Early Childhood Caries: A Public Health Intervention using Fluoride Varnish on Infants in North Carolina

by

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Abstract

National studies in the United States have demonstrated clear evidence that a disproportionate number of young children from lower socioeconomic status are suffering the majority of dental caries. At the same time there are only limited numbers of pediatric dental specialists available to treat young children, and often they are not able to take children covered by Medicaid or the State Children's Health Insurance Program (CHIP). This paper describes the occurrence of Early Childhood Caries (ECC), the barriers to prevention or treatment, and the development of new techniques that have potential to focus prevention on infants. A pilot study called Smart Smiles focusing on the use of these new techniques and their application in pediatric offices to infants at high-risk for ECC is currently being evaluated in North Carolina. This paper provides a review of methods to recruit low-income participants into the evaluation phase of the Smart Smiles project. The literature review indicates that ECC is a disease of rampant dental caries experienced extensively in a small percentage of usually low-income children. The dental community where this study takes place has difficulty in providing an acceptable level of oral health care to this population. It has been proposed that use of an existing infrastructure where infants are accessing medical care can be used to provide an intervention to limit the extent of ECC. A high level of community involvement will be required to develop a level of trust in the target population that will be conducive to eliminating
the multifactorial causes of ECC. Any successful intervention and following evaluation will include local participation of community leaders as well as target population parents and children's caregivers. Access to oral care at multiple levels, including health professions outside the field of dentistry will increase the provision of preventive measures towards ECC.
EARLY CHILDHOOD CARIES: DESCRIPTION OF A PUBLIC HEALTH CONCERN

Introduction

Dental caries is the single most common disease of childhood in the United States (US) as well as the highest unmet health need of children. (Waldman 1998) Since the 1980's a change in the distribution of caries has become evident in nationally representative surveys of the United States. The distribution has become highly skewed, with the majority of dental caries found in young children. By the age of seventeen 80% of US children have experienced dental caries, but 80% of those carious permanent teeth are found in just 25% of the 5 to 17 years olds. Data from the Third National Health and Nutrition Examination Survey (NHANES III, 1988-1994) demonstrated disparities in oral health by indicating that among children at or below 100% of the Federal Poverty Level (FPL), almost 80% of carious primary teeth in the two to five year old children have not been restored. (Vargas 1998) While the dental profession advocates for early intervention, the majority of the approximately 20 million children under the age of five never see a dentist. (Waldman 1995) The type of dental caries experienced by these preschool aged children manifests different patterns of disease processes than caries in other age groups, and recently has received increased attention in the United States. The caries developed in preschool children
have been identified by various names in the past but is now named Early Childhood Caries (ECC). The increased prevalence of ECC has drawn attention to the lack of dental services available to low-income children. Since the early 1990's, Headstart programs in the US have claimed that their primary health concern is access to oral health services. (Jones 2000) The US ratio of pediatric dentists to children is quite low at about 1.2 per 100,000. (Crall 1995) While the oral health care of American children has typically been shared by physicians as well as those in the dental profession, it has become apparent that these needs of the preschool age group are not being adequately met. ECC is an infectious disease in children that is mostly preventable, oral health care of this population is inadequate and therefore merits attention. In North Carolina more than 25% of all those children entering Kindergarten have untreated dental disease, and 30% of kindergarten students suffer from 95% of the tooth decay. (Silberman 2000)

Consequently, a public health intervention has been conducted in ten counties in mostly rural Western North Carolina, where there was an identified need for dental care in the preschool population enrolled in North Carolina’s Smart Start program, called Smart Smiles. During the three years of the intervention, dental caries screening, fluoride varnish applications, and caregiver oral health education were provided in pediatrician’s offices to low income children age nine months to three
years. The evaluation phase of the Smart Smiles study is currently being conducted. This literature review describes some of the issues associated with the epidemic of Early Childhood Caries and describes some aspects of the Smart Smiles study. The recruitment of a control population for the evaluation phase of the study presents some potential concerns, as the ten control counties are located in a poverty stricken rural area of the Appalachian counties of North Carolina. The purpose of this paper is to provide the reader with a description of ECC and present possible strategies for preventing the widespread occurrence of this disease in lower socioeconomic populations. An additional aim of the review of the literature is to identify possible strategies which may aid in the recruitment of sufficient numbers to provide a control population for comparison purposes in the Smart Smiles study.

**Background**

Over the past two decades an overall change in the distribution of dental caries has become evident in the United States. These changes are demonstrated by:

1) a general decline in the prevalence and severity of caries in children

2) a skew in distribution, with most caries now seen in a small number of children and

3) a concentration of pit and fissure carious lesions in the occlusal surfaces of teeth. (Burt 1998)
The Third National Health and Nutrition Examination Survey, (1988-1994) (NHANES III) conducted in the US has documented the redistribution of caries, and results from the most recent findings indicate sociodemographic disparities in the distribution of pediatric caries. Lower-income children were much more likely to have unmet dental treatment needs, with nearly 80 percent of decayed primary teeth not having been restored in the two to five year old age group. (Vargas 1998) Although the American Academy of Pediatric Dentistry and the American Dental Association currently recommend that the examination of a child’s oral health should ideally occur within six months of the eruption of the first primary tooth, there are several obstacles that hinder this recommendation. The majority of general dental practitioners are not prepared to take patients under the age of three, believing that the child will not be sufficiently developed behaviorally to cooperate for a dental examination before that age. (JADA 2000;Goepferd 1987) While there are pediatric dental specialists in the United States, they are limited in number and therefore in high demand, and not all are in agreement with the recommendation of 12 months. (Erickson 1997) Frequently, parents are not aware of the oral health needs of infants and don’t consider a dental consultation for their child to be of high priority. Parents in deprived areas have been found to have little understanding of how to control oral disease, and prefer to leave control of the disease to the dental profession. (Kay 1989) This evidence of extrinsic motivation provided by
the dental professional has been found to be related to non-appreciation of dental care by parents as opposed to those parents who are intrinsically (self) motivated to take control of their children's oral health. (Syrjala 1994)

Dental caries in the oral cavity of infants and toddlers have been associated with inappropriate feeding habits of the child, most often by extended use of baby bottle-feeding or breastfeeding past age 12 months. Due to these factors, a special type of dental caries, now known as Early Childhood Caries (ECC), has manifested itself in young preschool children in some US populations, and has silently reached epidemic proportions in certain areas. ECC is a mostly preventable disease, and the public health community has an obligation to investigate strategies that could prevent the disease in this highly vulnerable population. The dental profession already has the knowledge and effective technology to prevent dental caries in children.

**Clinical Characteristics of Early Childhood Caries**

There has so far been no widely accepted definition of Early Childhood Caries. It has been known by different names, such as baby-bottle tooth decay, nursing caries, and night bottle mouth, all synonyms for the same disease. At a 1994 Centers for Disease Control and Prevention (CDC) workshop it was recommended that the term ECC be used when describing any form of dental caries in infants, toddlers or preschool age children. This terminology emphasizes that the causes of ECC are
multifactorial and not merely caused by the use of baby-bottle feeding. (Reisine 1998) ECC has, however, also been associated with prolonged breastfeeding on demand by the child. It has been suggested that ECC be defined as the occurrence of any sign of dental caries on any tooth surface during the first three years of life. (Ismail 1998) More recently, it has been suggested that “early childhood” include all preschool aged children from birth to 71 months. (Drury 1999) ECC is known to demonstrate a very specific pattern of rampant caries. The carious lesions typically develop rapidly on tooth surfaces that would not normally be of high risk to decay. The smooth surfaces of the maxillary anterior incisors are most susceptible to this type of carious lesion. Primary maxillary incisors are usually among the first teeth to erupt (between age six to nine months) and thereby are at increased exposure to the oral environment. The carious lesion typically manifests itself first as a white spot, most often located along the gingival margin, where the enamel is the thinnest. This white spot is where sub-surface demineralization of the tooth enamel has occurred. At this point the lesion is called precavitated, and it is reversible. The early detection of precavitated white areas is crucial in order to prevent the progression of the lesion to cavitation. (Ismail 1998) ECC is recognized as having differing levels of severity, depending on the number (including noncavitated or cavitated) and the location (smooth or occlusal surface) of lesions. (Drury 1999) Protective factors in the balance of the caries process, such as saliva components,
oral hygiene, fluoride and proper diet can help the remineralization effect. Pathological factors such as reduced salivary flow, increased bacterial load and frequent carbohydrates in the diet can increase demineralization of the precavitated white spot. (Featherstone 2000) If the lesion is not detected at this very early stage, it frequently rapidly progresses to form a band of caries around the tooth at the gingival third of the crown of the tooth. The teeth that are the next most susceptible to ECC are the maxillary first molars, erupting between ages 12 to 18 months. The teeth that erupt after this time frame are at less risk of ECC, assuming that the child has been weaned from the breast or the bottle by that age. (Milnes 1996)

There are few well-designed clinical trials that have been completed to demonstrate evidence of preventive measures for ECC in infants. There have been three general types of approaches used to prevent ECC. (Berkowitz 1996)

- Community-based: Education of the mothers on dietary habits as well as community water supply fluoridation and preventive programs in high-risk communities.
- Professionally-based: Dental examination and preventive care in dental clinics.
- Home-based: Development of appropriate dietary and self-care habits in the home.
All of these approaches depend at least in part on educating the mother or caregiver to change habits. However, previous study results have indicated little evidence that patient education is an effective means of improving oral health. (Tinanoff 1995, Kay 1996)

**Etiology of ECC**

ECC is an ecological imbalance in the mouth and has been described as a three-step process. First, colonization of the infecting bacteria must occur, establishing a cariogenic (cavity causing) flora in the mouth of the infant. A microbial shift then occurs, resulting in accumulation of high levels of the infecting bacteria. A lower pH then occurs due to high levels of cariogenic sugars in the diet. Finally, demineralization and resulting cavitation takes place. (Twetman 2000) Other biological factors may make the infant more susceptible to caries as well. The bacterial flora and the immune system are in the process of developing and are not yet well established. The teeth are newly erupted and may have certain developmental defects due to immaturity of the enamel, suggesting that the tooth is at its most susceptible point to caries formation.

Mutans streptococci are the main type of bacteria involved with causation of coronal caries. This is also the case with ECC, and studies have indicated that concentrations of the organism can reach up to 50% in the mouth and up to 10% in the saliva. The child is typically infected by saliva
from the mother, with a minimum effective dose followed by repeated inoculation. (Seow 1998) In order for the bacteria to increase to levels sufficient to create caries, a high level of sugar, typically in the form of sucrose, glucose or fructose, has to be present in the child’s diet. These substances must also be consumed frequently to build up a level of bacteria that would be damaging to the child’s dentition. The saliva contributes to remineralization of the tooth enamel, but requires sufficient time in order to function at optimal effect. If the saliva buffering effect is not overwhelmed by the frequency of sugar intake in the diet, demineralization caused by high acid levels in the mouth will lead to remineralization. An important factor to consider with ECC is the consumption of sugar before and during periods of sleep. The flow of saliva decreases during sleep, allowing more time for the sugar substrate to interact with the bacterial plaque in the mouth.

Costs of ECC
The costs of ECC can be considerable, and include financial and quality of life aspects. Failure to prevent ECC can result in pain, inability to eat, poor speech patterns and for children, days missed from school and weight loss. (Acs 1999; Silberman 2000) This can progress to extensive treatment needs, requiring otherwise preventable hospitalization, use of sedation or anesthesia, with potential costs in the thousands of dollars. In 1997, the North Carolina Medicaid program paid $1,686,565 for 62,000 (preventable) emergency dental visits. (Silberman 2000)
A high level of caries in the primary teeth also appears to be a risk indicator for a high level of caries in the permanent dentition. (Kaste 1992) A study of 1,482 emergency room dental visits to Seattle's Children's Hospital and Medical Center indicated that 60% were for trauma, the remainder (40%) for infection or other reasons. (Zeng 1994) It has also been suggested that ECC may have an impact of somatic growth and development, resulting in lower body-weight in those children suffering from extensive caries. (Acs 1999)

**Fluoride**

Fluoride has long been a widely recognized effective means of caries prevention in the US with 56% of the total population currently having access to fluoridated water. (Burt 1999) There are various sources of fluoride available to children in the US. Most often children have access to fluoride in water, food, beverages, toothpaste and therapeutic treatments in dental offices. Water fluoridation is highly beneficial for preventing caries in the primary dentition, but it is not known if it has a direct effect on ECC. (Ismail 1998) Community water supplies have been fluoridated throughout the states, even though not all communities make use of this addition as a preventive action against caries. Fluoride exposure in dietary sources is difficult to control and variation in
consumption of foods and beverages makes estimation of preventive effects uncertain. (Levy 1995)

Since the 1970's fluoride varnishes have been widely used in Europe where they were first developed during the 1960's. A widely cited meta-analysis of fluoride varnish study results indicated the varnishes are effective in preventing caries. (Helfenstein 1994) Since 1994, the US Food and Drug Administration (FDA) has permitted the use of fluoride varnishes as a medical "device" to be used as cavity liners and for the treatment of hypersensitive teeth. Caries prevention would be a medical claim, therefore requiring manufactures to submit clinical trial evidence of effectiveness for review by the FDA before fluoride varnishes could be accepted as an anticaries product. The unapproved use of approved drugs, is called "off-label" use, and is very prevalent among pediatricians in the US. (Committee on Drugs, 1996) There are currently four fluoride varnish preparations available in the US: Duraphat, Durafluor, Cavity Shield and Fluor Protector. (Shen 2002)

Extensive research has been conducted outside of the US supporting the efficacy of fluoride varnish in the prevention of caries. Duraphat has been the most extensively studied fluoride varnish. However, relatively few studies have been conducted demonstrating the efficacy of fluoride varnish as a caries inhibitor in the primary dentition. It has been suggested however, that fluoride varnish appears to be the only safe, as
well as practical means of applying fluoride to the teeth of infants. (Bawden 1998) A recent systematic review of the evidence for caries prevention and management methods indicated that of all methods studied, there was insufficient evidence to support their use, but fluoride varnish studies provided a fair level of evidence to support its use for caries-active high-risk individuals. The same study indicated insufficient evidence for management of non-cavitated carious lesions. (Bader 2001) Additionally, at this point in time there is still insufficient evidence for the effectiveness of fluoride varnish in primary teeth, due to the limited amount of studies. (Rozier 2001) A public health intervention to prevent Early Childhood Caries by use of fluoride varnish could be warranted in an initial study to determine its effectiveness in infants dentition.

**Fluoride Varnish Use in Pre-school Children**

Fluoride varnishes can contain very high concentrations of fluoride (22,600 ppm) as compared to other fluoride products available for usage in the US. Due to the high fluoride content, these products are designed to be applied only by professional oral healthcare givers. (Beltran-Aguilar 2000) The current cost of varnish application in the US is about $0.65 and is comparable to the cost of fluoride gels generally applied ($0.55). (Beltran-Aguilar 2000) A summary of past studies indicated that there was minimal risk of toxic reactions in children to fluoride varnishes. (Beltran-Aguilar 2000) A study conducted in Sweden in 1979 showed an average
caries reduction of 1.6 surfaces in two years compared to a control group when fluoride varnish was applied twice yearly to three-year-old children. (Holm 1979) A Silane fluoride varnish was applied every six months during a two-year clinical study of preschool children in Sweden. At the conclusion of the study, it was found that preschool children aged four and five years demonstrated up to a 25% reduction of approximal caries when compared to the control group. (Petersson 1998) Recent European studies have studied the effects of using a fluoride varnish prevention program with children of high caries risk. A community of low socio-economic status and a generally high caries rate was chosen for the study. By application of the fluoride varnish three to four times per year over four years it was demonstrated that primary school children who had at least a minimum of two treatments per year showed significantly lower caries compared to the control group. (Zimmer 1999) A more recent study using a low-concentration varnish in high-risk children indicated a significant difference in reduction of incipient caries, however there was no difference in the decayed, missing and filled surface (dmfs) increments. The study concluded that the described program was not effective in preventing caries in high-risk children. (Zimmer 2001) These results may indicate that such an intervention can be more effective at an earlier age while caries are in the incipient stage and before rampant caries are manifest.
A study of 142 US children in Head Start schools (three to five years of age) indicated that children treated with fluoride varnish had 81.2% of active enamel lesions become inactive after a nine-month treatment phase. The study was designed to be done in schools, and was simple to administer since no gels, trays, or means for expectorating were required. The researchers concluded that the varnish was an effective means of arresting early enamel lesions in the primary dentition. (Autio-Gold 2001)

Currently, dentistry has the technology available and the knowledge to provide effective measures to prevent childhood caries. The combination of factors of ECC, improper feeding patterns, mother to child transmission of cariogenic bacteria and insufficient exposure to fluoride provide the rationale for early intervention in the oral health care of infants. (Goepferd 1987)

Barriers to Prevention of ECC

Several potential barriers have been noted that hinder the effective elimination of ECC. These include the following: (Ismail 1998)

- Insufficient involvement of dental and medical health organizations that treat young children.

- The dental community lacks a shared vision of the definition of the problem.
• No integrated plan to address social, health and economic issues facing lower socioeconomic populations.

• Weak support for oral health research.

• Dental health has not been a major priority of most federal programs.

• Restrictions of the current dental work force in treating lower socioeconomic populations.

These points emphasize that there are various determinants of ECC, other than those identified on a biological or epidemiological level. Addressing the above mentioned points would increase the success of any intervention to eliminate ECC.

**Risk Indicators and Risk Assessment for Dental Caries in Children**

In the past dentistry used a deterministic or "cause and effect" explanation for oral health disease; however, research over time has indicated that most diseases are multifactorial. Genetic, behavioral or environmental risk factors all have an influence on the probability of specific health outcomes. (Slavkin 2001) Risk can be defined as the probability that an undesired or harmful event may occur. The purpose of identifying infants with an increased risk for caries is to target the prevention strategies before clinical signs or caries are manifested. (Twetman 2000 ) Studies have been conducted to estimate the level of risk for dental caries in children. It has been suggested that individual caries risk for children in
Women, Infants and Children (WIC) programs, Head Start and Early Head Start may be indicated by: 1) presence of previous caries, 2) precavity lesions, 3) visible plaque on the teeth, and 4) perceived risk by examiners. (Kanellis 2000) Other indicators of increased individual risk for primary dentition caries include: brushing less than once a day, delay of beginning toothbrushing by one year, no use of fluoride, daily use of sugar, and more than two between-meal snacks. The same study indicated a relation to geographical differences in the study population, but reasons remain to be investigated in greater detail. (Vanobbergen 2001) Research has also implied that classification of risk at the individual level is imprecise, whereas classification at the group-level is more accurate. (Hausen 2000)

Few studies have investigated the caries development in very young children or the usefulness of preventive strategies for high-risk infants or toddlers. One longitudinal study of children from 2.5 to 3.5 years of age demonstrated a baseline of 11.3% caries and 36.7% caries one year later. Of those lesions diagnosed as initial caries at baseline, 64% progressed to manifest caries after one year. (Grindfjord 1995) These results indicate the need for early intervention to inhibit the progression of caries in this young population. The authors found that their study supported identification of high-risk populations before the age of two years in order to initiate interventions, including fluoride prophylaxis.
The successful application of a high-risk strategy for control of dental caries should have the following pre-requisites: (Hausen 1997)

- The occurrence of caries must be low enough in the target population to warrant the expense of identifying individuals at high-risk.
- There must be accurate and acceptable measures to identify at risk individuals.
- The preventive efforts should be based on effective measures.

**Strategies**

Due to the limitation of resources, including funding as well as manpower, an effective strategy for planning the prevention of ECC is indicated. Several possible suggestions have been promoted for use either at the individual or population level. The use of a high-risk strategy offers a more cost-effective use of limited resources. This type of preventive strategy has several advantages (Rose 1985):

- Intervention appropriate to individual
- Subject motivation
- Physician motivation
- Cost-effective use of resources
- Benefit-risk ratio favorable

Disadvantages for the "high-risk" strategy have been suggested as well, including:

- Difficulties and costs of screening
• Palliative and temporary
• Limited potential for individual and for population
• Behaviorally inappropriate

Another type of strategy is the population strategy or the attempt to control the determinants of the disease. Its advantages can include:
• Large potential for the population
• Behaviorally appropriate

Rose concluded that the “high-risk” strategy of prevention was needed for individuals, but only as long as the underlying causes of incidence of the disease remain unknown or uncontrollable. If causes can be removed, susceptibility ceases to matter. (Rose 1985) Another rationale for targeting high-risk is to improve cost-effectiveness but the underlying concern is the expense of identifying susceptible persons. If it becomes too expensive, then the rationale collapses. (Burt 1998)

A population approach focuses on everyone in a population, whether they are diseased or healthy. It has an additional advantage in that no administrative expenses are required for screening individuals. However, in light of the trends toward a changed distribution of caries in the US, the targeting of those children at especially high-risk for caries may make better use of limited resources. To address the skewed distribution of caries in the US, targeting would concentrate limited resources on the
approximately 25% of children with the disease, who need care the most, where overall caries prevention can be most productive. (Burt 1998)

The targeting philosophy presents two issues:

- Can the high-risk children be identified with sufficient precision to make targeting practical?
- Are targeted programs really more economically efficient than programs directed at the whole population?

The issue of recruitment for study participants for the intervention becomes pertinent under this second question, when economic costs must be considered.

It has been suggested that a targeting strategy that can be most efficient is that of targeting particular geographic localities, something between a population strategy and a high-risk strategy. (Burt 1998) Geographical differences have been identified as a risk indicator for primary dentition caries. (Vanobbergen 2001) With the increasing polarization of dental caries among child populations, the high-risk strategy has gained wider acceptance in the public health approach to prevention of caries. The approach allows scarce resources to be focused on the neediest and it requires a simple screening method to be most effective. The high-risk group strategy therefore aims for selected groups such as Head Start where the preventive approach is used to tailor activities to groups in an
otherwise low-risk community that have a high caries prevalence. (Twetman 2000)

**Issues of Access to Oral Health Care Providers**

Low-income populations have various available options to help make dental care financially affordable and keep financial barriers to access at a minimum. The Medicaid system has existed for about 40 years in America and, since 1997, the State Children's Health Insurance Program (CHIP) provides coverage for an additional three million children who did not have insurance coverage under Medicaid. (USGAO, 2000) Data concerning the unmet dental needs of children and especially pre-school age children are difficult to obtain. Reports of need for dental care are usually of small sample sizes of children who participate in pre-school programs such as Head Start. (Crall 1995) It has been documented that more children are unable to obtain dental care than any other single health service in the United States. Since the early 1990's, Head Start programs have identified access to oral health services as their number one health concern. (Jones) Unmet dental care is 6.1% versus 1.9% for unmet medical care for children in the US. (Waldman 1998) The United States General Accounting Office released a Congressional Report in September 2000 describing factors that contribute to low use of dental services by low-income populations in the United States. The results of their study indicated that the major difficulty is finding dentists who will treat low-
income populations, even when those populations are covered for dental services. Low payment rates, administrative requirements, and perceived frequent missing of appointments are reasons dentists cite for refusal to treat Medicaid patients. Recently 40 states have increased payments for dental services, resulting however, in inconsistent marginal increases in usage of dental services. (USGAO 2000) The Surgeon General’s report cited information from the National Access to Care Survey which found that 12% of Medicaid patients had unmet dental care needs whereas only 8% reported unmet medical needs. (USGAO 2000)

Patients have reported issues that affect their use of dental services. The USGAO report suggested patients often consider dental services deferrable and parent’s attitudes concerning dental care may be a factor in children’s use of dental services. Medicaid and other low-income populations have issues involving transportation, childcare and time off of work which may hinder their access to dental care as well. (USGAO, 2000) A recent North Carolina study revealed the following barriers to obtaining dental care as perceived by caregivers of Medicaid-insured children: (Mofidi 2002)

A. Access barriers to dental care
   - Difficulty in finding a provider
   - Appointment scheduling difficulties
   - Inconvenient and unreliable transportation
B. Quality of experience barriers in dental care setting

- Excessive wait times
- Demeaning interactions with front-office staff
- Negative interactions with dentists
- Discrimination because of Medicaid

A North Carolina study surveyed the pediatric dentist population. Forty-five dentists were identified as pediatric dental specialists in the state. Of those who responded to the survey, 47% accepted patients with Medicaid assistance, but 100% limited the number of such patients seen in their practices to some extent. Fifty percent of the respondents felt that another pediatric dentist was needed in their area, indicating they felt unmet needs existed in their area. In 1993, North Carolina had one of the lowest ratios of pediatric dentists in the US, 3.4 per 100,000 children. (Hughes 1999)

A North Carolina Institute of Medicine Task Force Study (1999) identified access to dental care problems specific to the state:

- Only a small number of dentists participate in the Medicaid program. (NC ranked 44th out of 50 states).
- There is an overall shortage of dental professionals. (NC ranked 47th out of 50 states).
- There is a maldistribution of dentists.

In addition, it was stated that North Carolina’s youngest children have not benefited as they should have from the progress made in decay prevention. More than 25% of all those entering kindergarten have
untreated dental disease and, 30% of kindergarten students suffer from 95% of the tooth decay. (Silberman 2000)

**Results of Literature Review**

While the precise dynamics of ECC are not yet entirely clearly understood, the literature indicates a need for early intervention in the management of the dental disease. There have been recognized changes in the distribution of dental caries over the past 30 years in the United States, with subpopulations, especially those children living in poverty, who now bear the major burden of dental caries. These children rarely have access to preventive or restorative dental care, due often to lack of awareness, or frequent unacceptance by dental professionals due to the patient's insurance status. The current dental workforce is restricted in its ability to provide care for low income populations due to limited accessibility to high-risk communities, restrictive dental practice acts, and low reimbursement for dental care covered by Medicaid. (Ismail 1998) North Carolina has recently identified all of these issues as barriers to providing oral health care to its low-income citizens. (Silberman 2000) The process of dental caries has come to be recognized as a dynamic condition of demineralization and remineralization of the enamel of the tooth. It is believed that the ECC process can be reversed or arrested while in its early stages if preventive action is taken in a timely fashion. The appearance of fluoride varnishes on the US market since 1994 provide an
acceptable and safe method of preventive treatment for the infant age group.

In order to address the ECC disease process at its earliest phases, an intervention soon after the eruption of the primary teeth provide the greatest preventive impact. Prevention methods should begin in the child’s first year of life for optimal effects in eliminating the occurrence of this transmissible and infectious disease. A public health intervention that addresses the multifactorial etiology of ECC and makes use of an existing infrastructure of infant care in the pediatric office setting would have great potential in addressing the unmet oral health needs of these low-income children who are deemed to be at high-risk for the development of ECC.

Description of the Smart Smiles Pilot Study

In order to address the excessive levels of Early Childhood Caries that are evident in entering Kindergarten classes in Western North Carolina, the Smart Smiles study was initiated. The Appalachian Regional Commission provided the main funding of the study. Established by the US Congress in 1965, the Appalachian Regional Commission (ARC) is composed of the governors of the thirteen states located in Appalachia along with an appointee of the federal government. Grassroots participation is encouraged through multi-county organizations. One of the goals of ARC is fostering healthy people. (ARC website) In order to meet this goal, ARC helps fund projects such as Smart Smiles to develop health-care
resources by use of congressionally appropriated funding. The project was administrated by the North Carolina Partnership for Children, known as Smart Start, and funded by the North Carolina legislature in 1993. The program was seen as a cornerstone of the administration of James B. Hunt Jr., North Carolina’s governor elected in 1992. At that time, North Carolina was ranked 39th out of the 50 states on the health and well-being of its children. The Smart Start program was created to provide quality early education, health care and other needed services for every child under the age of six in North Carolina. The Smart Start program was unique in that it required the individual counties or groups of counties to form local boards consisting of community leaders, parents, representatives of already existing social services and businesses and other interested parties. These boards would then create local nonprofit “Partnerships for Children” to design, run and administer local Smart Start Programs. (Hoffman) In 1996, local representatives of Smart Start identified ECC as one of the major problems in the Western counties of North Carolina. To assist in addressing this concern, the Smart Smiles pilot study was funded by ARC with nearly one million dollars from October 1998 to October 2001 to design and implement a program to address the dental decay problems of young children in the area. The project was a collaborative public dental health intervention between The North Carolina Division of Public Health, Oral Health Section; The University of North Carolina at Chapel Hill Schools of Public Health and
Dentistry, Dental Medicaid; The Ruth and Billy Graham Children’s Health Center and the NC Partnership for Children (Smart Start). Using studies identifying poverty as a predictive factor of ECC and supporting the use of fluoride varnish as an effective measure against the formation of ECC, the project targeted children under the age of three who were at high risk for caries (less than or equal to 200% of the federal poverty level). Ten counties of the Appalachian region of North Carolina were included in the pilot study for this community-based intervention. Dental Hygienists were designated as community development coordinators and by collaborating with other volunteers in each county, developed comprehensive plans to establish the Smart Smiles project in each of the intervention counties. The dental hygiene coordinators were responsible for community outreach, training of physicians and nurses in technical project procedures and development of project databases. The main focus of the intervention was application of a fluoride varnish on the teeth of infants deemed to be at high-risk for the development of ECC. The target group was infants of caregivers in low-income families (at or below the 200% FPL), those who were covered by Medicaid, North Carolina Heath Choice, WIC, etc. Parents whose infants were not covered by insurance were encouraged and aided in application for financial assistance through these insurance programs. The fluoride applications were made at times when the infants were typically due to have visits at the pediatricians’ offices, therefore making use of an existing infrastructure and treatment schedule. The
intervention included screening for ECC, the fluoride varnish application, and oral health education for the child's caregivers. The intervention was to occur five times for each child, starting at age nine months (when first teeth had erupted) up to the age of 36 months. Ten counties of the Appalachian region of North Carolina were included in the intervention planning, and ten other counties in the area are planned to be used as control counties for the evaluation of the Smart Smiles pilot study.

**Evaluation Issues**

It has been suggested that many of the oral health promotions of the past have been inadequately or inappropriately evaluated. (Watt 2001) Suggestions for improvement of the evaluation procedure include requirements of both qualitative and quantitative methods to fully evaluate the range of outcomes relevant to oral health interventions. (Watt 2001) Now that Smart Smiles has concluded the original intervention as of October 2001, an evaluation of the demonstration project has been proposed. The proposal includes a quantitative portion which focuses on the amount of caries found in those children aged three, who were involved in the intervention as well as aged three children who were not exposed to the intervention, (from the control counties). Both a longitudinal study, comparing the levels of caries present in the intervention and control groups at age five, when they enter Kindergarten and a comparison of historical levels of caries at age five are proposed for
the evaluation. The study design also includes a focus on the effects of the intervention on ECC treatment and its costs. A qualitative section has been proposed which will estimate the Oral Health Related Quality of Life experienced by those exposed to the intervention and controls. A concern to be addressed by the evaluation is accessing three-year-old children who are to be recruited from the control population. (Information gleaned from the evaluation grant proposal of the Principle Investigator, RG Rozier 2001). This young age group is not readily accessible because they are not yet enrolled in the North Carolina school system and yet the study design requires that these children of the control population also be examined within a two-month timeframe around the date of their third birthday. The following section is a continuation of the review of the literature and focuses on suggestions of previous studies to improve recruitment of difficult to reach populations.

**Recruitment of Study Participants**

Children identified as needing targeted prevention are usually the hardest ones to reach in a community. (Burt 1998) The costs involved in bringing the identified children into the intervention program make a careful consideration of recruitment methods an especially critical issue for hard to access populations. Prevention programs can be of low priority for families that have challenges meeting the everyday needs of their family. In order to recruit and retain these families in studies, a means of meeting
health needs as well as adapting to the everyday needs of the family should be considered.

Changes in the National Institutes of Health guidelines in the early 1990’s have required inclusion of minorities and women in health research. Since that time, an increase of knowledge in methods and challenges of recruitment have resulted in publications addressing the issue. Various recruitment methods into prevention studies have been directed at minority ethnic populations, rural and urban, and male and female populations, as well as variable age groups. A number of clinical and medically focused studies have reported on the subject of participant recruitment.

**Use of Focus Groups**

The initial phase described in most successful strategies was getting to know and becoming familiar with the demographics of the study population. Recent results of the 2000 census can help to provide that information. (Blumenthal 1995) Several studies used focus groups as a means of becoming familiar with the target populations health needs and motivations for participating in a study and remaining involved in the study until completion. (Brown DR 2000, Trettin 2000, Brown BA 2000, Jones FC 2001) The importance of using an experienced facilitator for the focus group was stressed in these studies.
Jones et al. focused on recruitment and retention of African American adolescents in their focus group. These youth valued honest and straightforward information as critical in the recruitment process. They had a strong desire for information and learning about their disease and the research process as a whole. These adolescents valued money, fun or food as incentives to being recruited. Recognition of their time, showing respect for their contributions, as well as logistical considerations of location and setting of interventions were also important. The youth found that understanding of family situations such as lack of transportation, or a sudden illness should be expected of the researchers, and would help to retain the youth in the studies. These adolescents believed money could be an incentive, but were satisfied with a realistic compensation for their time and effort. Youth in these focus groups also expressed a desire to have time built into the intervention that would allow them to get to know other members of their age group in the study and allow time to socialize and build relationships with them.

Brown DR et al. conducted a focus group with minority women to gain understanding of their issues with recruitment and retention in cancer screening, prevention and treatment. Recruitment issues were not consistent in the four different groups discussed in this study, but identified barriers to recruitment included lack of information, fear or mistrust, lack of transportation, interference with work or family responsibilities (child or
elder care) and financial cost. Factors that would increase retention in the study for this group of women included money or a gift certificate, doctors that made them feel comfortable, and a courteous staff. These studies also stressed that recruitment of minority women who are healthy and asymptomatic for a prevention study may be more difficult than recruiting those already diagnosed with disease.

Other focus groups concentrated on community volunteers who were interested in being neighborhood health advisers. (Trettin 2000) Although the volunteers had interest in helping with the study and were well known and trusted members of the community, these workers also required recognition of their efforts and wanted training that they could apply towards future job applications. Focus group members felt that certification of training would enhance their credibility in the community. The focus group helped dispel some of the assumptions of the research group towards volunteers in a community-based study. The Trettin study found that time spent early in the study to find ways of dispelling community distrust towards research and the health care system was critical to successful recruitment of study participants.

The feasibility of recruiting minority populations for a women’s health primary prevention trial was focused on in a multi-centered study. (Lewis 1998) Researchers found that the greatest source of randomized
participants came from mass mailing, followed by media promotion, referrals and community outreach. A dedicated recruitment staff used a variety of methods, including presentations at churches, distribution of brochures and personal referrals from previously recruited participants. Unpaid media coverage was the most cost effective, but the study did not find that any single strategy, used alone, would have had similar efficacy or yields. Overall, the yields for different recruitment strategies did not differ by ethnicity in this study, although different levels of effort were required. There was a lower yield for women of low socioeconomic status (SES). As in other studies (Senturia 1998, Grunbaum 1996) continuous tracking of recruitment and screening stages were managed using computer software. Each completed activity of recruitment was recorded as well as the final disposition of the targeted women as either ineligible, eligible but unwilling to participate, eligible and willing, or passive refusal.

**Use of the News Media**

Schoenfeld et al. found assistance of local news media and community and professional groups helpful in their recruitment process. The researchers received the largest single recruitment response from a local television broadcast followed by a newspaper story. By use of a toll-free 800 number and postage-paid recruitment postcards, participant costs were kept to a minimum. The office made use of a roll-over telephone system, with voice mail to eliminate the chances of busy signals or unanswered calls. Postcards were followed up by phone calls the
following business day. Incentives for participants in their study of diabetes awareness included samples of diabetes-related products and coupons, as well as a chance to win larger gifts donated by manufacturers. The researchers continuously monitored the distribution of study participants throughout the recruitment process. By this means researchers were able to detect select groups that needed an increase in recruitment and thus would refocus their publicity campaign by broadcasting a news segment directed at the desired minority group which resulted in increased enrollment of the select group. These researchers stressed the importance of maintaining community contacts even after the closing of the recruitment phase of the study. A referral network was developed and information on community diabetes resources was made available to those still interested in the study, thus leaving the possibility open for future recruitment efforts.

**Issues of Trust**

A study of recruitment and retention of health minority women was conducted by Gilliss et al. focusing on African-Americans, non-Hispanic European Americans and Mexican/Central Americans. They found that multiple methods of recruitment produced a diverse sample, with the face-to-face recruitment resulting in the highest yield with the lowest attrition, but also requiring more resources than other methods. These interactions consisted of street fairs, church coffee hours or parent-teacher meetings. Printed matter and broadcast media reached a greater number of women,
but this study found that the yield of eligible participants was lower using this method. Retention rates remained high, but the authors mentioned that a change in personnel, even when accomplished smoothly might effect retention.

Enlisting the help of trusted individuals, such as the school nurse can help facilitate access to students in a rural school setting. (Lamb 2001) An understanding of the culture of the setting, in this case a rural school, is important to maintain ongoing communication. Parents as well as students were alerted to the upcoming research study by an announcement in the school newsletter. The research team had all materials prepared before meeting the students, including consent forms, explanatory letter for the parents, posters for the school and a collection site for consent forms. Nonetheless, flexibility is important in this setting to allow time for unforeseen events, such as student illness, school closings, and teacher strikes or staff resignations.

**Flexibility**

Flexibility of the research team and recruiters is necessary when recruitment goals are not reached in the scheduled time frame. (Grunbaum 1996) The Project HeartBeat! revised recruitment strategies to suit the minority population’s priorities. The recruitment period was extended by one year, and mobile recruitment was established as opposed to the original field-center based visit. With these modifications,
which required much debate and reallocation of resources, a method was developed that worked for the specific community. Once implemented, the mobile method was highly effective and enrollment was quickly accomplished.

Little has been published concerning the experiences of the recruitment staff themselves. The Brown et al. study provided some insight to challenges they faced. Often recruiters worked additional hours, used home phones or met subjects in non-study locations. They were often expected to solve problems with recruitment failures, without support from the research team. The day-to-day difficulties of recruitment are often underestimated. Recommendations to assist recruiters included additional resources, time and staff. Multi-lingual staff can be a necessity at times. It was suggested that early collaborations between recruiters and principal investigators to assist in the development of the study design could result in the most successful recruitment of diverse populations.

**Summary**

A variety of methods used to recruit diverse populations bring the best results. Ness et al. found that evaluation of the assumption that "hard to reach" populations are more likely to refuse participation required more data on the proportion who could have been reached. Recruitment takes time and resources to build communication and trust in the community; a
trusted leader of the community can be helpful to gain access to minority groups. Flexibility is key to achieve goals of recruitment and adapting recruitment methods to fit the day to day schedules of the study population could increase chances of enrolling minorities into research studies. Generally, the most successful recruitment approaches identified in this review of the literature included community participation in the conception, design and implementation of recruitment. Use of the news media to increase the populations access to information about a study has proven to be successful. The early on building of trust between researchers and communities is essential, programs must be convenient for participants to access, and courteous staff would be an important part of a successful strategy. An issue of high salience is having the essential amount of time available to become familiar with the study population, build a trusting relationship. Additionally important is being open and flexible to feedback from the study population, being willing to incorporate changes that address their needs and identify barriers they have to participation.

**Conclusion**

A more accurate understanding of the Early Childhood Caries disease process indicates that the disease begins very early in the susceptible population. Recent availability of fluoride varnish in the US allows an easy and safe procedure to be effectively used as a preventive measure in infants. In order to address the unmet oral health care needs of a low-
income infant population, a variety of factors must be addressed. The support of community members as well as the health care providers of the community is essential to any potential success of a public health intervention targeted towards these children. Since preschool age infants and children are such a difficult population to gain access to even for the provision of effective preventive measures, it is important that trusted members of the community introduce the project. Recognizing a limit of available financial resources, it is most effective to use a strategy to target interventions to those high-risk populations most in need of oral health prevention methods. To gain access to this population, it is advisable to make use of an existing infrastructure where they already access health care, such as the pediatricians’ offices. For the long-term goal of reducing the prevalence of ECC, an extensive involvement of the entire community will be needed in order to influence the behaviors that play a role in the occurrence of ECC. Emphasis needs to be placed on evaluation of current interventions and further creation of novel interventions directed towards the prevention of ECC in those groups who are at highest risk.
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