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# Preventing caries in preschoolers: Successful initiation of an innovative community-based clinical trial in Navajo Nation Head Start ☆

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ABSTRACT

Navajo Nation children have the greatest prevalence of early childhood caries in the United States. This protocol describes an innovative combination of community-based participatory research and clinical trial methods to rigorously test a lay native Community Oral Health Specialists-delivered oral health *intervention*, with the goal of reducing the progression of disease and improving family knowledge and behaviors.

*Methods/Design:* This cluster-randomized trial designed by researchers at the Center for Native Oral Health Research at the University of Colorado in conjunction with members of the Navajo Nation community compares outcomes between the manualized 2-year oral health fluoride varnish-oral health promotion intervention and usual care in the community (*child–caregiver* dyads from 26 Head Start classrooms in each study arm; total of 1016 dyads). Outcome assessment includes annual dental screening and an annual caregiver survey of knowledge, attitudes and behaviors; collection of cost data will support cost–benefit analyses.

*Discussion:* The study protocol meets all standards required of randomized clinical trials. Aligned with principles of community-based participatory research, extended interaction between members of the Navajo community and researchers preceded study initiation, and collaboration between project staff and a wide variety of community members informed the study design and implementation. We believe that the benefits of adding CBPR methods to those of randomized clinical studies outweigh the barriers and constraints, especially in studies of health disparities

*Abbreviations:* AI/AN, American Indian/Alaska Native; BRFQ, Basic Research Factors Questionnaire; CBPR, community-based participatory research; CNOHR, Center for Native Oral Health Research; COHS, Community Oral Health Specialist; DCC, data coordinating center; dmft, decayed, missing and filled teeth; ECC, early childhood caries; FV, fluoride varnish; HS, Head Start; HSC, Head Start Center; IHS, Indian Health Service; NIDCR, National Institute of Dental and Craniofacial Research; NN, Navajo Nation; NNHRRB, Navajo Nation Human Research Review Board; OHP, oral health promotion.

☆ **Competing interests**: The authors declare that they have no conflict of interest.

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and in challenging settings. When done well, this innovative mix of methods will increase the likelihood of valid results that communities can use.



## 1. Introduction

Early Childhood Caries (ECC) is defined as dental caries (commonly known as dental decay) in the primary teeth of children aged 6 years or younger [1]. Although ECC is largely preventable, it is the most prevalent chronic infectious disease in children in the United States [2], and the level of disease seen in American Indian/Alaska Native (AI/AN) children is by far the highest, suggesting disparate risk and the need for effective, culturally accepted interventions [3–5]. The most recent Indian Health Service (IHS) report cites caries rates of 68.4% for AI/AN preschool children (45.8% with untreated dental decay) and a mean decayed and filled teeth (dft) measure 3 times greater than for their non-Native counterparts [3]. In the Navajo population, dental decay among preschool children is especially severe; a recent survey reported a mean prevalence of 6.5 decayed, missing, and filled teeth (dmft) for 2–5 year olds [3], the highest in Indian Country.

Simple clinical procedures such as the application of fluoride varnish (FV) and oral health promotion (OHP) activities have shown promise in the prevention of ECC [6,7]. Among clinical interventions to prevent caries in children, the use of fluoride demonstrates the strongest evidence base and most predictable success [8,9]. FV, a professionally available topical agent, has been employed in the prevention of caries since 1964. The unique and favorable clinical characteristics of FV have prompted the publication of clinical practice recommendations from the American Dental Association and the American Academy of Pediatric Dentistry [10] that support off-label use of FV as the preferred technique for cost-effective caries prevention in children under the age of six [11,12]. The goals of OHP programs for children and caregivers are to increase knowledge, encourage positive attitudes toward oral health care, and improve parental behaviors related to ECC and contributing factors such as regular dental visits, feeding and nutrition, and oral hygiene practices [6]. With the possible exception of interventions focused on nutrition education [13], the few well-designed dental health education intervention studies have not found strong evidence that interventions relying on OHP alone result in long term behavior change with significant reductions in caries incidence [6,14–16].

Although OHP alone may not produce desired behavior change, relatively simple intervention approaches that combine FV with OHP activities for children and parents in a community-based setting appear to offer effective and efficient ECC prevention [6]. Dental providers are not always available, especially in geographically isolated communities. In other areas of health care, trained paraprofessionals from the community (including Community Health Representatives in AI/AN communities [17]) have effectively delivered services, because members of a community are better able to communicate with patients and understand the barriers to care [18,19].

This paper describes the protocol for a study to assess the effectiveness of a combined OHP–FV intervention for children enrolled in the Navajo Nation (NN) Head Start (HS) program and their parents/caregivers ("caregivers" henceforth), delivered by lay AI Community Oral Health Specialists (COHSs). The primary outcome measure is reduction in caries increase for children receiving the intervention, compared with children in similar HS Centers receiving usual care only. We are unaware of any other pediatric OHP–FV clinical research trials conducted on NN.

## 2. Rationale

### 2.1. Combined research strategies

The protocol for this study combines community-based participatory research (CBPR) and clinical trial methods. Community ownership contributes to effective, culturally sensitive health interventions [20,21]. CBPR collaboratively engages community and academic partners in a manner "that *equitably involves* all partners in the research process and recognizes the unique strengths that each brings" [22]. Advantages include the ability to test an intervention in real-world samples that reflect the community population of interest and place greater importance on sensitivities of the community, but the quasi-experimental design of most such studies excludes an unbiased comparison group. Clinical trials generally remove the selection bias by drawing participants from a carefully selected sample (i.e., excluding individuals with potentially confounding characteristics) and randomly assigning them to study arms but may have other restrictive criteria that can impede community participation in and understanding of the design and implementation of a low-risk research study.

Few clinical trials to date have incorporated CBPR methods. De Las Nueces et al. [20] conducted a review of recent peer-reviewed literature (2003–2010) and found only 19 articles that reported such studies. None of the studies took place in AI/AN settings or addressed oral health (one examined parent/child relationships; 10 explored weight, nutrition, physical activity, smoking, and/or blood pressure). Reported CBPR methods generally, but variably, included community involvement in identifying the problem, recruitment, intervention development and delivery, data collection, or a community advisory group. Fewer reported community involvement in interpreting analytic results or disseminating findings. Ten of the studies used a cluster randomization similar to that used in the study reported here.

Investigators in the Center for Native Oral Health Research (CNOHR) and the Centers for American Indian and Alaska Native Health designed this protocol, building on a strong foundation with the community beginning long before study initiation. They shared (and continue to share) the community's commitment to better health for their children and developed an intervention acceptable to the community while also employing scientifically valid clinical trial methods.