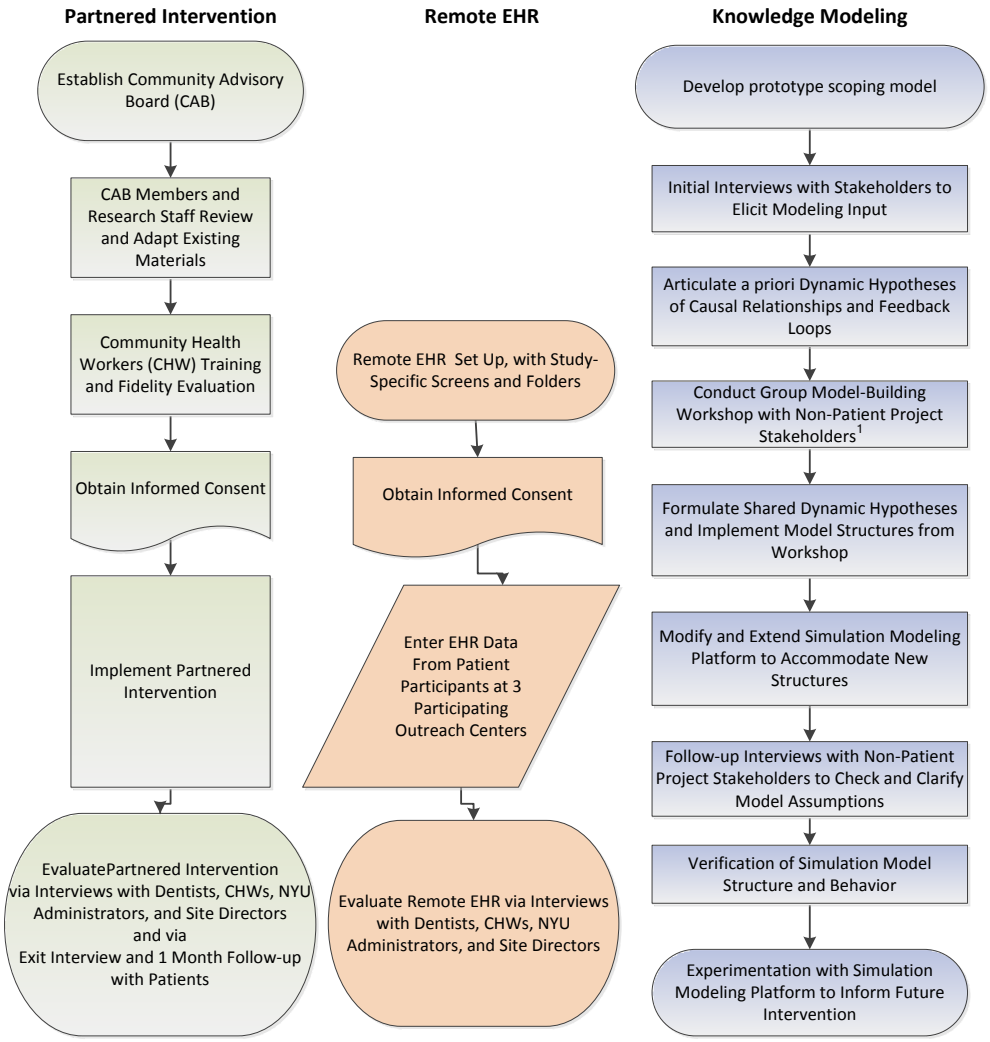
Subject Participation Duration: Participation duration refers specifically to the period of time when data are collected from individual participants. It does not capture periods of time when individual participants are remotely entering EHR data or administering aspects of the intervention or protocol. That information is captured elsewhere in this protocol.

- 1 year for the community outreach centers
- 1 or more days for each research staff member, NYU administrator, provider (dentist or CHW), CAB member, or outreach site director to respond to questions about the partnered intervention and/or the remote EHR implementation
- Up to approximately 2 months (includes 1 in-person visit and 1 telephone follow-up) for each enrolled interview patient participant
- 1 day for each research staff member, NYU administrator, provider (dentist or CHW), CAB member or outreach site director to provide their input about factors affecting health care utilization among the clients of the outreach centers

Estimated Time to Complete Enrollment:

- Approximately 1 month to select the 3 participating outreach centers from the partners that have previously pledged their commitment to the study
- Research staff, administrators, providers (dentists and CHWs) and clients/patients may be responding to feasibility and acceptability questions at any time during the study. Therefore, enrollment of these individuals can be open for the entire year of the study; participation in a particular set of questions can be completed in 1 day.
- Enrollment of research staff, NYU administrators, providers (dentists and CHWs), CAB members and outreach site directors providing their knowledge about factors that influence access to oral health care and care-seeking behaviors among low-income, urban Chinese American adults can be open for the entire year of the study.

Schematic of Study Design:



[1]May occur either before or after the start of the implementation of the partnered intervention

1 KEY ROLES AND CONTACT INFORMATION

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Responsibilities: Dr. Metcalf and her team will be primarily responsible for modeling the knowledge gained about factors at the community, site, family, provider, and patient levels to enhance community- and clinic-based oral health service

delivery and improve health and health care. Dr. Metcalf will oversee all of the group model building and simulation activities.

Chau Trinh-Shevrin, DrPH – Co-I: As the lead investigator at the NYU School of Medicine, Dr. Trinh-Shevrin will oversee all CBPR and CHW components of the intervention.

Andrew Schenkel, DMD, MS – Co-I: As a Co-I and the Program Leader for the study, Dr. Schenkel will be primarily responsible for overseeing the Local Community Outreach Programs that will host the screening events for this implementation science research. He will also be key in planning and implementing the remote EHR system to enable tracking at the community, site, provider, and patient levels of receipt of oral health care visits, services, and health and health care measures. Finally, he will participate in the group model building exercises, interpretation of findings, and manuscript preparation for this study.

Mark Wolff, DDS, PhD – Co-I: As a Co-I and Project Champion for the study, Dr. Wolff will support, market, and drive through the implementation of the enhanced EHR community outreach program and contribute his expertise and experience to the group model building activities and the writing of manuscripts that emanate from this research.

Andrea Troxel, ScD – Co-I: As a Co-I and Biostatistician for the study, Dr. Troxel will provide guidance on all aspects of study design and analysis.

Nadia Islam, PhD – Co-I: As a Co-I for the study, Dr. Islam will provide oversight and guidance on study implementation using a CBPR approach and intervention design using CHWs.

Stella Yi, MPH, PhD – Co-I: As a Co-I for the study, Dr. Yi will provide oversight and guidance on study implementation and design regarding the implementation of EHR-based referrals and data collection.

2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

Lack of access to oral health care contributes to profound and enduring oral health disparities in the United States and worldwide. Vulnerable and underserved populations who commonly lack access to oral health care include but are not limited to racial and ethnic minorities, including immigrants and non-English speakers.

Asian Americans are the fastest growing minority group in the United States, yet are rarely included in oral health care research. The Center for the Study of Asian American Health (CSAAH) at the New York University School of Medicine (NYU Medicine) is the only National Institute for Minority Health & Health Disparities Center of Excellence in the United States solely dedicated to research and evaluation on Asian American health and health disparities. A Chinese Community Health Resources and Needs Assessment conducted by CSAAH and its community partners identified cardiovascular disease and oral disease to be the top health concerns among community members. Chinese are the largest Asian ethnic group in New York, NY, with higher poverty rates for working age and older adults relative to all residents and a higher proportion of foreign-born residents. NYU College of Dentistry (NYU Dentistry) and NYU Medicine have partnered on community-based participatory research (CBPR) initiatives to improve oral health and health care in Sikh American community-based settings using CHW models.

Interventions often fail or even worsen the problems they are intended to solve due to a lack of understanding of real world structures and dynamic complexity. In longstanding collaboration with the University at Buffalo Department of Geography (UB Geography), our research team has examined how factors at multiple levels contribute to oral health and care-seeking behaviors for racial and ethnic minority older adults. To improve our mental models of the real world, we have employed system science methodologies such as system dynamics, agent-based modeling, geographic information science, and social network simulation.

The 2011 report by the National Academies titled, Improving Access to Oral Health Care for Vulnerable and Underserved Populations is based on the following 2 well-established and evidence-based principles: (1) Oral health is an integral part of overall health and, therefore, oral health care is an essential component of comprehensive health care. (2) Oral health promotion and disease prevention are essential to any strategies aimed at improving access to care. Our long-term goal is to improve Asian American health.

2.2 Rationale

The study intervention, a partnering package of evidence-based intervention strategies, and the process of implementing remote EHR data entry and tracking in diverse

Chinese American community outreach sites are guided by 2 complementary, multi-level frameworks: Consolidated Framework for Implementation Research (CFIR) and Implementation Outcomes Framework (IOF). Specifically, CFIR provides a menu of constructs that have been associated with effective implementation and have been used in a range of applications, whereas IOF is clear in distinguishing implementation, service, and patient outcomes. In other words, while IOF provides an evaluation framework that organizes the multiple facets that affect implementation of new interventions, CFIR provides a framework for understanding the multiple domains that influence implementation and adoption of these interventions. Because our proposed intervention is both multi-level and dynamic with numerous involved constructs, we intend to model knowledge about factors at the community, site, provider, family, and patient levels to improve oral health using a participatory group modeling approach.

This feasibility and acceptability study will make a vital contribution by conducting formative research intended to provide preliminary information about the feasibility and acceptability of the intervention and the data collection methodology. This information may be used to inform the design and implementation of a larger, randomized, controlled trial of the intervention to improve the oral and general health of low-income Chinese American adults and to identify the mechanisms by which these strategies may be scaled up and adapted for other Asian ethnic groups.

2.3 Potential Risks and Benefits

2.3.1 Potential Risks

Despite the enhanced computer security (see Section16), patient data may be at a higher risk for computer hacking, leading to a loss of medical record confidentiality.

2.3.2 Potential Benefits

Outreach center clients/patients may benefit from the intervention, including the translated and culturally customized literature, by being influenced to pursue dental care and conduct twice-daily dental hygiene using evidence-based products and procedures.

3 OBJECTIVES

The ultimate goal of this study is to provide information for the design and implementation of a larger, randomized, controlled trial of a participatory, multi-level, partnered intervention to improve the oral and general health of low-income Chinese American adults. Toward this end, this study has 3 objectives.

3.1 Study Objectives

Primary:

- To evaluate and enhance the feasibility and acceptability of a partnered intervention designed to improve oral health for low-income, urban Chinese American adults at 3 community sites

Secondary:

- To evaluate and enhance the feasibility and acceptability of using remote entry features of electronic health record (EHR) software at NYU Dentistry to enter patient information at 3 Chinese American community sites. Note that the remote EHR referenced throughout this protocol will be set up and managed by NYU Dentistry information technology staff, under the direction of Drs. Wolff and Perelman.

- To model knowledge held *a priori* by non-patient participants about factors that influence access to oral health care and care-seeking behaviors among low-income, urban Chinese American adults, in order to enhance the intervention during and/or after the study for use in future implementations

3.2 Study Outcome Measures

3.2.1 Primary

Patient satisfaction with the partnered intervention components, based on exit interviews.

3.2.2 Secondary

Table 1 reflects the series of secondary outcome measures associated with the objectives of the study (i.e., the feasibility and acceptability of the partnered intervention).

Table 1. List of secondary outcome measures, with their corresponding constructs, levels of analysis, and data sources.

Constructs	Levels of Analysis	Measures (Quantitative / Qualitative)	Data Sources
IMPLEMENTATION OUTCOME MEASURES			
Acceptability	Provider	satisfaction with the partnering components and perceived ease of use of the remote entry EHR	exit interviews with patients; semi-structured interviews
Adoption	Provider Institution	uptake and utilization of remote entry EHR and partnering components by providers and program	observation; semi-structured interviews; EHR
Costs	Institution	intervention and implementation costs, including investment, supply, and opportunity costs	semi-structured interviews; EHR
Feasibility	Provider Site	extent to which the remote EHR entry and partnered intervention model are compatible with resources and training	semi-structured interviews; EHR
Fidelity	Provider	adherence to program protocol and quality of delivery	CHW logs; self-report
Sustainability	Institution Site	sustained remote EHR use at outreach events and partnering package of interventions	semi-structured interviews; EHR
SERVICE OUTCOME MEASURES			
Equity	Community Provider Family Patient	support from community partners, providers (including NYU Dentistry), family members & patients to direct resources to less well-served and less well-studied populations (Chinese American adults)	baseline survey; follow-up patient interviews; semi-structured interviews; EHR
ORGANIZATIONAL CHARACTERISTICS			
Engagement	Institution Site	commitment, involvement & accountability of leaders with the implementation	semi-structured interviews

- Work flow analysis of the interviews of research staff, NYU administrators, and providers (dentists and CHWs) is a secondary measure designed to evaluate and refine the use of the remote EHR.

- Knowledge of the research staff, NYU administrators, providers (dentists and CHWs), outreach site directors, and CAB members about factors that influence access to oral health care and care-seeking behaviors among low-income, urban Chinese American adults are secondary measures designed to be used in simulations to represent dynamics at multiple levels (patient, family, provider, site, and community).

- The simulation modeling platform is a research product of the study that will be used to experiment with strategies to promote preventive care through regular dental visits and self-efficacy among Chinese Americans.

4 STUDY DESIGN

This feasibility and acceptability study will be conducted at 3 community outreach centers serving an urban, low-income Chinese American population. The study will evaluate the feasibility and acceptability of implementing a partnered intervention to improve the oral and general health of low-income, urban Chinese American adults and of using remote entry into an electronic health record (EHR). The evaluation will include group adaptation sessions and workflow analyses of the EHR implementation, involving multiple recorded sessions with NYU administrators, providers (dentists and CHWs), outreach site directors, and research staff. The study will also model *a priori* knowledge held by non-patient participants to evaluate and enhance the intervention during and/or after the study for use in future implementations.

Approximately 50 patient participants who self-identify as Chinese American from each of 3 center (n = 150) will be consented to allow the entry of their data (e.g., demographic information, medical history, receipt of oral health care visits, dental hygiene behaviors, and health and health care measures) into the remote EHR by authorized NYU Dentistry staff (EHR patient participants). Of these 150 EHR patient participants, research staff will survey approximately 30 Chinese American patient participants from each of 3 outreach centers (n = 90) regarding their satisfaction with the intervention components (interview patient participants). The study team will also evaluate feedback from approximately 32 non-patient participants selected from the following groups: research staff, CAB members, outreach site directors, NYU administrators, and providers (dentists and CHWs); these individuals will be interviewed about various aspects of the partnered intervention and/or the remote EHR implementation process and/or their *a priori* knowledge of factors that influence access to oral health care and care-seeking behaviors among low-income, urban Chinese American adults.

5 STUDY ENROLLMENT AND WITHDRAWAL

5.1 Subject Inclusion Criteria

Outreach center patients will be enrolled into either or both of 2 groups.

Approximately 50 patients from each of 3 centers (n = 150) will be consented to allow their data to be entered via the remote EHR. These EHR patient participants must meet all of the following criteria to be enrolled:

1. Greater than or equal to 21 years of age
2. Self-identify as being of Chinese ethnicity
3. Live in any of the 5 boroughs of New York, NY and visit a participating outreach center
4. Able and willing to provide informed consent to have their data entered into the remote EHR

Approximately 30 patients from each of 3 centers (n = 90) will be consented to participate in an exit interview and a follow-up interview. This is a subset of the 150 EHR patient participants. We anticipate that about 60% of EHR patient participants will be able to complete an exit interview and a follow-up interview. These interview patient participants must meet all of the following criteria:

1. Greater than or equal to 21 years of age
2. Self-identify as being of Chinese ethnicity
3. Live in any of the 5 boroughs of New York, NY and visit a participating outreach center
4. Able and willing to provide informed consent and participate in an exit interview and a follow-up interview

Approximately 20 research staff, NYU administrators, outreach center directors, and providers (dentists and CHWs) will be enrolled to participate in interviews about the partnered intervention and/or remote EHR. These non-patient participants must meet all of the following criteria:

1. Greater than or equal to 18 years of age
2. Be employed or volunteers at participating outreach centers or employed at NYU
3. For CHW-staff, speak and read Mandarin Chinese

4. Able and willing to provide informed consent

Approximately 32 non-patient participants (research staff, NYU administrators, CAB members, outreach site directors, and providers (dentists and CHWs) will be enrolled to participate in interviews and a group model-building workshop to inform model development by sharing their knowledge about factors that influence access to oral health care and care-seeking behaviors among low-income, urban Chinese American adults. These individuals must meet all of the following criteria:

1. Greater than 18 years of age
2. Be employed or volunteers at participating outreach centers or employed at NYU
3. Able and willing to provide informed consent

5.2 Subject Exclusion Criteria

Individuals meeting any of the following criteria will not be enrolled as either EHR patient participants or interview patient participants:

1. Have an acute or terminal illness or a serious mental illness or any other severe health condition(s) that might preclude visiting an oral health care provider
2. Are currently participating in another oral health study

Individuals meeting any of the following criteria will not be enrolled to complete the interviews about the partnered intervention or remote EHR or to provide input to the knowledge modeling activities:

1. Staff in functional areas that do not directly service patients (e.g., custodial staff)

A patient participant may participate in either the EHR patient participant group only or both the EHR patient and interview patient participant groups (interview patient participants are a subset of EHR patient participants). A non-patient participant may participate in any or all of the non-patient participant data collection activities.

5.3 Strategies for Recruitment and Retention

Five Chinese American community-based organizations have already volunteered to participate in this study. The 3 outreach centers for this study will be selected from among the affiliated outreach centers of these organizations.

Adults served by the outreach centers will be recruited by NYU research staff working with 3 Chinese American community sites in New York, NY.

EHR patient participants (of whom certain individuals are also interview patient participants) will receive a voucher worth $205 for oral health care at NYU Dentistry to

cover her/his comprehensive oral examination, treatment plan, and prophylaxis at no charge and with no co-payment required as compensation for participation.

Non-patient participants--research staff, NYU administrators, providers (dentists and CHWs), outreach site directors, and CAB members--will receive no monetary compensation for their participation in the study, over and above their salaries/stipends.

5.4 Subject Withdrawal

5.4.1 Reasons for Withdrawal

Any of the various participants (i.e., CAB members, outreach site directors, EHR patient subjects, interview patient subjects, research staff, NYU administrators, dentists, and CHWs) may withdraw from the study at any time. Patients will have the right to refuse to participate without any compromise of their health or dental services. Also, if a participant is uncomfortable during an interview or survey administration, s/he may stop at any time without penalty.

5.4.2 Handling of Subject Withdrawals or Subject Discontinuation of Study Intervention

If an EHR patient participant withdraws consent, no further data from that patient will be entered into the EHR for that participant. Depending on the nature of the request to withdraw, it may be necessary to remove existing data for that patient from the EHR.

5.5 Premature Termination or Suspension of Study

This study has no explicit stopping rules. The study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the MPIs and/or the NIDCR, as applicable. If the study is prematurely terminated or suspended, the MPIs will promptly inform the Institutional Review Boards (IRBs) and provide the reason(s) for the termination or suspension.

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

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

6 STUDY INTERVENTION

6.1 Administration of Intervention

Initially a CAB will be established to guide all aspects of the study.

Partnered intervention: Our partnering package of interventions builds upon the evidence-based practices of the NYU Dentistry Local Community Outreach Programs and the results of our pilot study in the Sikh American community, and aligns with the implementation strategies from the Expert Recommendations for Implementing Change (EPIC) project. We will work closely with the directors of 3 Chinese American outreach sites to create written agreements of collaboration that outline the roles and responsibilities of the investigative team and the sites. An integral part of effectively implementing oral health activities with low-income, racial and ethnic minority, and immigrant populations, including Chinese Americans, is to develop program materials that are specific to the local community. Training lay individuals of the same cultural and linguistic background as participants, e.g., CHWs through train-the-trainer techniques, has been found to be an acceptable approach for delivering culturally-appropriate, community-based oral health interventions as well as for recruiting participants into interventions through community and social networks. CHWs have been found to be effective in providing dental education and counseling, leading interactive demonstrations of brushing with fluoride toothpaste and flossing, and improving access to dental care through dental coverage enrollment and linkage to local dentists.

Development of culturally-tailored and language-specific materials: The CAB will be responsible for reviewing existing program materials as an integral part of adapting them for the local Chinese American population. This will entail a multi-step process. Existing English and simplified Mandarin Chinese language materials will be presented to the CAB. Dr. Yi will then lead a guided discussion structured around the 4 P's of social marketing. For product, CAB members will be asked if the materials encourage prevention of oral conditions through regular dental visits and brushing with fluoride toothpaste. For price, CAB members will be asked how much it will cost a person to take on the desired behaviors in terms of time and effort, not merely dollars and cents. For place, CAB members will be asked to help compile a list of local dental providers in addition to NYU Dentistry who provide culturally-tailored and language-specific oral health care to Chinese American families. For promotion, CAB members will be asked to identify other Chinese American community change agents to promote the program through word of mouth, social media, and neighborhood venues. CAB input will also be sought on incorporating appropriate imagery and cultural beliefs regarding oral health in the Chinese American community. This guidance will then be used to adapt both print and online materials. Finally, the adapted materials will be presented back to the CAB to ensure their input was accurately captured.

6.2 Procedures for Training Interventionists and Monitoring Intervention Fidelity

Both CHWs in this study were formerly trained as CHWs, have a history of engaging in health promotion with the Chinese American community, and are bilingual in English and Mandarin Chinese (the primary dialect of participating community outreach sites). Specifically, the project CHWs were previously trained in a core competency program that employed diverse training methods, guided by adult learning principles and popular education philosophy. We will further train the project CHWs in the oral health promotion demonstration protocol and on oral health services and programs available at local clinics and hospitals. The investigative team and CAB members will also collect, assess, and deliver to the CHWs updated information regarding health and dental insurance and access to oral health programs available for low-income and immigrant communities. NYU Dentistry investigators and staff will train the CHWs using models on evidence-based oral health practices, stressing the importance of drinking fluoridated water and brushing teeth for 2 minutes twice a day with a soft-bristled toothbrush and fluoride toothpaste. This train-the-trainer model will promote peer support and allow the project to be replicated and sustained across settings. Interactive educational techniques will be integrated into the demonstrations.

At the end of the training, the CHWs will collaborate in groups to practice delivering short excerpts from the curriculum to their peers and project team members, with the trainers providing comments and assistance. Approximately 1 month before the CHW training is complete, the curriculum will be pilot tested to ensure its cultural appropriateness with patients. Two mock educational sessions and a final examination of knowledge and evaluation of trial encounters with mock participants will be conducted with project investigators and CAB members. Individuals who score below the threshold level of knowledge regarding oral health promotion will receive intensive 1-on-1 tutoring and be required to take a second examination of knowledge. Quality assurance controls will be built into the intervention. Drs. Northridge and Yi will meet with the CHWs on an approximately bi-weekly basis to ensure that the model components are being consistently applied. Each CHW will keep a log of activities and communication around their follow-up of patients. These logs will be reviewed as necessary to evaluate the type and nature of communications between the CHWs and their assigned study participants.

6.3 Assessment of Subject Compliance with Study Intervention

Not applicable. There is no assessment of subject compliance.

7 STUDY SCHEDULE

The study will extend for approximately 1 year. An approximate timeline for implementation of the various aspects of this study is as follows:

Table 2. Timeline of study activities

Study activities	Months 1-6	Months 7-12
Recruitment of CAB and outreach sites		
Review, update, and finalize CHW training materials / IRB		
Train CHW, evaluate fidelity, retrain as necessary		
Implement partnered intervention		
***Exit and 1 month follow-up interviews of enrolled patients who participated in the partnered intervention*		
***Semi-structured interviews of non-patient participants regarding partnered intervention (including materials review prior to implementation)*		
Workflow analysis for remote EHR entry		
Pilot testing and live-usability for remote EHR		
***Semi-structured interviews of non-patient participants in EHR implementation.*		
***Semi-structured interviews of non-patient participants to inform model*		
***Group model-building workshop*		
Development of simulation modeling platform		

***Data collection activity.*

7.1 Pre-intervention Activities

- Create written agreements of collaboration that outline the roles and responsibilities of the investigative team and the outreach sites
- Develop culturally-tailored and language-specific program materials
- Train CHWs in the intervention protocol
- Conduct a workflow analysis of remote EHR data entry at Chinese American outreach centers

7.2 Outreach Center Activities

- Health Insurance Portability and Accountability Act (HIPAA) certified research staff members or volunteers will explain the consent form, confidentiality agreement, and liability release to each potential patient participant and obtain her/his signature
- Remote EHR Data Collection and Dental Screening:

- Authorized NYU Dentistry personnel will directly enter the demographic information of patient participants into the customized EHR using the study-specific SCREENING option

- EHR patient participants will complete a short paper intake form that will be scanned directly into a designated SCREENING folder in the EHR regarding medical conditions that could affect, or be affected by, their oral health (Yes / No checklist) and a brief questionnaire on self-reported receipt of a dental visit in the past year and dental hygiene behaviors (Oral Health Survey). These questions will be based on the World Health Organization (WHO) Oral Health Questionnaire for Adults: (1) How often do you clean your teeth? (Never, Once a month, 2-3 times a month, Once a week, 2-6 times a week, Once a day, Twice or more a day); (2) Do you use any of the following to clean your teeth? (Toothbrush, Wooden toothpicks, Plastic toothpicks, Thread (dental floss), Charcoal, Chewstick / miswak, Other (Please specify); (3) For those who nominate Toothbrush: What type of toothbrush do you use? (Hard-bristled, Medium-bristled, Soft-bristled) (4) Do you use toothpaste to clean your teeth? (5) For those who nominate Toothpaste, Do you use a toothpaste that contains fluoride? Correct responses to all 5 questions will indicate that EHR patient participants are following the guidance of the American Dental Association (ADA) on brushing with fluoride toothpaste. These measures will be collected in person via self-report to ascertain baseline status at the beginning of each screening event and scanned directly into the NYU Dentistry remote EHR customized for community outreach events.

- An NYU Dentistry faculty dentist will conduct a head and neck / oral examination on each EHR patient participant and directly enter the results into the customized EHR

- The dentist will review the examination results with the EHR patient participant using a customized walkout statement with screening results and follow-up notes and answer any questions regarding oral health concerns

- CHW Initial Intervention: Trained CHWs will deliver a culturally-tailored and language-specific oral health promotion program focusing on demonstrations with role-playing of proper brushing with fluoride toothpaste and flossing techniques. They will also provide culturally customized literature to the patients.

- Acceptability Data Collection: Research staff will conduct a brief exit interview with each interview patient participant regarding acceptability of

the intervention and self-efficacy around oral health behaviors, requesting permission to contact her/his regular dental provider regarding receipt of a follow-up dental visit and providing a voucher worth $205.00 for oral health care at NYU Dentistry to cover her/his comprehensive oral examination, treatment plan, and prophylaxis at no charge and with no co-payment required. The questions for this survey will be based on our previous oral health promotion program in the Sikh American community to assess acceptability. Prior to finalizing the survey for distribution to the interview patient participants, CAB members and research staff will adapt the questions as deemed appropriate for the Chinese American community and to be consistent with the ADA guidance on brushing with fluoride toothpaste.

- Feasibility Data Collection: We will also develop a checklist of 10 key components based on process (e.g., patient engagement) and the curriculum (e.g., topics covered) and ask if each one was covered. Endorsement of 8 of the 10 checklist items (80%) by the non-patient participants will be considered as the bar for success for feasibility. Finally, we will allow for open-ended collection of feedback on the feasibility of each of the partnered program components.

7.3 CHW Follow-up Contact with Interview Patient Participants (Feasibility Data Collection)

- CHW follow-up of oral health care receipt and dental hygiene behaviors will occur at approximately 1 month (window of -7 days to +1 month) after the partnered intervention. This contact may be via telephone or in person.
- Feasibility Data Collection: During this contact, the CHWs will assess whether or not each interview patient participant has received or has scheduled a dental visit. The CHWs will also inquire about use of fluoride toothpaste and frequency of teeth brushing since the last visit in a modified Oral Health Survey.
- If no visit has occurred or been scheduled, the CHW will offer to help schedule a dental visit for the interview patient participant or her/his family members at NYU Dentistry, her/his regular dentist, or one of the project-approved local oral health care providers.

7.4 Post-intervention Activities

- Feasibility and Acceptability Data Collection: Semi-structured interviews with participating dentists, CHWs, and other non-patient participants will be conducted (see section 8.1.3)
- Feasibility Data Collection: EHR data will be reviewed to assess feasibility

7.5 Knowledge Modeling Activities

- Create the interview guide for non-patient participant input into the modeling (pre-intervention)
- Conduct initial non-patient participant interviews to inform model development
- Conduct the group model-building workshop
- Conduct follow-up non-patient participant interviews to clarify assumptions

8 STUDY PROCEDURES /EVALUATIONS

8.1 Study Procedures/Evaluations

8.1.1 Workflow analysis

The team will conduct a workflow analysis, adapted from the Agency for Healthcare Research and Quality (AHRQ) recommendations on workflow assessments, which includes:

1. Direct entry of patient demographic and appointment (site) information into the EHR by patient service representatives (PSRs) or other authorized users;

2. Ability to scan patient medical history (plus baseline oral health measures of self-reported receipt of a dental visit in the past year and brushing with fluoride toothpaste as recommended) directly into a designated SCREENING folder, followed by transcription and review by faculty dentists;

3. MiFi (Wi-Fi hotspot) configuration to each specific laptop (electronic tablet) that will only allow EHR access to the matching laptop (tablet);

4. Multiple layers of security embedded to comply with all applicable policies;

5. Dual authentication process through Citrix via NYU active directory followed by login to the EHR via NYU ID card;

6. Direct entry of screening results into the EHR by dentists; and

7. Customized walkout statements for interview patient participants with screening results and follow-up notes.

A matrix will be created with 3 categories: people, documents, and information content. The group adaptation session will be guided by a user-centered design facilitation protocol that sequentially leads the group through presentation of specific remote EHR use cases that include variations on the original EHR data entry screens adapted to the workflow characteristics of local community sites. For each presented use case, the group discussion will focus on the workflow at the site around the role responsibilities (people), documents, and information content (patient medical history, self-reported outcome measures, head and neck / oral examination results) with regard to reviewing customized EHR protocols based on the findings. The discussion will be digitally recorded and each non-patient participant will be given color-coded response sheets to record their perspectives on how to enhance the usefulness of the customized EHR protocols within the community outreach site setting. The digital recordings and response sheets will then be processed, summarized, and converted into adaptation recommendations by the study team. Next, the study team will transform the recommendations into proposed revisions and document them in revised standard

workflow diagrams that build on established workflows to minimize changes at the sites or new work for the dental providers. The insights will then be used to adapt the customized EHR protocols and related workflows and will be validated in a follow-up group meeting at each site where the adapted EHR screens will be presented and assessed according to the IOF implementation outcome measures of acceptability and adoption. During these follow-up meetings, we will identify any additional workflow variations that the EHR protocols may need to support. Candidate workflows will then be discussed with the project team and other non-patient participants to finalize the adapted workflow integration approach.

8.1.2 Pilot testing and live usability for remote EHR

Pilot testing and live-usability: In order to account for real world conditions, the intervention will be pilot tested at 3 Chinese American outreach sites. Early formative observations / short interviews will be conducted with dental teams at each of the pilot sites regarding interaction with the customized EHR. This pilot testing will examine impact on workflow, uncover any new usability problems, and identify any educational needs to be included before large-scale implementation. As providers at the pilot sites engage with the EHR, live-usability testing will be conducted, consisting of direct observations by the research team. Live usability is ideal for observing the impact of new tools on real setting workflows and for observing alternative workflows that can be missed during simulations.

8.1.3 Semi-structured interviews regarding the remote EHR and partnered intervention

Semi-structured interviews will be conducted with participating dentists, CHWs and other non-patient participants in administrative and technical roles after the intervention. We anticipate conducting approximately 20 interviews before obtaining data saturation. The interviews will be informed by the Consolidated Framework for Implementation Research (CFIR) and Implementation Outcomes Framework (IOF) constructs and will assess specific barriers to sustaining the partnered intervention and strategies for addressing those barriers to facilitate integration of the intervention into the routine workflow of the NYU Dentistry Local Community Outreach Programs.

In addition to survey questions, acceptability will also be assessed using open-ended questions, such as:

- Please tell us what you liked most about the program.
- Please tell us what you did not like about the program.
- Please tell us what changes can be made to improve the program.
- Overall program satisfaction (scale of 1-10 answer range)
- How did you feel about the topics covered?

- How did you feel about the length of time of the dental screening and oral health promotion demonstrations?

Feasibility will be assessed among the dentists, CHWs, NYU administrators, and site directors at the 3 partnering organizations. The following questions will be asked:

- How did you feel about the intake procedures?
- How did you feel about the oral health demonstrations by CHWs?
- How did you feel about the length of time of each dental screening?

8.1.4 Participatory modeling of non-patient participant knowledge

The third aim of this study is to model knowledge held by non-patient participants about factors that influence access to oral health care and care-seeking behaviors among low-income, urban Chinese American adults. This information will be used in designing simulation models at multiple levels, from multiple perspectives. A systems science approach will be undertaken to integrate knowledge held by non-patient participants into simulation models to explore alternative paths toward improved health and health care for low-income, urban Chinese American adults via community-based outreach followed by clinical care. These simulation models will be designed using a multi-method approach, in which principles of system dynamics (SD) are used to incorporate feedback effects and delays through stocks that accumulate flows (rates of change over time). The SD approach will be integrated with an agent-based modeling (ABM) framework that is used to appropriately represent dynamics at the community, site, provider, family, and patient levels. The model platform developed for this study will contain multiple model structures that characterize different dynamics and reflect participant input.

Modeling to anticipate effects of interventions. The models in this platform will simulate implications of hypotheses elicited *a priori* (before implementation of the partnered intervention) from non-patient participants. The *a priori* model platform will enable comparison to models that are later developed with hindsight from implementation of the remote EHR and partnered interventions. This model platform will therefore test the relative effectiveness of the interventions as anticipated under these *a priori* assumptions. Toward this end, this effort will involve design of scoping models that establish a baseline for simulating access at the community level and care-seeking behaviors at the individual level.

A participatory SD modeling process will be undertaken via a group model-building workshop held with non-patient participants as well as semi-structured interviews with individual non-patient participants to elicit targeted model input and feedback on assumptions. The UB Geography Systems Science Modeling Team will work closely with non-patient participants to devise indices for input parameters and indicators for outcomes of simulation experiments. In addition to informing the design of model structures, this participatory approach will enable non-patient participants to better

assess the results of the simulation models developed in this *a priori* model platform for authenticity and identification of insights for subsequent implementation research. The resulting model platform will establish a multi-level agent-based GIS framework for simulation modeling of access to oral health care and care-seeking behaviors by low-income, urban Chinese American adults at the community, site, provider, family, and patient levels.

9 ASSESSMENT OF SAFETY

9.1 Specification of Safety Parameters

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

9.1.1 Unanticipated Problems

The Office for Human Research Protections (OHRP) considers unanticipated problems 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.

9.1.2 Unanticipated Problem Reporting to IRB and NIDCR

Incidents or events that meet the OHRP criteria for unanticipated problems require the creation and completion of an unanticipated problem 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 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 unanticipated problem;
- a description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the unanticipated problem.

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

- Unanticipated problems that are serious adverse events will be reported to the IRB and to NIDCR within 1 week of the investigator becoming aware of the event.
- Any other unanticipated problem will be reported to the IRB and to NIDCR within 2 weeks of the investigator becoming aware of the problem.
- All unanticipated problems 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 unanticipated problems 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

9.2 Halting Rules

This study includes no halting rules.

10 STUDY OVERSIGHT

Dr. Northridge as the Lead Principal Investigator is responsible for study oversight, in collaboration with the NIDCR Program Official.

11 CLINICAL SITE MONITORING

Not applicable.

12 STATISTICAL AND EVALUATIVE CONSIDERATIONS

12.1 Study Hypotheses

Primary: Based on exit interviews, patient participants in the program will be satisfied with the partnered intervention components.

12.2 Sample Size Considerations

No formal sample size estimates were performed for this F & A study. The bar for success for both feasibility and acceptability is 80% of enrolled patient participants report being satisfied or very satisfied with the partnered intervention components.

12.3 Planned Interim Analyses (if applicable)

Because this is a feasibility study, there will be interim reviews of interview data in order to modify aspects of the partnered intervention and the remote EHR processes during the course of the study.

12.3.1 Safety Review

Not applicable.

12.3.2 Efficacy Review

Not applicable.

12.4 Final Analysis Plan

Acceptability of the partnered intervention will be assessed through exit interviews of the interview patient participants.

As we did with the Sikh American project, we will utilize a pre-post retrospective evaluation design. In this format, all questions will be asked in a single exit interview, but where applicable, will use the phrasing, “Prior to the beginning of the program…” followed by, “At the present time…” Table 3 lists the questions/domains we will use, and expected % changes we hypothesize we will observe in the current study. The percent change from pre-post will be compared using t-tests for proportions. Given that many of the answer choices are non-binary, we will also compare the shift of responses from pre-post across the categories of response using chi-squared tests. Note that this is not an exhaustive list of questions that will be asked; we are simply highlighting those questions that we will use to quantify acceptability. The full planned questionnaire is attached.

Health care utilization and oral health promotion measures: Our ultimate health care utilization measure of interest is receipt of a dental visit within the last 12 months. This will be measured using the Medical Expenditure Panel Survey (MEPS) definition, where dental visit refers to care by or visits to any type of dental provider. This will allow for

direct comparison with Healthy People 2020 Leading Health Indicator OH-7 to increase the proportion of children, adolescents, and adults who used the oral health care system in the past year.

Our central oral health promotion measure is self-reported brushing of teeth for 2 minutes twice a day with a soft-bristled toothbrush and fluoride toothpaste at the interview patient participant's 1 month follow-up visit. For the primary health care utilization measure of receipt of a dental visit within the last 12 months, we will also access the NYU Dentistry EHR database and follow-up with oral health care providers identified by participants in HIPAA approved procedures to ascertain receipt of a dental visit in the last 12 months.

Table 3 provides the measures and definitions of the oral health promotion, self-efficacy, and acceptability measures used in our prior research with the Sikh American community that will be adapted for the present F & A study with the Chinese American community.

Table 3. Measures and definitions of oral health promotion, self-efficacy, and acceptability measures

Question/Domain	Observed Change in Sikh American Project	Expected Absolute Percent Change	Expected Relative Percent Change*
How often do you brush your teeth for at least two minutes?	Increase from 17.9% to 64.7% of those reporting "More than once a day"	+45%	+261%
How often do you floss?	Increase from 4.4% to 22.1% of those reporting "More than once a day"	+20%	+400%
How confident… a) are you that you know how to take good care of your mouth, teeth, and gums? b) do you feel asking your dentist or oral hygienist questions?	a) Increase from 0% to 65.7% of those reporting "Very confident" b) Increase from 7.4% to 75% of those reporting "Very confident"	a) +65% b) +65%	a) +6500% b) +864%
Agreement with the following statements: a) CHW answered my concerns and questions b) CHW helped me to improve how I take care of my health c) Information and topics were informative d) In-person demonstrations helpful in improving oral health	Reported "Strongly Agree" a) 57.4% b) 60.3% c) 69.1% d) 76.1%	N/A	N/A

**We additionally list relative percent change in the case that baseline behaviors among the Chinese American community are very different from the Sikh American community.*

The threshold for success for acceptability of the partnered intervention will be that 80% or more of interview patient participants rate all 4 acceptability questions as agree or strongly agree.

13 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

Study staff will maintain appropriate 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 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.

Patient participant data will be remotely entered directly into the EHR.

14 QUALITY CONTROL AND QUALITY ASSURANCE

The MPIs will be responsible for ensuring that the study is conducted according to the protocol and ensuring data integrity. The MPIs will review the data for safety concerns and data trends at regular intervals, and will promptly report to the IRB and NIDCR any Unanticipated Problem (UP), protocol deviation, or any other significant event that arises during the conduct of the study.

15 ETHICS/PROTECTION OF HUMAN SUBJECTS

15.1 Ethical Standard

The MPIs 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.

15.2 Institutional Review Board

The protocol, informed consent form(s), recruitment materials, and all patient participant and non-patient participant materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any patient participant or non-patient participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented in the study.

15.3 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. Extensive discussion of risks and possible benefits of study participation will be provided to patient participants and their families, if applicable. A consent form describing in detail the study procedures and risks will be given to the patient participant in English or Mandarin Chinese (primary dialect of participating community sites). Consent forms will be IRB-approved, and the patient 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 patient participant and answer any questions that may arise. The patient participant will sign the informed consent document prior to any study-related assessments or procedures. Patient 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 patient participant for their records. The rights and welfare of the patient 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.

Consent for non-patient participant interviews for the knowledge modeling will take place where the interview happens, verbally over the telephone. Dr. Metcalf, the Principal Investigator of the modeling site, will send the consent information sheet by e-mail when scheduling the interview, which will be at least 2 days in advance of the interview. To ensuring ongoing consent for follow-up interviews, Dr. Metcalf will remind

the non-patient participants about their previous consent and will resend the consent document if needed. Dr. Metcalf will obtain verbal consent for any subsequent recording of information collected during follow-up interviews. Dr. Metcalf will send the consent document ahead of time. Before recording, Dr. Metcalf will ask: Have you reviewed the information? Do you have any questions? If the non-patient participant answers “yes” to the first question and “no” to the second question, then she will ask: Is it OK if we start the interview now? and if taping the telephone call: Is it OK if I begin audio recording? After the participant answers “yes,” the interview will begin.

15.4 Exclusion of Women, Minorities, and Children (Special Populations)

The proposed study will enroll Chinese adults aged 21 years and older. No children will be included since there are separate and targeted NYU Dentistry programs for this age group. The study population is Chinese American adults living in any of the 5 boroughs of New York, NY. We estimate that approximately 60% of our enrolled patient participants will be women, based on our experience with conducting community-based screening events. All enrolled patient participants will be of self-reported Chinese ethnicity, to ensure that our partnerships and materials are culturally and linguistically relevant. Study sites will be concentrated in lower Manhattan (Chinatown and the Lower East Side) and the Sunset Park area of Brooklyn, which include dense ethnic enclaves of Chinese Americans.

15.5 Subject Confidentiality

Subject confidentiality is strictly held in trust by the investigators, study staff, and the 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 subjects.

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 sponsor.

The study monitor or other authorized representatives of the sponsor may inspect all study documents and records required to be maintained by the investigator, including but not limited to, medical records (office, clinic, or hospital) for the study subjects. The clinical study site 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-funded human subjects research are required to protect identifiable research information from forced disclosure

per the terms of the NIH Policy (see 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.

16 DATA HANDLING AND RECORD KEEPING

Dr. Northridge as the Lead Principal Investigator is 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 patient participants and non-patient participants, including accurate case report forms (CRFs), and source documentation.

The remote EHR entry of data will be protected by means of dual authentication process through Citrix via NYU active directory followed by login to the EHR via NYU ID card.

No research data will be stored on computer hard drives or USB drives. The following approved HIPAA-compliant data storage methods will be utilized:

1. REDCap is a secure web application for building and managing online surveys and databases. It provides automated export procedures for seamless data downloads to Excel as well as common statistical packages such as SPSS, SAS, Stata, and R. REDCap is available for both NYU *internal* and *external* users. Web-based REDCap for data storage is free to all NYU investigators at REDCap.nyumc.org; and

2. NYU Medical Center Information Technology managed network drives will be set up specifically for this study to provide offsite backup storage.

16.1 Data Management Responsibilities

Data collection and accurate documentation are the responsibility of the study staff under the supervision of the MPIs. All source documents and laboratory reports must be reviewed by the study team and data entry staff, who will ensure that they are accurate and complete. Unanticipated problems and adverse events must be reviewed by the MPIs or their designees.

16.2 Data Capture Methods

Patient participant data will be entered remotely into the EHR. Other data will be collected on paper forms and/or digitally recorded.

16.3 Types of Data

Patient participant data will be captured in the EHR. Data from interviews of patients, research staff, NYU administrators, and providers (dentists and CHWs) will also be captured.

16.4 Schedule and Content of Reports

16.5 Study Records Retention

Study records will be maintained for at least 3 years from the date that the grant federal financial report (FFR) is submitted to the NIH.

Study documents should be retained for a minimum of 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or until at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by local regulations. No records will be destroyed without the written consent of the sponsor, if applicable. It is the responsibility of the sponsor to inform the MPIs when these documents no longer need to be retained.

16.6 Protocol Deviations

A protocol deviation is any noncompliance with the clinical study protocol, Good Clinical Practice, or Manual of Procedures requirements. The noncompliance may be on the part of the subject, the investigator, or study staff. As a result of deviations, corrective actions are to be developed by the study staff and implemented promptly.

These practices are consistent with investigator and sponsor obligations in ICH E6:

- Compliance with Protocol, Sections 4.5.1, 4.5.2, 4.5.3, and 4.5.4.
- Quality Assurance and Quality Control, Section 5.1.1.
- Noncompliance, Sections 5.20.1 and 5.20.2.

All deviations from the protocol must be addressed in study subject source documents and promptly reported to NIDCR and the local IRB, according to their requirements.

17 PUBLICATION/DATA SHARING POLICY

This study will comply with the *NIH Public Access Policy*, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication.

The International Committee of Medical Journal Editors (ICMJE) member journals have adopted a clinical trials registration policy as a condition for publication. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE policy requires that all clinical trials be registered in a public trials registry such as *ClinicalTrials.gov*, which is sponsored by the National Library of Medicine. Other biomedical journals are considering adopting similar policies. For interventional clinical trials performed under NIDCR grants and cooperative agreements, it is the grantee's responsibility to register the trial in an acceptable registry, so the research results may be considered for publication in ICMJE member journals. The ICMJE does not review specific studies to determine whether registration is necessary; instead, the committee recommends that researchers who have questions about the need to register err on the side of registration or consult the editorial office of the journal in which they wish to publish.

U.S. Public Law 110-85 (Food and Drug Administration Amendments Act of 2007 or FDAAA), Title VIII, Section 801 mandates that a "responsible party" (i.e., the sponsor or designated principal investigator) register and report results of certain "applicable clinical trials:"

Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulation; and

Trials of Devices: Controlled trials with health outcomes of a product subject to FDA regulation (other than small feasibility studies) and pediatric postmarket surveillance studies.

NIH grantees must take specific *steps to ensure compliance* with NIH implementation of FDAAA.

18 LITERATURE REFERENCES

SUPPLEMENTAL MATERIALS

These documents are relevant to the protocol, but they are not considered part of the protocol. They are stored and modified separately. As such, modifications to these documents do not require protocol amendments.