



Dental Public Health Activities & Practices

Practice Number: 06004
Submitted By: The Center to Address Disparities in Children's Oral Health, UCSF School of Dentistry
Submission Date: March 2010
Last Updated: March 2010

SECTION I: PRACTICE OVERVIEW		
Name of the Dental Public Health Activity: The Mother and Youth Access (MAYA) Project		
Public Health Functions: Assurance – Population-based Interventions Assurance – Oral Health Communications Assurance – Building State and Community Capacity for Interventions Assurance – Access to Care and Health System Interventions		
Healthy People 2010 Objectives: 21-1 Reduce dental caries experience in children 21-2 Reduce untreated dental decay in children and adults 21-5 Reduce gingivitis among adults and periodontal disease among adults 21-10 Increase utilization of oral health system 21-12 Increase preventive dental services for low-income children and adolescents		
State: California	Federal Region: West Region IX	Key Words for Searches: Early caries prevention, access to dental care, early prevention, children's oral health, perinatal oral health, pregnant women oral health
Abstract: <p>The Mothers and Youth Access (MAYA) Project was a randomized clinical trial that began in 2002. The study aimed to assess the effectiveness of a prevention management model to reduce childhood tooth decay (Early Childhood Caries [ECC]), to improve children's access to preventive oral health services, and to reduce oral health disparities in a border population at high risk for dental disease. The trial compared the 3-year incidence, or new development, of ECC in children ages 12-36 months of primarily Hispanic women. Mothers and their children were randomized to a Control Group or an Intervention Group, each with different prevention strategies. For the <u>Control Group</u>: (a) mothers received parental oral health counseling to promote positive oral health behavioral change, and (b) children who developed early tooth decay without any break in tooth structure received therapeutic "rescue" fluoride varnish applications at the same frequency as the Intervention Group. For the <u>Intervention Group</u>: (a) new mothers received parental counseling and a therapeutic 3-month regimen of chlorhexidine mouth rinse to reduce the bacteria that causes tooth decay, and (b) all children received preventive fluoride varnish applications to remineralize tooth surfaces at 6-month intervals starting at age 12 months and continuing to age 36 months. The study provided insight into effective recruitment and retention strategies for participation of an underserved, Hispanic population, and an example of a set of comprehensive interventions that concurrently aimed to address various elements at work in the disease process- physical, social, and cultural.</p> <p>* This study was supported by US DHHS/NIH/NIDCR & NCMHD U54DE142501.</p>		
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SECTION II: PRACTICE DESCRIPTION

History of the Practice:

The Mother and Youth Access (MAYA) Project is one of multiple projects of the **Center to Address Disparities in Children's Oral Health (CAN DO)** at the University of California, San Francisco (UCSF), School of Dentistry. CAN DO is a research center funded as a cooperative agreement by the National Institutes of Health, National Institute of Dental and Craniofacial Research.

The CAN DO Center aims to understand, prevent, and reduce oral health disparities among young children with the primary focus of preventing Early Childhood Caries (tooth decay in young children, also known as "baby bottle tooth decay" or "nursing caries"). CAN DO uses a multi-level, disease prevention management conceptual model to investigate and understand oral health disparities in young children from many perspectives, including those of the child, family, and community.

The Center's research mission is to:

- Identify cultural, environmental, workforce, behavioral, and biologic factors associated with oral health disparities among ethnic/racial groups in very diverse California environment;
- Enhance the ability to target children likely to be at risk for dental caries; and
- To test the efficacy and provide successful interdisciplinary interventions to prevent disease and reduce oral health disparities.

All of the CAN DO projects, including the MAYA Project, provide:

- Support for primarily patient and population-oriented research related to reducing oral health disparities in children;
- Core facilities to provide technical services and resources to Center-affiliated projects;
- An enriched environment for training future health-care professionals and scientists, especially those from underrepresented groups; and
- Mechanisms to increase collaboration among investigators in Center-Supported projects, across health professions and affiliated collaborating public and private institutions on the west coast.

Justification of the Practice:

Although Early Childhood Caries (ECC) is a chronic, multi-factorial, transmissible, and infectious disease, it is largely preventable. Most existing research at the inception of the MAYA study did not address the prevalence of ECC among children younger than age three. While some risk factors for ECC had been identified, their effects on specific ethnic groups or on very young preschool children had not been sufficiently investigated.

The 1993-94 California Oral Health Needs Assessment Survey found the prevalence of ECC to be 14% among all preschool children, but 44% among Asians and 39% among Latino children from low-income families enrolled in Head Start programs. In a more recent study of more than 2,000 young children near the California-Mexican border, the ECC prevalence was 58%. Furthermore, recent NHANES data reports that children ages 2-5 are the only age group with increasing rates of dental disease, with 28% of children experiencing dental caries.

Inputs, Activities, Outputs and Outcomes of the Practice:

Purpose and Overview of the MAYA Project

The Mother and Youth Access (MAYA) Project was a clinical trial that began in 2002. The purpose of the MAYA Project was to test the effectiveness of an approach to prevent and manage tooth decay involving new mothers, infants, and toddlers.

The trial assessed the effectiveness of a dental disease prevention management model in reducing the incidence of early childhood caries (new tooth decay) in children of Hispanic women. The objectives were to build upon current understanding of caries risk factors to assess the effectiveness of a prevention management model to reduce the incidence of ECC, to improve children's access to preventive oral health services, to provide health information to low-income pregnant women and new mothers, and to reduce oral health disparities in a border population at high risk for dental disease.

The MAYA Project advanced understanding and efforts in addressing racial/ethnic disparities in oral health. The research study focused on testing the effect that culturally sensitive dental hygiene counseling and education, early and frequent dental visits, the use of maternal chlorhexidine mouthrinse, fluoride varnish, and the establishment of a dental home can have on dental outcomes.

The MAYA Project evaluated strategies to recruit and retain pregnant women for participation in the study. In 2004, a workshop convened by the Hispanic Dental Association and the University of Puerto Rico recommended advancing Latino oral health research to address the oral health disparities and growing needs of this population. The MAYA Project sought to understand the most effective way to prevent dental problems in an underserved population of predominantly Hispanic, highly transitory families.

Design of the MAYA Clinical Trial

The MAYA study was designed as a randomized, blinded, controlled, clinical trial.

The study was based at the San Ysidro Health Center (SYHC), located in San Diego County, California near the US-Mexico border at the world's busiest land border crossing. This is an area with widespread poverty. As a federally qualified health center, SYHC has focused on integrated delivery of a full scope of services to high-risk, traditionally underserved populations, providing low-cost comprehensive primary care, oral health, and behavioral health services to approximately 50,000 patients.

Pregnant women, mothers, and their new babies were targeted for pro-active counseling and oral health preventive services. The women and their children were randomly divided into a Control Group or an Intervention Group, with each group given different treatments to prevent the development of dental decay. Most of the patients in the study were Hispanic (85%), and lived at or below the federal poverty level (70%). The trial sought to recruit 512 pregnant women during a 36-month period.

The MAYA Project recruited women in the second trimester of pregnancy. At baseline, consenting women completed an oral health questionnaire and received a dental exam and oral health counseling. Four months postpartum, women returned with their babies for randomization with follow up at 9, 12, 18, 24, 30, and 36-month postpartum visits. A percentage of patients continued for 42- and 48-month postpartum visits.

To assess predictors of retention, data on respondents' demographics and oral health-related knowledge, attitudes, and behaviors were obtained by questionnaire and analyzed by logistic and discrete time-to-event regression analyses.

Early Childhood Caries Intervention

The intervention was developed to be specific for the community, based on the results of an SYHC needs assessment, which demonstrated a high prevalence of early childhood caries among young children and lack of access to dental care.

Mothers and their 4-month-old infants were randomly assigned to one of the two treatment groups.

- Group A (the Control Group) received oral health counseling only.
- Group B (the Intervention Group) received counseling, chlorhexidine rinse for mothers, and fluoride varnish applications for children.

Mothers and children in Groups A and B provided saliva samples for microbiological analysis of mutans streptococci (MS) and lactobacilli (LB) bacteria levels.

The counseling protocol used for mothers in Groups A and B was based on recommendations from the American Academy of Pediatric Dentistry for anticipatory guidance in pediatric dental care. A culturally sensitive script was developed in consultation with health center staff, and pilot tested before implementation by the research assistant in the appropriate language (English or Spanish).

Starting at 4 months postpartum, mothers in Group B were instructed to rinse twice daily with 0.5 oz. of a chlorhexidine gluconate 0.12% solution (Peridex, OMNII Oral Pharmaceuticals) for 14 days followed by a 14-day rinse-free interval for three consecutive months.

Children in Group B received an application of 0.25mL of fluoride varnish containing 5.6mg of fluoride (CavityShield, OMNII Oral Pharmaceuticals) every 6 months, from age 12 to 36 months. At each follow-up visit, children were monitored for precavitated white spot (demineralized) lesions, dental caries, and adverse events. Children with white spot lesions or dental caries were referred to the SYHC dental clinic.

Children in Group A (receiving oral health counseling only), who developed precavitated lesions, were allowed to continue in the study. In addition, with the Data and Safety Monitoring Board's recommendation, children in Group A received therapeutic fluoride varnish applications once signs of disease were identified, in the same 6-month periodicity as children in Group B. Children in Group A with white spots or caries were deemed as having treatment failures, and they were invited to be tracked by the study for follow-up. Also, any mother in Group A with acute dental infection was referred immediately for dental treatment.

Recruitment and Retention Strategies

Beginning in the design phase, considerable effort was directed toward developing the recruitment and retention infrastructure, which can be summarized into three categories: (1) barrier reduction, (2) incentives, and (3) relationship building. Cultural sensitivity and cultural competence were considered overarching and essential elements for recruitment and retention, and steps were taken to ensure these concepts were incorporated into the study. A bilingual, bicultural staff was assembled from the target population's community. Input on the local cultural and economic climate was obtained from community members including longstanding health care providers, members of the clinic board, representatives of local organizations, regional policy makers, and consumers. The community made recommendations on recruitment strategies, hiring outreach coordinators, and on how to monitor and encourage participation.

Several strategies were used to recruit participants. An outreach representative gave a brief presentation about the MAYA Project at the SYHC prenatal orientation classes held at its four clinics, SYHC Medi-Cal (federal Medicaid program in California) orientations, and meetings of the Women, Infant, and Children program (WIC). The presentation emphasized the importance of oral health during pregnancy and provided information on the purpose of the study, the time required, criteria for participation, and monetary incentives. In addition, flyers were posted at the SYHC and at the WIC program. The SYHC staff from the OB/GYN department notified pregnant women in their second trimester already enrolled in the SYHC prenatal program about MAYA during their appointments. Recruitment also occurred at MAYA-sponsored monthly baby showers at the SYHC and the WIC center in National City. Free breakfast and raffles with prizes, such as baby clothes, diapers, wipes, and bottles, were provided. Health fairs sponsored by the SYHC and WIC provided additional recruitment opportunities. MAYA staff was available at booths to provide information and distribute flyers and toothbrushes to promote the study.

A comprehensive approach to retention was implemented at the beginning of the study. Efforts were made to establish a warm personal bond or personalismo (an important cultural value in the Latino population) with the study participants. These efforts included spending time without rushing, showing interest in the participant's life, and displaying socially appropriate physical contact. Examples included:

- Phone calls were made to mothers on their birthday,
- All active participants received a quarterly newsletter with information on oral health issues and upcoming MAYA project events,
- Saturday appointments were made available one day per month for working mothers,
- Use of the SYHC shuttle service was available for transportation between participants' homes and the clinic,
- A \$20 grocery voucher was given after each visit as an incentive to continue with the study,

- Free dental cleanings and discounted dental services were offered by the SYHC (maternal discounts from 0 to 50%, depending upon income and a 75% discount for babies, regardless of income),
- Opportunities for social interaction with numerous parties were held for special occasions,
- Gift items were distributed at specific milestones of the study, and
- Referral services for issues not related to oral health were available.

Participation and Sample

The MAYA Trial recruited pregnant women to participate in the study during a 36-month period. The various outreach efforts yielded a total of 2,891 referrals. Of 556 predominantly Mexican-American women recruited at baseline, 195 (35%) were excluded after baseline for failing to meet inclusion criteria, and 361 (65%) continued to randomization at the 4-month postpartum visit. Most exclusions (78%) occurred before the 4-month visit, either due to missed appointments or to relocation. Reasons for exclusion thereafter were high-risk pregnancy (7%), voluntary exit (7%), abortion or child death (2%), or other reasons (6%). Most of the patients participating in the study were Hispanic (85%) and lived at or below the federal poverty level (70%).

Outcomes Measures and Data Collection

The primary outcome measure for the trial was dental caries experience in children. Caries measures included precavitated white spot lesions (an early sign of tooth decay). The National Institute of Dental and Craniofacial Research (NIDCR) Criteria was used to diagnose dental caries with supplemental information from a NIDCR workshop for precavitated lesions. Other secondary outcome measures included salivary levels of mutans streptococci and lactobacilli (tooth decay-causing bacteria), and oral health-related behavior changes in mothers from baseline to post-intervention.

Demographic and socioeconomic data and oral health-related knowledge, attitudes, and behaviors were measured with an instrument based on a questionnaire used in the SYHC's Infant Oral Care project. The latter questionnaire was expertly reviewed, validated, and pilot tested in focus groups and intercept interviews with participants from the target population.

The primary method of data entry involved customized web-based forms that were accessed over a secure internet connection by the research assistants. Ongoing data management and cleaning included automatic data-coding and variable checking upon data entry.

Outcomes, Results and Conclusions

The study showed that clinical disease prevention trials can successfully recruit and retain pregnant Hispanic women. The 3-year study retention rate for this highly migratory population was 67%. Lessons learned for successful recruitment and predictors of continued retention of pregnant women in a randomized controlled clinical trial to prevent early childhood caries include:

- Factors such as race/ethnicity, annual household income, household composition, and oral health-related knowledge and behaviors were significantly related to retention until randomization. Women reporting a higher annual household income were less likely to be lost to attrition before randomization into the Control or Intervention Group, and Mexican/Mexican-American women were less likely to be lost after randomization.
- Recruitment and retention efforts for pregnant Hispanic women should place heavy emphasis on cultural factors, as ethnicity remained the only borderline significant predictor in post-randomization retention. The 65% retention rate from enrollment to randomization is likely due, in large part, to the creation of a culturally appropriate and targeted recruitment and retention plan.

This ECC intervention study illustrates a comprehensive approach to preventing dental disease in young children, that address clinical elements as well as bio-behavioral components that facilitate behavior change. Additionally, the MAYA Project points to the need for additional studies on appropriate antibacterials and other interventions that could be used with high caries risk children.

Budget Estimates and Formulas of the Practice:

In addition to typical research and development costs, key expense components for the MAYA Project included:

- Time and expertise required to develop culturally sensitive materials and questionnaires;
- The collection, transport, testing, as well as short- and long-term storage of saliva samples for evaluation of cariogenic bacteria;
- The development of a secure, web-based data system with remote data entry capabilities.

Lessons Learned and/or Plans for Improvement:

The lessons learned from the MAYA Project support the use of culturally sensitive, comprehensive, and targeted recruitment strategies to ensure that research studies are able to recruit and retain participants from high caries-risk, underserved populations most likely to benefit from interventions being tested.

While the results are pending on the efficacy of the interventions used in the MAYA Project for the prevention of ECC, it is clear that the Hispanic community responded positively to a culturally appropriate program, and to culturally-sensitive efforts at recruitment and retention. The integral role that "Personalismo," trust, and respect can play in the recruitment and retention success of a community-based study has been demonstrated by the MAYA project.

Acknowledgements:

The authors (Ramos-Gomez, Chung LH, Beristain R, Santo W, Jue B, Weintraub JA, Gansky SA) thank the San Ysidro Health Center, the entire study team and all the study participants without whom this effort would not have been possible. The MAYA study was supported by US DHHS/NIH/NIDCR & NCMHD grant U54 DE142501.

Available Information Resources:

1. The Center to Address Disparities in Children's Oral Health (CAN DO) - The MAYA Project Website at <http://dentistry.ucsf.edu/cando/project2.html>
2. Ramos-Gomez, Chung LH, Beristain R, Santo W, Jue B, Weintraub JA, Gansky SA. Recruiting and retaining pregnant women from a community health center at the US-Mexico border for the Mothers and Youth Access clinical trial. *Clinical Trials* 2008; 5: 336-346.

SECTION III: PRACTICE EVALUATION INFORMATION

Impact/Effectiveness

How has the practice demonstrated impact, applicability, and benefits to the oral health care and well-being of certain populations or communities (i.e., reference scientific evidence, outcomes of the practice and/or evaluation results)?

The MAYA Project showed that the three key elements of Personalismo, trust, and respect were successfully integrated into a culturally appropriate strategy to recruit and retain study subjects. These elements can be incorporated into efforts to establish a dental home and regular oral care and hygiene routines for a high-risk, underserved Hispanic population.

Efficiency

How has the practice demonstrated cost and resource efficiency where expenses are appropriate to benefits? How has the practice demonstrated realistic and reasonable staffing and time requirements? Provide unit cost analysis or cost-benefit analysis if appropriate.

Word of mouth in the tight-knit Hispanic neighborhoods, accompanied by the social and personalized outreach practices used in MAYA promoted and sustained the program. Trust barriers became easier to breach and relationships easier to forge.

Demonstrated Sustainability

How has the practice showed sustainable benefits and/or how has the practice been sustainable within populations/communities and between states/territories? What mechanisms have been built into the practice to assure sustainability?

An important aspect to the MAYA Project was the employment of culturally competent, bilingual professionals, and integration of cultural competency in every element of the project.

Collaboration/Integration

How has the practice built effective partnerships/collaborations among various organizations and integrated oral health with other health projects and issues? What are the traditional, non-traditional, public and private partnerships/collaborations established by the practice for integration, effectiveness, efficiency and sustainability?

It was recognized at inception that community involvement was crucial in creating a relevant, readily-acceptable program. The MAYA study proactively sought guidance from the community's leaders to ensure their support of the program. The role of community leaders, especially among minority communities, cannot be underestimated, and was crucial to the study's success.

Objectives/Rationale

How has the practice addressed HP 2010 objectives, met the National Call to Action to Promote Oral Health, and/or built basic infrastructure and capacity for state/territorial/community oral health programs?

Without a doubt, the barriers to oral health care for the Hispanic, and other minority communities, are formidable. Research studies such as MAYA cannot address access issues such as a fundamental lack of service providers. Instead, MAYA focused on testing the efficacy of combined interventions that can reduce early childhood caries as well as exploring innovative new methodologies to shift the cultural paradigm towards good oral health hygiene and practices.

Extent of Use Among States

Describe the extent of the practice or aspects of the practice used in other states?

The MAYA Project, on a practical level, can be applied to any community and/or cultural group. In addition to adopting effective interventions, key elements of the program included:

- Establishing partnerships with community leaders
- Identifying the community's traditional barriers to accessing services
- Adapting the program to overcome those specific barriers
- Creating materials and outreach programs appropriate to the specific community
- Seeking, whenever possible, professionals and study staff from within the community.