# Retraining: GOH Study June 4, 2018 9:00 AM – 11:00 AM

GOOD ORAL HEALTH: A BI-LEVEL INTERVENTION TO IMPROVE OLDER ADULT ORAL HEALTH PROTOCOL NUMBER: 14-046-E

### Agenda

- Review of Study Components
- Consent
- Interventions
- Clinical and skills assessments

### II. Roles and Responsibilities: SDM and ICR

• <u>SDM</u>: Official contact with NIDCR; maintain regulatory binder; manage and submit budgets; all reporting; supervision of dental hygienists; provision of expert dental education; overall project oversight with ICR PI; IRB review and updates; conceptualization, data analysis, papers and presentations.

### Roles and Responsibilities: SDM and ICR

• **ICR**: Conceptualization, regular oversight of field operations including work of dental hygienists; oversight of data collection, storage and synthesis; coordination with SDM on IRB and report writing; implementation of interventions; collection and management of all study evaluation data; data analysis, papers, presentations; dissemination of data to community.

### II. Responsibilities of Study Staff

<u>Interventionists</u>: The interventionists will be trained in the creation and implementation of the tailored AMI intervention and in working with residents to implement their oral health plan. They also will be trained to administer and score the oral health skills assessment (practice to mastery). Interventionists will also implement the campaigns with building residents.

The intervention coordinator will be responsible for coordinating and scheduling and ensuring quality administration of the tailored AMI intervention and the campaigns, and storing and integrating fidelity data for the intervention (focal points, implementation plan and practice to mastery pre and post data). (See Campaign Trainers)

<u>Survey Administrators:</u> The survey administrators will be trained in administering consents, and the survey, saving the QDS files to a backup file in the field and uploading the files to a centralized server at ICR. The survey coordinator (evaluation field coordinator) will be responsible for coordinating the collection and integration of clinical assessment, and skills assessment data.

### Responsibilities of Study Staff

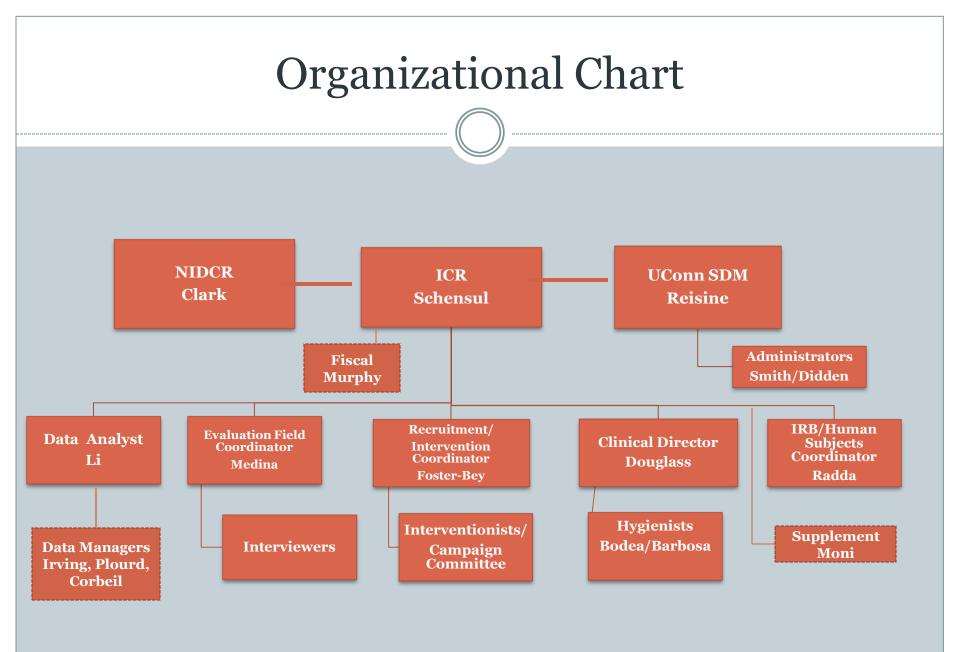
<u>Campaign Trainers</u>: Campaign trainers will deliver the campaign curriculum and work with building residents to develop campaign messages and materials for the campaigns (see above for Interventionists).

<u>Expert Dental Educators/Supervisor Trainers</u>: Ensure calibration of clinical assessment protocols and P to M; oversight of clinicians, provision of expert education at Campaign events.

<u>Dental Examiners</u>: Hygienists will serve as dental examiners and conduct the clinical assessments. They also will be responsible for assuring that clinical data are properly recorded.

<u>Research Assistant/Recruiters</u>: The research assistant/recruiter will assist with recruitment, survey administration, note taking during project and Campaign Committee meetings and transcription.

<u>IRB coordinator</u>: Will work closely with the CRC to make sure that all IRB applications are up to date.



### **Good Clinical Practice**

Good Clinical Practice-we have all completed GCP training

### • Records Retention

- All source documents will be kept in or transferred into electronic files.
- Hard copy files are retained in locked cabinets in Survey Coordinator office.
- Data files will be cleaned, de-identified and password protected to be stored on ICR server, UCHC server, and at federal record center for 7 years after the grant is officially closed.

### Type of Study

- The study is a community effectiveness trial.
- It is designed to disaggregate and test the components of an effective intervention against each other, and to compare their cumulative effect.
- It is community-based, meaning that it involves the administration of the housing units in helping to coordinate the interventions on site, and members of the affected community in active involvement in the administration of one of the two interventions (CBPR).
- It is rigorous in its assessment of intervention acceptability and fidelity of implementation at both levels.

### **Study Objectives**

### **Primary Objectives**:

- 1. To assess the separate and combined effectiveness of two components of a cognitive/behavioral intervention that together improve oral hygiene behaviors and oral hygiene status;
- 2. To assess whether differentially sequenced combinations of these components has a differential effect on behavioral and clinical outcomes;
- 3. To investigate the mediation effects of cognitive/behavioral factors in changing clinical outcomes.

**Primary Outcome Measures**: Plaque Scores and Gingival Index

Secondary Outcome Measure: Oral Health Related Quality of Life

### Sample and Enrollment Goals

- <u>Sample size</u>: 360 (from six buildings, 60 per building)
- <u>Gender</u>: Males and Females
- <u>Age</u>: Children and adults aged 18-61 with disabilities, and those aged 62 and older (quota of 52 aged 62+, 8 aged 61 and under)
- <u>Demographic group</u>: Vulnerable adults or children who are residents of low income senior housing in Central Connecticut. Residents in these buildings must meet income guidelines and be over the age of 62 or be disabled adults or children (meaning 18+).
- <u>General health status</u>: The participants in low income senior housing must be able to live independently without conservator
- <u>Geographic location</u>: Central Connecticut

### Bi-level FFD Design---Matched Building Pairs

То	Component 1	+	T1	Component 2	Т	T2 T3	3
	Adapted Motivatio Interviewing-tailo face to face intervention (N=6	red		Oral Health Campaigns with Resident Committee (N=60)			
	Oral Health Campaigns with Resident Committee (N=60)			Adapted Motivation Interviewing-tailor face to face intervention (N=60	ed		
	Component 2		+	Component 1			
	Clinical Assessment Survey Skills Mastery	Clinica Assess GOHA Skills Master	ment I	AMI Tailored face to face intervention (N=60)		Oral Health Campaign with Resident Committees (N=60)	

## **Theoretical Framework**

(From Fishbein 2008 and Bandura 1987)

#### Background Moderators

Demographic Health status ADLS\* CES-D Self-assessed oral health

status

addressed P-M Pre-post score

Intervention

(fidelity)

**AMI focal** 

points

Exposure to campaign messages (dosage)

Recognition of campaign messages Cognitive Behavioral Mediators

Oral health knowledge\* Perceived oral health risks\* OH health consequences\* OH social support\* OH self-efficacy\* OH self-management fears and worries\* OH norms/beliefs\* OH reported behaviors\* Dry mouth\* Diet\* Behavioral Intentions

OH selfmanagement intentionality\* Outcomes

Plaque score Gingival index GOHAI

\* AMI focal points and Campaign messaging

### Informed Consent: Forms

### Forms include:

- General Study Consent Form (Building AB or BA, as appropriate)
- Consent Comprehension Form
- Authorization to Use and Disclose Protected Health Information for Research Purposes (HIPAA Form)
- HIPAA Authorization to Photograph/Video/Audiotape Form
- Campaign Committee Consent Form

### **Consent Process**

- Consenters are all trained and certified in human subjects protections
- Consenters will use only UCHC IRB stamped forms
- Consent will be explained and administered in English or Spanish, based on language of participant's preference
- All participants will be asked to review and sign the general and 2 HIPPA consent forms.
- Only prospective Campaign Committee members will sign the Campaign Committee Consent Form.
- Consent forms will be kept on file and a signed version of all consent forms will be given to participant
- Confirmation of understanding will be through appropriate response to five questions

### **Inclusion Criteria**

- Adults 62 and over (52 of 60) and adults 18 61 (8 of sixty) including both male and female building residents, and minorities and non-minorities
- Permanent residence in sample buildings
- Independent of conservator
- Must be able to speak English or Spanish
- Judged competent to participate based on ability to respond correctly to five key questions about information covered during administration of informed consent
- Have two or more natural teeth

# Exclusion criteria

- Considered by research staff to be cognitively unable to give informed consent (based on response to five comprehension questions)
- Exhibition of continued disruptive behavior while participating in the project (termination)
- History of infective endocarditis, prosthetic cardiac valve replacement in past 6 months, insertion of an arterial stent in past 6 weeks, myocardial infarction (heart attack) in past 6 weeks, joint replacement surgery, on dialysis currently
- Under conservatorship
- Fewer than two natural teeth

### Repeat eligibility criteria (T1-T3): Exclusions

- History of infective endocarditis
- History of prosthetic cardiac valve replacement in past 6 months
- Insertion of an arterial stent in past 6 weeks
- A myocardial infarction (heart attack) in past 6 weeks
- History of joint replacement surgery
- Fewer than two natural teeth
- Under conservatorship
- Currently on dialysis

### Health Status Screener

#### **GOH Eligibility Form**

If participant answers Yes to Q1 - 5, 7, 8 or No to Q6, then he/she is not eligible for the clinical exam portion of this intervention, skills assessment or surveys. He/she may join the Campaign Committee, and is welcome to participate in the oral health fairs. Ρ D

T2

articipant ID	#:
0	T1

ate	:	

T3

1. Have you ever had surgery to replace a joint, such as a hip, knee, shoulder or elbow? (pins, plates and screws do not count)	yes	no
2. Have you had a heart valve replacement in the past 6 months?	yes	no
3. Have you had an infection inside your heart? (this means probably had to have antibiotics for 4-6 weeks during your heart infection)	yes	no
4. Have you had a stent (a small tube that keeps your arteries open) placed in your heart within the past 6 weeks?	yes	no
5. Have you had a heart attack (known as an MI) in the past 6 weeks?	yes	no
6. Do you have at least two natural teeth?	yes	no
7. Do you have a conservator? (a guardian appointed by a judge to protect and manage your financial affairs and/or your daily life)	yes	no
8. Are you currently on dialysis? (a medical process that takes over the role of your kidneys when they no longer can work properly; you		
have a tube or other form of access through your arm, leg, neck or abdomen)		

### Study Visit/Schedule of Events

#### Building A – Tailored intervention first followed by campaign

Visit	Activity	Timing	Compensation
1.– To	Clinical assessment, skills assessment – 20 minutes	Entry to study	\$15.00
2. – To	Survey – 1 hour	Entry to study	\$15.00
3.	Tailored educational session 45 min – 1 hour	Up to 45 days post To	None
4. – T1	Survey – 1 hour	1-3 months after educational session	\$15.00
5. – T1	Clinical assessment, skills assessment – 20 minutes	1-3 months after educational session	\$15.00
	3 Campaign Events/Oral Health Fairs – 2-3 hours each	2-5 months after T1	None
6. – T2	Survey– 1 hour	1-3 months after campaigns	\$15.00
7. – T2	Clinical assessment, skills assessment – 20 minutes	1-3 months after campaigns	\$15.00
8. – T3	Clinical assessment, skills assessment, GOHAI – 20 minutes	6-7 months after T2	\$20.00

### Study Visit/Schedule of Events

#### Building B – Campaigns first followed by tailored intervention

Visit	Activity	Timing	Compensation
1.– To	Clinical assessment, skills assessment – 20 minutes	Entry to study	\$15.00
2. – To	Survey – 1 hour	Entry to study	\$15.00
	3 Campaign Events/Oral Health Fairs – 2-3 hours total	2-6 months after study entry	None
3. – T1	Survey– 1 hour	1- 3 months after campaigns completed	\$15.00
4. – T1	Clinical assessment , skills assessment – 20 minutes	1- 3 months after campaigns completed	\$15.00
5.	Tailored educational session 45 min. to 1 hour	Up to 45 days after T1	None
6. – T2	Survey– 1 hour	1-3 months after educational session	\$15.00
7. – T2	Clinical assessment, skills assessment – 20 minutes	<b>1-3 months after educational session</b>	\$15.00
8. – T3	Clinical assessment, skills assessment, GOHAI – 20 minutes	6-7 months after T2	\$20.00

### **Study Procedures**

- Clinical assessments to assess Plaque Score and Gingival Index
- Mastery skills assessment
- A survey administered by trained research assistants
- Administration of the AMI-PM
- Recording of the AMI-PM to assess fidelity of the intervention
- Training sessions for the campaign committee to develop campaign messages, materials and activities that are consistent with the conceptual model. Examples of materials will be provided to committee members based on the pilot study.
- Three campaign events

### **Clinical Armamentarium and Assessment**



### **Recruitment and Screening**

- Participants will be recruited through bilingual presentations (2), fliers and individual conversations.
- Participants will indicate interest on sign-up sheets at events.
- Non-attendees and those not screened at the time of the presentations will be followed up through other events, and study team regular presence in the buildings.
- Participants will be screened in privacy in English or Spanish at sign-up events to determine initial eligibility.
- Eligible participants will be given a date and time for consenting, clinical assessment and mastery assessment on appointment cards. Appointment will be registered on a group calendar.
- Date and time will be entered into tracking data base on site.

### Re-Screening, Consent, Enrollment and Assessment

- At appointment participants will be administered repeat eligibility screening
- Consent administration
  - Explanation in English or Spanish
  - Reading of consent form with explanation
  - Five questions for verification of understanding
- Signature and copies of all consent forms for file and for participant
- Those who consent successfully will be administered the Mastery Assessment by research staff
- For Committee Members:
  - Consent read and signed at first meeting
- Clinical assessment explained and conducted
- Participants will be entered into the tracking data base
- Appointment for the survey in Spanish or English
- Scheduled appointments will be entered into the tracking data base

Calibration Training Clinical Data GOH Study

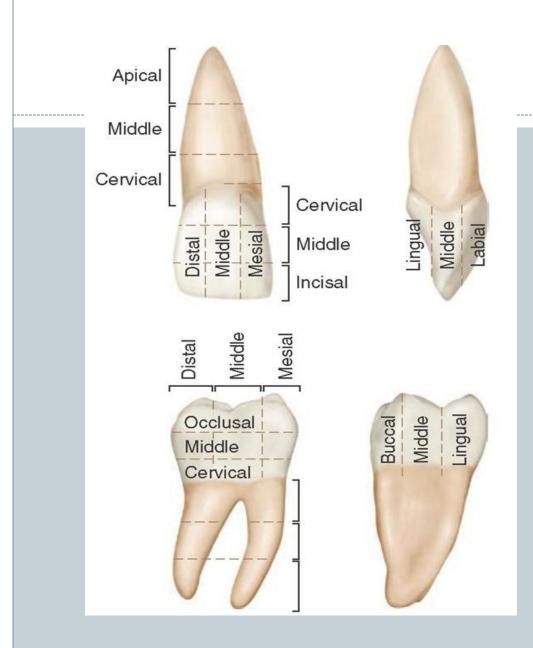
### Study Outcome Measures

### • Primary

- The primary outcome measure is the clinical assessment of oral hygiene status:
  - × Plaque Index
  - × Gingival Status
- Secondary

### • Oral Health Related Quality of Life (OHRQoL):

 General (Geriatric) Oral Health Assessment Inventory (GOHAI), a commonly used 12-item measure initially developed for older adults that has been used with low income populations (Atchison & Dolan, 1990).



### **Tooth Anatomy**

## **Gingival Status**

- The Gingival Index (GI) (Loe & Silness, 1963) will be used to assess the gingival status related to six surfaces of each tooth. Each surface is scored for gingival inflammation:
  - o=no visual signs of inflammation
  - 1=slight change in color and texture of the gingiva but no bleeding
  - 2=visual sign of inflammation and bleeding upon swiping
  - 3=overt inflammation and spontaneous bleeding. The index is calculated by summing each surface GI and dividing by the total number of surfaces (mean value). Individual scores are summed to obtain a mean.

# Healthy Gingiva Score =0





Figure 2-28 Shape of interdental gingival papillae correlated with shape of teeth and embrasures. A, Broad interdental papillae. B, Narrow interdental papillae.

#### From Carranza's Clinical periodontolog

# Lack of Stippling



# Gingival Index

### **Before Gingival Sweep**



### After Gingival Sweep: Problems of Seepage



# Score= ( discuss)



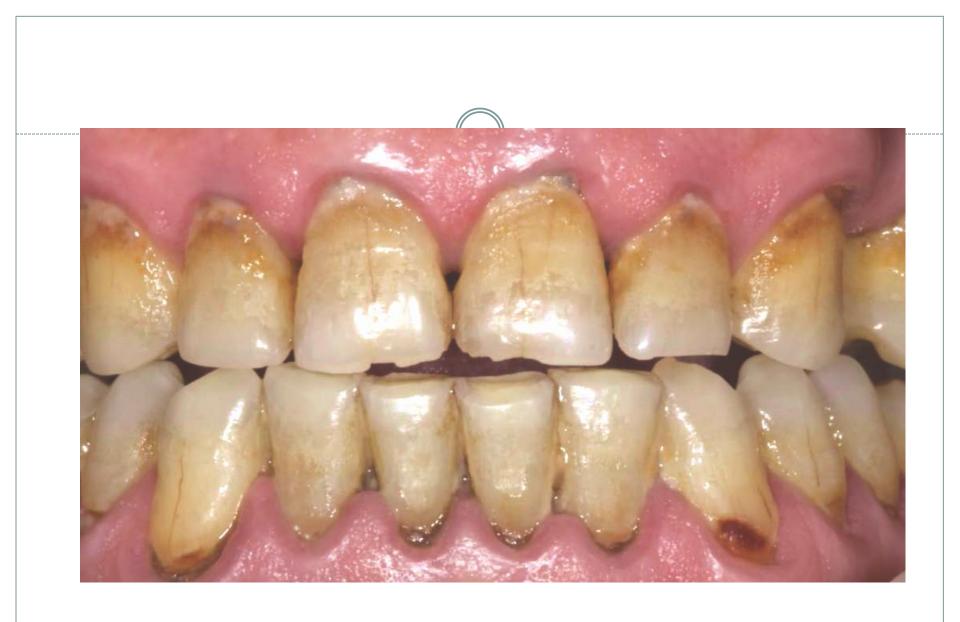
Courtesy: Dr Hebert



### Gingival Index Discuss scoring before and after gingival sweep



From: Novak and Novak, Carranza's Clinical Periodontology, Chapter

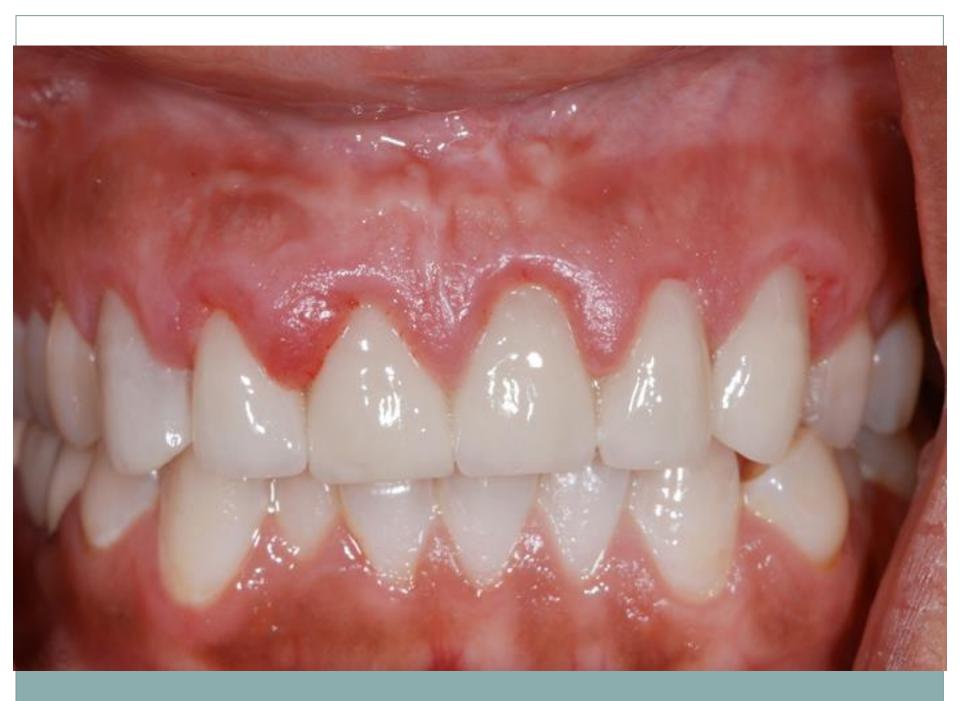


















### Plaque Index

- We will use a plaque scoring scheme developed by O'Leary (O'Leary, Drake, Naylor, 1972). This index consists of dichotomous presence or absence scores for plaque on each tooth surface.
  - The supra-gingival bacterial plaque will be assessed with the use of erythrosine disclosing solution in six surfaces of each tooth. The non-toxic vegetable-based solution will be applied to the teeth by the examining hygienist or dentist.
  - The number of surfaces stained red will be calculated over the total number of surfaces and the plaque score will be expressed as a percentage of surfaces with plaque as a ratio. We used this measure in the pilot study and demonstrated significant reductions in plaque after the intervention.
- Plaque scored has to be touching the gingiva

#### Anatomy and Line Angles Posterior Teeth



## Use of Staining Agent to Disclose Plaque





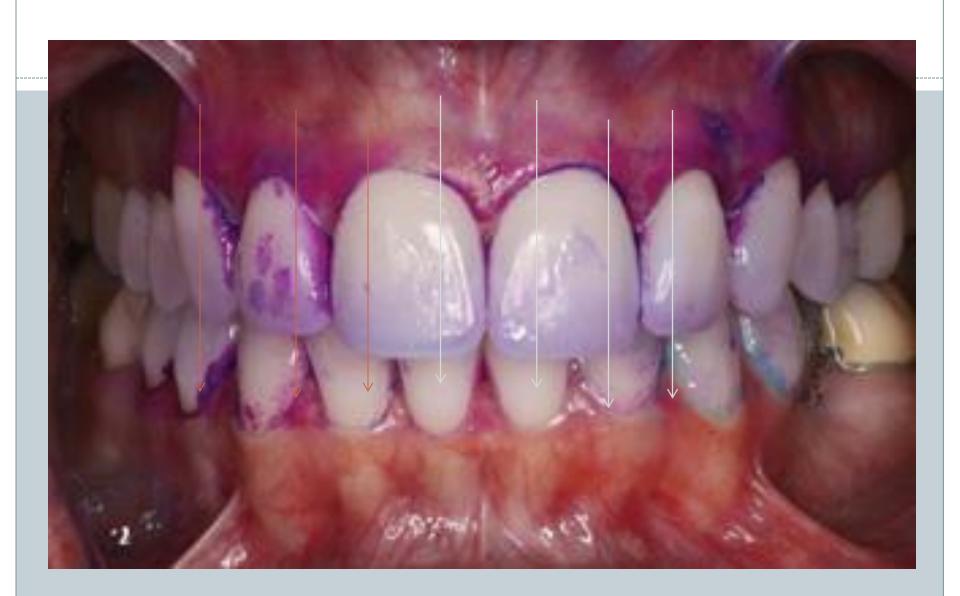
### Plaque Index

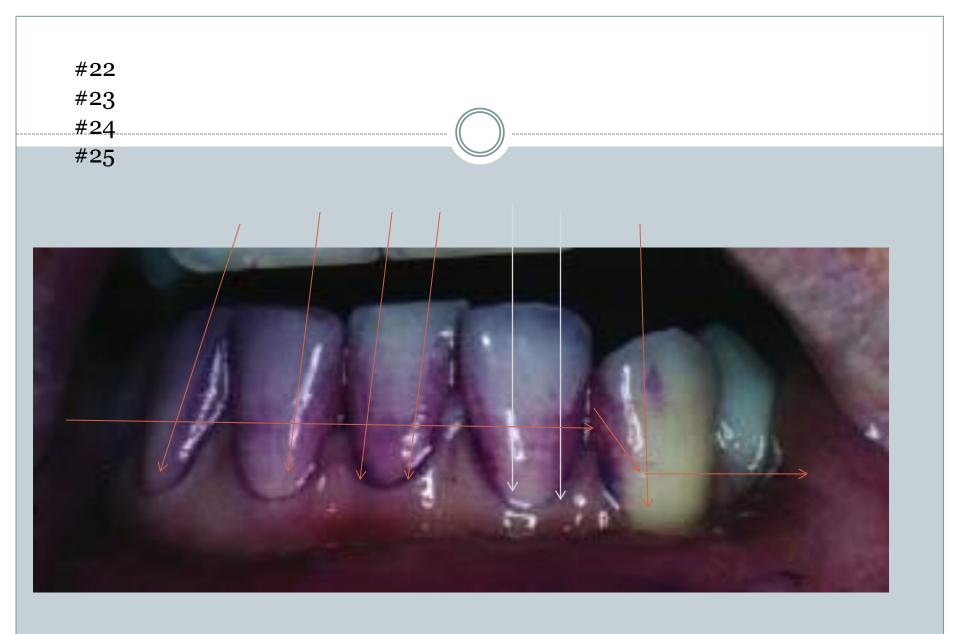
- Plaque MUST touch gingiva to be counted. Be sure to differentiate calculus and plaque.
- Touch stain with perio probe to ensure it can be removed. If not it is likely to calculus or stained dentinal root surface.











#### **Plaque Scores**

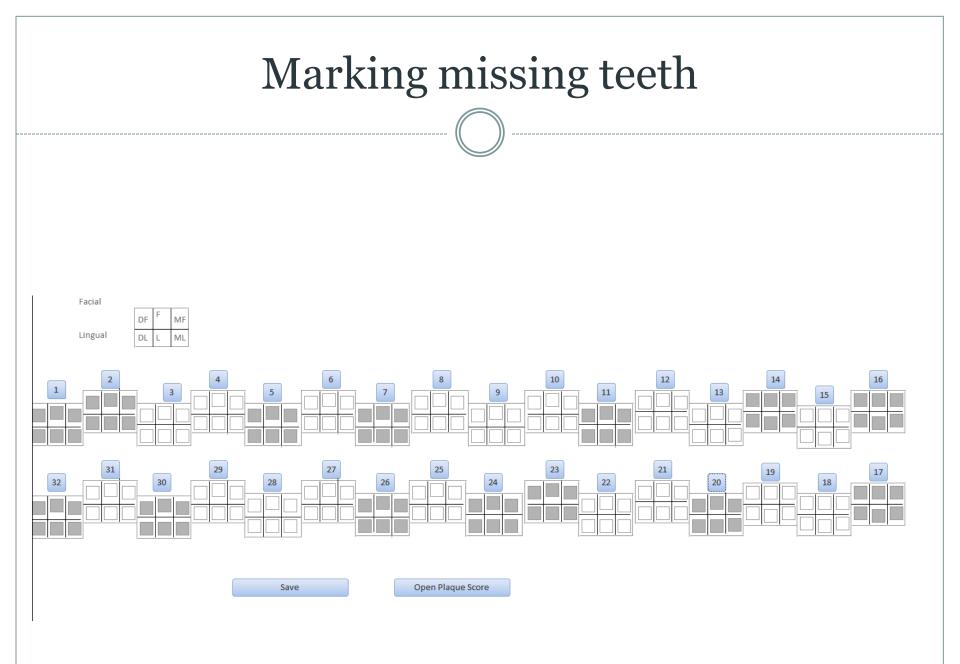


- #5=y,y,y
- #6=y,y,y
- #7=y,y,y
- #8=y,y,n
- #9=n,y,n

## Clinical Data Entry Training Session



	Soft Tissue Exam
	Participant ID: (2 letters of initial + 2 digits birth month + 2 digits birth day)
ι.	Please describe the participant's denture use below 0 = does not have and is edentulous in the dental arch (upper or lower) 1 = has denture or partial, and wears at night 2 = has denture or partial, and wears for eating only 3 = has denture or partial, and wears for esthetics only
	Put a number in each of the boxes below corresponding to the clinical exam.
	Upper Denture/Overdenture Upper Removable Partial Denture
	Lower Denture/ Overdenture Lower Removable Partial Denture
	Check here if soft tissue exam is completed
•	Check here if referral for emergent care is recommended
	Please mark (by clicking on the tooth number) all missing teeth or root tips according to the tooth number, then fill out Gingival Index in each box presenting a surface of a tooth.
	caminer: please call off tooth number and direction to the recorder]



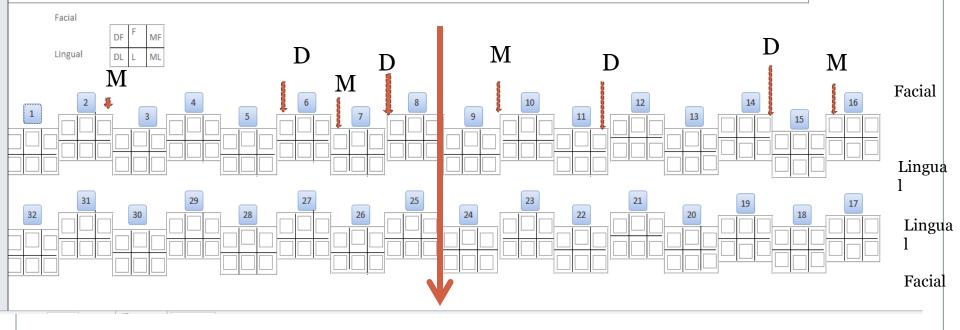
### Gingival Index

4. Please mark (by clicking on the tooth number) all missing teeth or root tips according to the tooth number, then fill out Gingival Index in each box representing a surface of a tooth.

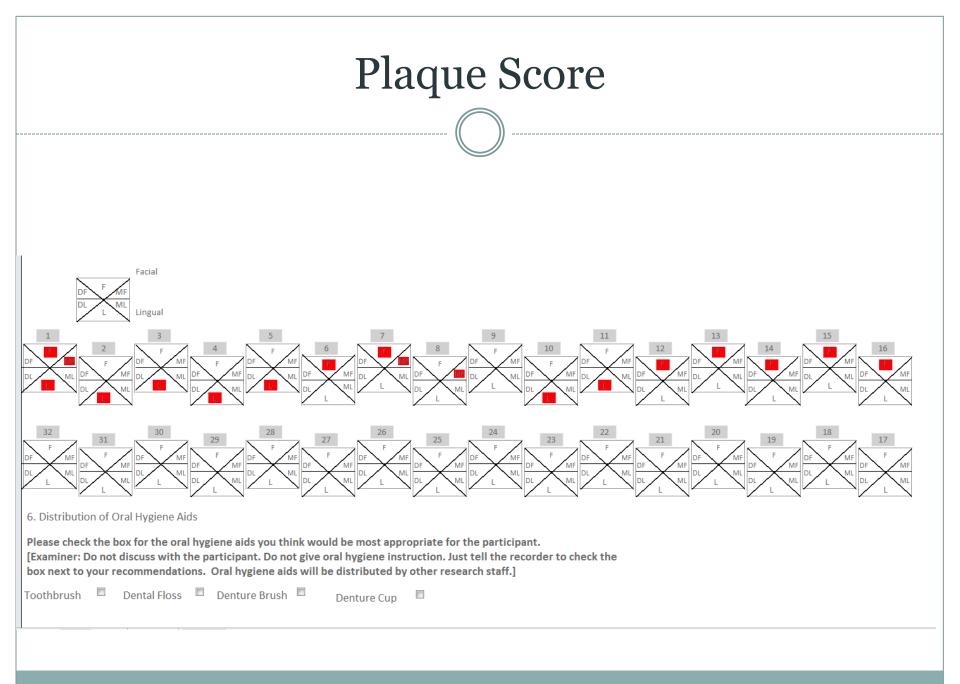
#### [Examiner: please call off tooth number and direction to the recorder]

Key: 0 = No signs of inflammation

- 1 = Mild inflammation redness, enlargement due to edema, no bleeding provoked by drawing a probe circumferentially within the gingival sulcus
- 2 = Moderate inflammation erythema, enlargement, and bleeding provoked by drawing a probe circumferentially within the gingival sulcus
- 3 = Severe inflammation or ulceration tendency to bleed spontaneously



Plaque Score
[Examiner: Apply Vaseline to lips. Use disclosing solution per instructions in the pre-filled applicators.] Plaque is scored as present or absent on 6 surfaces (MF, F, DF, ML, L, DL) located in the dentogingival junction of each tooth by clicking the correspondent surface in the diagram below Facial
1 3 5 7 9 11 13 13 15 16 16 16 16 16 16 16 16 16 16
32 30 29 28 27 26 25 24 23 22 21 20 19 18 17 DF MF DL L L DF MF DL L L L L L DF MF DL L L L L L L L L L L L L L



### Oral Hygiene Aids

6. Distribution of Oral Hygiene Aids

Please check the box for the oral hygiene aids you think would be most appropriate for the participant. [Examiner: Do not discuss with the participant. Do not give oral hygiene instruction. Just tell the recorder to check the box next to your recommendations. Oral hygiene aids will be distributed by other research staff.]

Toothbrush 🛛 Dental Floss 🕅	Denture Bru	ush 🗖	Denture Cup			
Adaptive Tubing for patients with grip	problems suc	ch as arthritis	5			
Tooth brushing Brochure English		Tooth brush	ning Brochure	Spanish		
Dental Flossing Brochure English		Dental Floss	sing Brochure	Spanish		
Denture Brochure English		Denture Bro	ochure Spanisł	ı		
	Sav	10		-		
	Jdv			Close		
ord: H 🚽 1 of 1 🔰 H 🜬 🦹 K No Filter Search					1	

## Survey Administration: Preparation

- Receive interview schedule and Master ID.
- Interview schedule produced from Access queries
- Survey packets in files with Participant ID in locked cabinet in Zahira's office
- Participant folders include:

Packet Checklist (content of package)
 Participant Record Checklist
 Signed Consent forms (Eng or Sp)
 HIPAA Audio consent form
 Signed HIPAA form (Eng or Sp)
 Completed Eligibility Form
 Re-Eligibility Form-(blank)
 Campaign consent form
 UCHC Consent Addenda (Eng or Sp)
 Payment envelope (\$15.00)

- Reminders until confirmation
- Survey Packet:
  - Hard copy of survey (Eng/Sp)
  - Response cards
  - > Payment envelope
  - Receipt book
- Interviews are conducted in private location
- After completion participant is paid \$15.00. Receipts to participant and in file

# Interventions

#### AMI

#### **CAMPAIGN**

### **AMI - Preparation**

- A completed custom-constructed focal point checklist
- Copy of baseline clinical assessment results
- Oral Hygiene Skill Assessment Evaluation Form
- Copy of blank Audio consent form
- Practice to Mastery equipment: mouth models, tooth/denture brushes, floss
- Laptop loaded with: educational videos for instructions on proper brushing, flossing, and denture care; results of the baseline skills assessment; a blank form for Personal GOH Plan
- Audio recorder
- Portable printer, paper, and extension cord
- Handouts with instructions on proper brushing, flossing and denture care that reflect the instructions in the educational videos
- Oral hygiene kit (toothbrush, toothpaste, denture brush, tongue cleaner, floss, and floss handle)

#### Cut-off Points Linking Survey to Focal Point Checklist

\_\_\_\_\_

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Do	omain	Cut-off Points				
1.	ADLs	Need help on any of these				
2.	Oral health knowledge	<5 correct				
3.	Oral health self-efficacy (a)	Mean of items $<3$ (disagree and strongly disagree)				
3.	Locus of control (b)	If response to this item was agree or strongly agree				
4.	Oral health norms - Beliefs about importance of oral hygiene	1 or 2 on any item (not at all important; not very important)				
5.	Oral health social support	If one or more items is "o" (none)				
6.	Oral hygiene behaviors	<2 times per day				
7.	Perceived oral health risks	Mean <3 (4, very unlikely; 3, unlikely; 2, likely, 1, very likely)				
8.	Self-management worries	Mean <3 for scale (4 = not at all; 3= not much)				
9.	Self-management fears	Mean $< 3$ (4= not at all; 3 = not much)				
10.	Oral health self-management intentionality	Mean <1 (0= no possibility; 1= slight possibility)				
11.	Dry mouth	Yes				
12.	Diet	>2-3 times a day on any item.				
	Clinical Assessment	All participants				

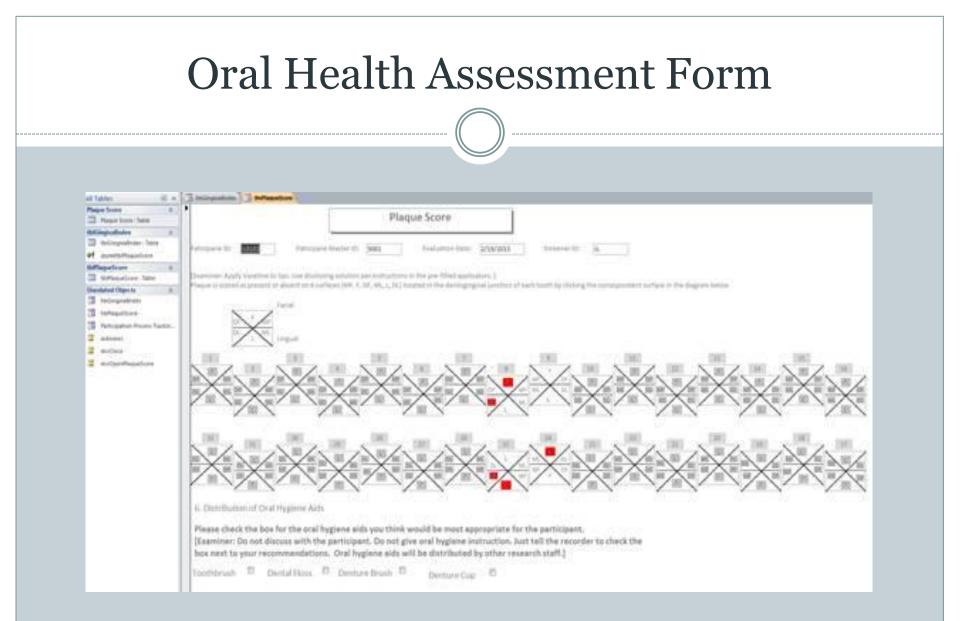
#### Focal Point Checklist

#### **Check List - Focal Points Worksheet**

Focal Point	$\checkmark$	Describe problem	Participant's Responses
Intervention Domain 1: ADLs/IADLs			
Intervention Domain 2: Knowledge			
Intervention Domain 3: Self- efficacy/ Locus of control			
Intervention Domain 4: Oral Health Beliefs			
Intervention Domain 5: Social Support			
Intervention Domain 6: Oral hygiene behaviors			
Intervention Domain 7: Perceived oral health risk			

#### AMI-Practice to Mastery Skills Development Process

- Discuss with participant the importance of taking care of teeth, mouth, gums in keeping one well and healthy
- Explain areas of concern based on survey and show the focal point checklist
- Prioritize and discuss these areas of concern and how to remedy them
- Skills development
  - Review results of baseline assessment using typodont
  - Show videos and discuss brushing and flossing
  - Demonstrate
  - Participant demonstration (maximum 3 times)
  - Complete Mastery assessment
- Develop personal action plan with participant



#### Oral Hygiene Skill Assessment Evaluation Form AMI - Practice to Mastery

IRB Review IRB NUMBER: 14-188-6 IRB APPROVAL DATE: 02/20/2017 IRB EXPIRATION DATE: 02/19/2018

Master ID		Date
Participant ID	Cycle: AMI	Researcher ID

**Examiner:** Prior to the Practice to Mastery skills assessment, ask if participant is using any modification or adaptive device to his/her toothbrush or denture brush (i.e.: plastic tubing, aluminum foil), or using a floss handle in order to better clean their teeth/denture/partial. If yes, provide the participant with the appropriate adaptive device to use during this skills assessment. If no, and you determine that the client has a physical disability and cannot manage the oral hygiene aids (for example, due to arthritis), then you may suggest the tubing to adapt their tooth/denture brush or a floss holder.

#### Criteria for coding mastery skills:

**Excellent (4):** Is able to easily use the appropriate oral hygiene aids and correctly mimic the instruction from the video/live demonstration without additional instruction.

**Good (3):** Is able to use the appropriate oral hygiene aids and requires no more than two corrective instructions to correctly mimic the instruction from the video/live demonstration.

**Fair (2):** Has difficulty using the appropriate oral hygiene aids and requires three or more corrective instructions to correctly mimic the instruction from the video/live demonstration.

**Poor (1):** Does not understand the concepts in the video clips. Uses the incorrect brushes to demonstrate on the models. Needs complete instruction or intervention to mimic the oral hygiene instruction from the video clip or live demonstration.

Skill	Mastery Lacks manual dexterity due to physical Level disability (i.e. arthritis, stroke)*			Sensory impairment limiting or modifying oral hygiene instruction (i.e. visual or aural impairment)**			
	Code #	Code #	Comments	Code #	Comments		
Tooth brushing							
Flossing							
Cleaning Dentures or Partials							

Not Applicable (96): Does not use dentures or only uses them rarely

**\*Dexterity codes**: **4** = full dexterity; **3** = good dexterity-can manage well without any help; **2** = requires some help, having difficulty if not using any help; **1** = having high level of difficulty in demonstrating skills.

\*\*Sensory impairment (visual or aural) codes: 4 = no sensory problem apparent for either; 3 = some visual or aural impairment; request for repetition of instructions and vocabulary; some difficulty with print size (not related to literacy); 2 = has difficulty hearing and/or can't see instructions at all; 1 = cannot hear sufficiently to respond to a question properly (not a language problem), and/or cannot see enough to recognize the pattern of plaque on teeth (not a comprehension problem).

#### Skills Assessment Data Entry

»	-8	T-T3 Skill Assessment
	E	-T3 Skill Assessment
	•	MasterID ParticipantID ResearcherID Date_SkillAss Cycle T3
		Examiner: Prior to each oral hygiene skills assessment, ask if participant is using any modification or adaptive device to his/her toothbrush or denture brush (i.e.: plastic tubing, aluminum foil), or using a floss handle in order to better clean their teeth/denture/partial. If yes, provide the participant with the appropriate adaptive device to use during this skills assessment.
		Criteria for coding mastery skills:Excellent (4)Is able to easily use the appropriate oral hygiene aids.Good (3)Is able to use the appropriate oral hygiene aids and would require no more than two corrective instructions.Fair (2)PodHas difficulty using the appropriate oral hygiene aids and would require three or more corrective instructions.(1)Does not understand the concepts in correct oral hygiene. Uses incorrect brushes to demonstrate on the models.
Navigation Pane		Lacks manual dexterity due to physical disability (i.e. arthritis, stroke)*       Sensory impairment limiting or modifying oral hygiene instruction (i.e. visual or aural impairment)**         Brushing Skill
Navig		Flossing Skill
		Cleaning Denture and Partials* * Enter 96 = N/A, if participant doesn't have denture nor partials.

#### Dexterity codes:

4 = full dexterity; 3 = good dexterity-can manage well without any help; 2 = requires some help, having difficulty if not using any help; 1 = having high level of difficulty in demonstrating skills.

#### \*\*Sensory impairment (visual or aural) codes:

4 = no sensory problem apparent for either; 3 = some visual or aural impairment; request for repetition of instructions and vocabulary; some difficulty with print size (not related to literacy); 2 = has difficulty hearing and/or can't see instructions at all; 1 = cannot hear sufficiently to respond to a question properly (not a language problem), and/or cannot see enough to recognize the pattern of plaque on teeth (not a comprehension problem).

## Plan

- Prepare plan based on intentions of participant
- All plans should include brushing and flossing properly plus at least one cognitive/behavioral domain (e.g. adjusting for ADL; dealing with worries or fears)
- Copy of plan for file and for participant printed on site
- Participant gets an information packet
- Tracking data entered into tracking form
- Intervention data (elements of plan) entered same day into data base

IRB Review IRB NUMBER: 14-18 IRB APPROVAL DATE. IRB EXPIRATION DAT.

1

	Plan Personal BSB
Problema Domino	Plan del Participante para Lidiar con el Problem
Cepillado	
Uso de Hilo Dental	
Actividades del Diario Vivir (ADV)	
Apoyo Social	
Boca Seca	
Dieta	
Otro	

	Personal GOH Plan
Problem Domain	Participant's Plan to Address Problem
Brushing	
Flossing	
Activities of Daily Living (ADLs)	
Social Support	
Dry Mouth	
Diet	
Other	

IRB Review IRB NUMBER: 14-188-6 IRB APPROVAL DATE: 02/20/2017 IRB EXPIRATION DATE: 02/19/2018

Individual Personal GOH Plan v1.2 6/29/16

	Data	Entry Form	- ACCESS	
	Q-Linked AMI Recording			
<u>م</u> *	Form: Linked AMI Data	a Entry		
sport Sta	MasterID 9005 Participant	t Code cd8979 Date 1/15/2015	Staff Initial	
nent nent ssment	Did audio recording actually occure du Did the resident receive oral health h		Did resident review oral health hytic Did the resident develop, sign and re	
\$ sta Entry \$ sport Sta ita Entry	DM1_AD 🗹 DM1 Scrip 🗹 DM1 inPlat 🕅 DM1 Participant Response	DM4_Orlhnorn DM4_inPlan DM4_Scrip DM4_inPlan DM4_Participant Response	DM7_PercvRisi 🗹 DM7_Scrip 🗹 DM7_inPlar 🖾 DM7_Participant Response	DM10_MangInter  DM10_script  DM10_i DM10_Participant Respons
	DM2_Orlknowig DM2 Scrip DM2_inPlai DM2 Participant Response	DM5_SocialSuprt  DM5_Scrip DM5_inPlat  DM5_Participant Response	DM8_Worn 🖻 DM8_Script 🗐 DM8_inPlar 🗐 DM8_Participant Response	DM11_DryMouth DM11_scrip: DM11_ir DM11_scrip: DM11_ir DM11_Participant Respons

### Campaign Planning

- Recruit committee (up to 10 people)
- Train committee (6 10 sessions)
  - MODULE 1 Session 1: Building group identity and scope of work
  - MODULE 2 Sessions 2 & 3: Review of the components of the Pro-GOH Campaign; Protecting and respecting other residents; Effective communication
  - MODULE 3 Sessions 4 & 5: Oral health and oral health selfmanagement behavior; Confirmation of campaign event schedule
  - MODULE 4 Session 6 & 7: Creation of a campaign plan
  - MODULE 5 Sessions 8 & 9: Development of campaign material
  - MODULE 6 Session 10: Preparation for campaign events
  - Additional 2 sessions to finalize campaign and practice scripts

# **Campaign Administration**

- Prepare messages, materials and stations
- Ensure location and times for events
- Invite residents and "experts"
- Promote events in building
- Identify staffing and placement of stations
- Prepare process for assigning and collecting passports on entry and exit



# Standardized campaign elements

- Campaign messages
- Expert mini-lecture plus Q & A
- Resident testimony
- Campaign background materials
- Campaign recruitment
- Pro-GOH Campaign Activity Guide and checklist
- The Campaign Passport

### Pro-GOH Activity Guide (bilingual)

- Oral health informational materials and tools
- Games
- Demonstrations
- Poster contest
- Performance
- Oral health video
- Guest speaker
- Testimonials
- Other ideas?

- Materiales informativos e instrumentos de salud bucal
- Juegos
- Demonstraciones
- Competicion de afiches
- Representacion
- Video sobre salud bucal
- Orador invitado/tabla con un experto
- Testimonios
- Otras ideas?

# Campaign Materials Available for Use

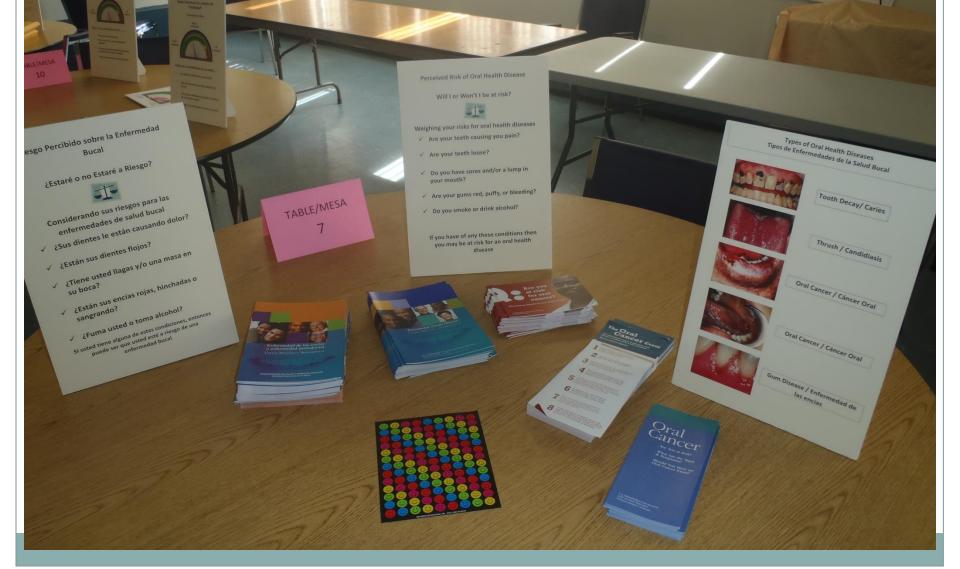
- Scripts developed by residents and researchers
- Oral health flip books
- Games
- Posters
- Oral health movie











### Passport



Passport to Good Oral Health

\_\_\_\_\_

Name: Date: <62 62+ Time In: Time Out:

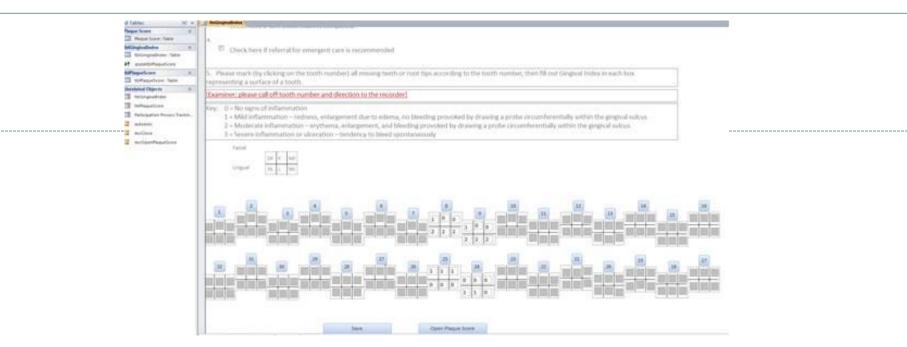
Table 1	-		Table 7	•	-
Table 2	-	C C	Table 8		-
Table 3	-		Table 9		-
Table 4	-		Table 10	•	-
Table 5	-		Table 11		-
Table 6	-	0	Table 12		-

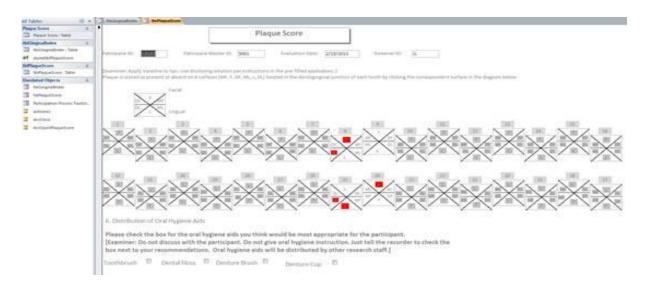
### Source Documents (1)

Outcome Evaluation Assessment	Content	Collection Format	Quality Control		
Survey	Demographics; general health history & status; oral health history & status; oral health experience and decision-making; reported oral health behavior; Scales measuring the study's theoretical domains 1 - 12; access to oral health care;	QDS	Built-in Control; Immediate survey review; Random audit; Systematic logic check/cleaning in SPSS		
Clinical Assessment	Gingival Index and Plaque Scores (open link to CAF) <u>DentalExam (01092015).accdb</u>	Access	Calibration & re- calibration; Built in control; Random audit		
Oral Hygiene Skills Assessment	Mastery of brushing and flossing skills	Access	Built in control; Queries; Random audit		
Campaign Participation/ Dosage	Attendance and participation at oral health activities assessed through stamped passports indicating participation at specific activities.	Access	Built in control; Queries; Random audit		

### Source Documents (2)

Intervention Process/Fidelity Documents	Content	Collection Format	Quality Control
Face-to-Face AMI Delivery	Survey export focal points to be addressed Scripted message for each of the 12 domains; Participant comments entered into access data base <u>Intervention Process Tracking (01282015).accdb</u>	Audio record Access	Random audit Observation
Campaign Committee	Record of participation at training sessions, content and attendance	Paper	Observation Note taking
Campaign Participation/ Dosage	Attendance and participation at oral health activities assessed through stamped passports indicating participation at specific activities.	Access	Built in control; Queries; Random audit
Other Data	Content	Collection format	Quality Control
Participation Tracking Database	Participants' basic demographics, contact information, scheduling and completion of each steps of evaluation and intervention activities <u>Participant Tracking 02062015.accdb</u>	Access	Multiple queries to compare entries with evaluation, intervention, and field records





#### Record Checklist (for file)

Participant ID #: \_\_\_\_\_

Forms Completed & In Folder ("\")

Comments

Study Consent Form	
Consent Comprehension Form	
HIPAA	
Audio/Video/Photo Authorization Form	
Campaign Consent Form	
Focal Points Checklist	
Personal GOH Plan	
Oral Health Fair Passports	

#### Forms Completed and in Folder ( put " $\sqrt{}$ ")

#### **TO TAMI T1 T2 T3**

Comments

Eligibility Screening Form			
Clinical Assessment Form			
Skills Assessment Form			

# Training Log (example)

Project GOH Training on: Institute for Community Research

Date(s):			
Print Name	Signature		