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Symposium on Early Childhood Caries in American Indian and Alaska Native Children



Panel Report

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November 2009

Panel Report

Acknowledgements

The following individuals devoted numerous hours to planning the 2009 Symposium on Early Childhood Caries in American Indian and Alaska Native Children. Without their tireless efforts, the Symposium would not have been possible.

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The views expressed in this report reflect the opinions of the individual members of the Panel on Early Childhood Caries in American Indian and Alaska Native Children and do not necessarily reflect the official position of the American Dental Association.

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Executive Summary

Early childhood caries (ECC) is a chronic disease that has a relatively low prevalence and minimal morbidity among most populations of U.S. children. By contrast, in many American Indian and Alaskan Native (AI/AN) communities, the prevalence of ECC is extremely high—approximately 400 percent higher than the U.S. all races. More important, ECC among AI/AN children also has a very high morbidity, with a large proportion of children developing rampant caries. Programmatic efforts by the Indian Health Service (IHS) and tribal health programs, using interventions found effective in preventing ECC in other populations, have shown minimal to no long term benefit. There is a pressing need to examine ECC among AI/AN children in light of the current scientific understanding and identify effective new research and programmatic strategies that are science-based.

To achieve this goal, on November 4, 2009, the American Dental Association (ADA) Council on Access, Prevention and Interprofessional Relations (CAPIR), in cooperation with the IHS Division of Oral Health, co-hosted the Symposium on Early Childhood Caries in American Indian and Alaska Native Children. A small, select group of individuals was invited to participate, including representatives from three groups: 1) academic researchers with extensive experience in caries research, 2) career IHS dentists and pediatricians, and 3) individuals with expertise leading health research in AI/AN communities. To ensure that all participants were sensitive to the tribal community perspective on this health issue, the Symposium included three Native Americans, one of whom is from a small Southwest tribal community and is the mother of a child who had ECC despite her efforts to provide a healthful diet and good hygiene.

The Symposium was divided into two general sessions. In the morning, several presentations described the prevalence and severity of ECC among AI/AN children, which a former IHS pediatrician described as being a “*different disease*” from ECC among most other U.S. population groups. Among the reported differences are:

- ECC in AI/AN children has a very early onset (often by 18 months of age).
- ECC follows an aggressive and destructive course in many AI/AN children.
- ECC in AI/AN children has been largely refractory to interventions effective in other populations.

Newly acquired data from four geographically diverse AI/AN communities indicate that a likely explanation of why ECC is a *different disease* for these children is the role of cariogenic bacteria, especially *Streptococcus mutans* (*S. Mutans*). AI/AN children are colonized by *S. mutans* very early in life, and these bacteria soon become the dominant oral flora for many of these children—at times becoming almost a mono-culture. This evidence led to the suggestion that, in order to control ECC among AI/AN children, the paradigm about ECC needs to change to consider it an *infectious disease of childhood with a dental manifestation*, instead of a *dental disease*. Although there are, at present, no Food and Drugs Administration (FDA) approved products with specific indication of controlling cariogenic bacteria, there are two ongoing studies to evaluate the effectiveness of therapeutically controlling the level of these bacteria in AI/AN mothers and children.

The majority of the afternoon session consisted of discussions of specific issues raised in the morning presentations. One of the key points that the group returned to several times was the lack of adequate measures to define the true burden of disease from ECC for AI/AN children. The standard population surveillance measure of “decayed, missing or filled teeth” (dmft) does not adequately address the variations in severity of caries. Possible new measures were proposed, including a standardized way to assess severity of the caries for each tooth surface, plus standardization of the assessment of level of cariogenic bacteria in the child.

At the conclusion of the Symposium, many participants agreed that ECC in AI/AN children may represent a *different disease* from that experienced by other populations of children. To achieve control of ECC among AI/AN children, new multimodal approaches will be required, with an enhanced emphasis on controlling the infectious etiology of the disease. Control will also require the development of new metrics to better characterize the disease and measure the effectiveness of new prevention approaches.

The participants commended the ADA for its support of the ECC Symposium and recommended that the ADA build on the momentum and interest generated by the Symposium and explore ways to host a follow-up two to three-day ECC workshop in 2010. This second meeting would allow more time to present and discuss the relevant research issues and develop the framework for a research agenda directed toward reducing the remarkable health disparity from ECC among AI/AN children.

Contents

Introduction	1
Presentation Summaries	1
Topic 1: Reducing the Burden of Disease from Early Childhood Caries in American Indian and Alaska Native Children Patrick Blahut, DDS, MPH Steve Holve, MD	1
Topic 2: A “Different Disease” Dee Robertson, MD, MPH	2
Topic 3: The Epidemiology of Early Childhood Caries in Indian Country Kathy Phipps, DrPH	2
Topic 4: Past and Current Indian Health Service Programmatic Control Efforts Patrick Blahut, DDS, MPH	2
Topic 5: Early Childhood Caries in Indian Children—20 Years Working at “Ground Zero” Stuart Holmes, DDS James Singleton, DDS John Zimmer, DDS Don Marianos, DDS, MPH	3
Topic 6: Past and Current Research to Prevent Early Childhood Caries in Indian Country Lara Baha—Tribal Community Member Perspective on ECC Research Steve Holve, MD <i>Applying Fluoride Varnish in a Pediatric Clinic</i> Dee Robertson, DDS, MPH <i>Applying 10% Chlorhexidine (CHX) Varnish to the Mother’s Dentition: A Randomized Clinical Trial; Cavity-Free in 2-0-1-3: A Multimodal, Community-based ECC Prevention Study</i> David Drake, PhD, MS <i>Transmission of S. mutans in a Northern Plains Tribal Community</i>	4
Topic 7: Essential Cariology Page Caufield, DDS, PhD <i>Factors likely to be Determinants of Early Childhood Caries in American Indian Children</i> Wenyuan Shi, PhD <i>Microbiological Tools to Assess Risk for Severe Early Childhood Caries</i>	5
Topic 8: Epidemiology of Pediatric Infectious Disease in Small, Crowded “Closed” Communities Jim Campbell, MD	6
Topic 9: New Products for Early Childhood Caries Prevention Wenyuan Shi, PhD <i>Glycyrrhiza uralensis (the licorice plant); Specifically Targeted Antimicrobial Peptides</i> David Drake, PhD, MS <i>1.0% Flavored Chlorhexidine (CHX) Gel</i> Kathy Phipps, DrPH <i>Silver Diamine Fluoride</i>	7
Topic 10: Existing Infrastructure for Early Childhood Caries Prevention in Indian Country Jim Campbell, MD <i>Johns Hopkins Center for American Indian Health (CAIH) Research Program</i> Jane Weintraub, DDS, MPH <i>Center to Address Disparities in Children’s Oral Health at the University of California, San Francisco</i> Terry Batliner, DDS, MBA <i>Center for Native Oral Health Research, Centers for American Indian and Alaska Native Health at the University of Colorado at Denver</i>	7
Topic 11: Expert Opinions on Promising Early Childhood Caries Prevention Research Strategies, including Risks and Benefits of Antimicrobials in Very Young Children Page Caufield, DDS, PhD; David Drake, PhD, MS; Norm Tinanoff, DDS, MS; Wenyuan Shi, PhD	9
Topic 12: Metrics, Common Ground and Priorities for Future Research Directions	10
Next Steps	11
Conclusion	11
Appendix A: Symposium Agenda	12
Appendix B: Panelists	14

Introduction

Early childhood caries (ECC)¹ is a chronic disease that has a relatively low prevalence and minimal morbidity among most populations of U.S. children. In many American Indian and Alaskan Native (AI/AN) communities, the prevalence of ECC is extremely high—approximately 400 percent higher than for U.S. all races children. Of far more importance, ECC among AI/AN children has an extremely high burden of disease, with over 25 percent of pre-school children in some communities requiring full mouth restoration under general anesthesia—a rate that is about 50 to 100 times the rate in U.S. children of all other races. In addition to the considerable morbidity from severe ECC for the children themselves, it can also lead to a lifetime of dental disease.

Decades of programmatic efforts by Indian Health Service (IHS) and tribal health programs—including community water system fluoridation, attempts to improve children’s diets and oral hygiene and, more recently, application of fluoride varnish and use of xylitol gum—have resulted in little or no long term improvement in ECC prevalence or severity. Thus, interventions found effective in preventing ECC in other populations have shown no demonstrable long-term or sustainable benefit in most AI/AN communities. There is a pressing need to examine ECC in light of the current scientific understanding and identify new research and programmatic strategies that are science-based.

Symposium Objectives

- Establish a common knowledge base among Symposium participants of ECC in tribal communities, including past programmatic and research efforts to control ECC, the current ECC epidemiology in AI/AN and other U.S. children, and preliminary data from ECC research in progress.
- Review the current state of the science about the initiation and progression of severe ECC, with special emphasis on the bacterial etiology of the disease.
- Understand the limitations in generalizing the results of ECC prevention research done in non-Indian communities to AI/AN communities.

- Identify cultural, demographic and institutional factors that are likely to influence clinical research and programmatic efforts to control ECC in Indian communities.
- Develop research questions to fill in gaps in the understanding of why ECC is so severe among AI/AN children.
- Make recommendations to the American Dental Association (ADA), Indian Health Service (IHS) and other relevant organizations for the next steps to be taken to improve ECC prevention and research for AI/AN children.

Presentation Summaries

Topic 1: Reducing the Burden of Disease from Early Childhood Caries in American Indian and Alaska Native Children

Patrick Blahut, DDS, MPH

- Efforts to reduce the burden of disease from ECC, over the last three decades, have had limited impact. “At best, we have had minor, transient victories from our efforts.”
- The consequences of ECC extend far beyond childhood. Often children with severe ECC become edentulous adults, which likely begins with the early colonization with cariogenic bacteria as children.
- An additional burden of disease extends beyond the patients themselves to the IHS and tribal program dental providers. Their education and training do not prepare them for the never-ending demand for services that exceeds the supply. Many providers leave IHS because of the frustration this burden causes. The ramifications of ECC reach far beyond the child in pain. Interventions to reduce the entire burden of ECC on children, families and communities should be developed and implemented.

¹ Early Childhood Caries is defined as the presence of one or more decayed (non-cavitated or cavitated lesions), missing (due to caries) or filled tooth surfaces in any primary tooth in a preschool-age child between birth and 71 months of age. The term “Severe Early Childhood Caries” refers to “atypical” or “progressive” or “acute” or “rampant” patterns of dental caries (*ADA Trans.* 2000:454).

Steve Holve, MD

High rates of ECC in AI/AN children have been documented for decades. The latest available data indicate there has been an *increase* in the rate of ECC in Indian Country.

- This has occurred despite increased community water system fluoridation, ongoing educational efforts and more dentists.
- ECC is an infectious disease caused by *S. mutans*. All infectious diseases are more common in communities that are poor and crowded. In AI/AN communities, *S. mutans* is acquired at an early age and in high colony counts. Poor dietary habits increase *S. mutans* levels. The burden of disease from ECC in AI/AN children will likely not be reduced until there is a paradigm shift from a surgical model (drilling and filling) and behavioral model (education) to an infectious disease model.
- Approaches to ECC prevention in AI/AN children since the 1970s have not worked. There are good models for approaching ECC through the infectious disease model. Additional efforts should be focused in that direction.

Topic 2: A “Different Disease”

Dee Robertson, MD, MPH

- The *S. mutans* levels were very high among most Head Start children in one Northwest Indian community, but the highest levels (>1,000,000 cfu/ml) were found in children who had previously had full mouth restoration for severe ECC. Although dental restorations address the end result of cariogenic bacteria, fillings and crowns do not have a long term effect in reducing the infectious agent of the disease.
- In a recent *S. mutans* surveillance project in a Southwest tribal community, the mean count was 930,000 (a very high level for young children), or 33% of total flora. In some children, *S. mutans* represented 70 to 80% of total oral flora (normal is less than 2%).
- A small group of Southwest AI/AN mothers participating in the Women, Infants and Children (WIC) supplemental nutrition program were tested for cariogenic bacteria and were found to have the highest *S. mutans* levels ever seen in saliva samples analyzed by Dr. Wenyuan Shi’s lab at UCLA School of Dentistry.

- ECC should be viewed as pediatric infectious disease with dental manifestations, rather than simply a dental disease.
- ECC among AI/AN children requires a different vocabulary:
 - The term “High risk for ECC” is used nationally for rates of ECC that would be very low for AI/AN communities.
 - “Success” in reducing the mean dmft² or dmfs³ (i.e., the current standard measures of ECC) may have little clinical significance.
 - A new way of describing the burden of disease is needed that encompasses the disability, expense and long term consequences of ECC.

Topic 3: The Epidemiology of Early Childhood Caries in Indian Country

Kathy Phipps, DrPH

The highest incidence of caries in children in the U.S. occurs among AI/AN children. A recent analysis of Medicaid data for several states showed a far higher prevalence and severity of ECC for AI/AN children compared to Medicaid eligible white children, even after controlling for income level. There is little understanding of why ECC is so severe among AI/AN children, because the basic ECC studies have not been done with these children. Possible contributing factors may include crowded living conditions, diet and lack of access to oral hygiene supplies like toothbrushes and toothpaste.

Topic 4: Past and Current Indian Health Service Programmatic Control Efforts

Patrick Blahut, DDS, MPH

The IHS is service based, not focused on research. A review of the IHS efforts to control ECC found seven characteristics that are integral to most of its activities:

1. Strong emphasis on patient education and oral hygiene instruction
2. Fluoride (topical and systemic)
3. Integration with other programs
4. Emphasis on community outreach
5. Community receives consistent messages from all health workers

² decayed, missing and filled teeth
³ decayed, missing and filled surfaces

6. Interventions should be institutionalized, so if the “champion” leaves, the program does not die.
7. Prevention and health messages need to be integrated with activities of daily life. Successful examples of this approach include the use of child safety seats and seat belts, and prevention of sudden infant death syndrome (SIDS).

Topic 5: Early Childhood Caries in Indian Children—20 Years Working at “Ground Zero”

Stuart Holmes, DDS

The Indian Health Service has had a long history of trying to impact the caries burden of its patient population, from increasing access to care to extensive behavior modification programs.

As a means of assessing a baseline caries rate and its correlation to bacteria counts, *S. mutans* levels were taken in a Head Start program consisting of 4 year olds during the years of 1978 and 1993. Based upon results from these samples and in-field dental exams, it was found that “neither the caries prevalence (95%) nor the prevalence of caries patterns differed from the 1978-79 and 1993 cohorts. However, the level of treatment received in 1993 was greater than that in 1978-79.” It was further concluded that “the caries prevalence found in [this group of 4 year old] preschool Native Americans is among the highest reported for this age group...”⁴

Studies such as these have demonstrated the persistent nature of the caries burden in the pediatric population even with an increased access to treatment during the evaluative periods. The average child today that receives care in the operating room for full mouth rehabilitation requires eight to 12 stainless steel crowns, four pulpotomies and four extractions.

In the 1980s, the IHS Navajo Area implemented several extensive behavior modification programs to address the high caries rate. Only minimal success was achieved by those efforts. Since then, chemotherapeutic interventions have gained more favor as possible solutions to preventing caries. Various approaches have been tried, ranging from iodine swabbing to fluoride varnish. Because of non-compliance with monthly applications, no conclusive results were obtained from

the iodine study. A multi-service unit chlorhexidine (CHX) varnish study is now concluding that evaluated the impact of CHX on mother-child transmission of *S. mutans* during the so-called “window of infectivity.”

Recent monoclonal antibody studies have shown extremely high levels of *S. mutans* in the very young pediatric population (See “A Different Disease” by Dr. Dee Robertson).

James Singleton, DDS

In Alaska, dentists and allied dental team members have traveled to villages and treated children who were brought in by school programs. The thought was that, after a couple years, the children’s oral health outcomes would be better. Instead, dental teams found children dropped further and further behind. Alaska is unique in that many young children have to be flown to regional clinics for dental care, which costs about \$1000 per patient trip. Restorations are routinely done under general anesthesia, because there is often a single opportunity to fix all of a child’s dental needs. Culturally, pre-chewing food for young children supports inoculation with *S. mutans*.

There has been a dental chair in the Anchorage Head Start program for seven years, and there has been a decrease in the caries rate at that facility. This Head Start is run by the South Central Foundation. The program is a controlled environment where dietary needs are met, and there is a collaboration with pediatricians and a fluoride varnish clinic. Dental care delivery is consistently provided to these Head Start children.

John Zimmer, DDS

Dr. Zimmer showed a slide of a severely decayed extracted tooth as an extreme example of an Indian community that provided all the indicated and conventional ECC-prevention practices, without reducing the long-term consequences of severe ECC. The child in this case received full mouth restoration under general anesthesia at four to five years old. Later, the child participated in a school based sealant program. At age 13, the only enamel remaining on his first molar was the area protected by the sealant. Despite all customary activities, severe tooth decay was not prevented in this child. Even with the best efforts in early intervention and prevention, IHS and tribal dental programs are still extracting the permanent molars of teenage children.

4 Douglass JM, O’Sullivan DM, Tinanoff N. Temporal changes in dental caries levels and patterns in a Native American preschool population. J Public Health Dent. 1996 Summer;56(4):171-175.

On our reservation, many elementary schools have fluoride rinse programs and sealant programs. Through a five-year Maternal Child Health Bureau grant a person was hired to go to the WIC program to provide perinatal oral health counseling. The oral health educator provided xylitol and anticipatory guidance to the mothers prior to being discharged post-partum and routinely collaborated with Early Head Start and Head Start programs.

Toothpaste and toothbrushes were provided, and fluoride varnish was applied to children in group settings like Head Start. At the end of the five-year grant period, the average caries prevalence was reduced slightly (from 5.5 to 4.5 dmft), but efforts did not appear to reduce the number of children with severe caries who require full mouth restoration in an operating room.

The tribal community expects sustainability for new health programs, because both short term success and long-term benefits should be realized. An intervention must be incorporated into the local health system. Currently, glass ionomer sealants are placed on children under age 5 in an attempt to reduce the incidence of occlusal decay in the primary molars. Dr. Zimmer has noticed tiny voids on the buccal surface of primary first molars and hypoplasia (i.e., incomplete development or underdevelopment of tooth enamel) on the occlusal/lingual groove of the permanent first molars. This observation causes him to wonder what role enamel defects might play in severe ECC.

Don Marianos, DDS, MPH

In the late 1970s, as the dental director for a Southwest tribal community, Dr. Marianos reported that “our dental program did it all”: community water system fluoridation, toothbrushes and toothpaste and oral hygiene instruction, community and individual education. There were no other ECC-prevention measures left to try, but nothing really worked. The caries rate decreased minimally (from 75% down to 68%). In the mid-1980s, Dr. Marianos went to the U.S. Centers for Disease Control and Prevention (CDC) to oversee the national caries prevention program. When he returned to the same Southwest tribal community 20 years later, nothing had changed in terms of early childhood caries.

While the CDC has seen a favorable trend for the country as a whole, the severity of ECC in AI/AN communities is the same or getting worse. “If we keep following the same path, nothing will change in the future,” Dr. Marianos said. “I believe it is a national shame that ECC remains so prevalent and so severe in Indian communities.”

Topic 6: Past and Current Research to Prevent Early Childhood Caries in Indian Country

Laura Baha

Tribal Community Member Perspective on ECC Research

Ms. Baha has lived her entire life in a small tribal community. She has seen and experienced severe tooth decay in young children first hand. Her first child, a daughter, had moderate tooth decay, despite Ms. Baha's efforts to be careful with diet and oral hygiene and despite repeated visits to a pediatric dentist. Because of this experience, when the CHX varnish tooth decay prevention study started in her community, Ms. Baha enrolled herself and her second child, hoping this child would not have to go through the experience of tooth decay like her first child. Even though Ms. Baha knew there was only a 50% chance she would receive the active CHX herself, she felt it was worth the effort if it might give her son healthier teeth. She was very happy to report to the Symposium participants that her son who participated in the study had zero cavities through his final study exam.

She became so enthusiastic about the study that she joined the study staff, first as the study recruiter to get other young mothers to participate, and later became the study director. Even though Ms. Baha still does not know whether she received the CHX varnish or the placebo, she is convinced her participation made the difference for her son. She said her community needs the benefit that ECC research can bring to children, but she cautioned that efforts need to be seen as long term—not just another study that comes and goes and leaves little long term benefit for the community. Research on prevention of ECC in a tribal community requires an on going commitment, increasing the likelihood of community support and research success.

Steve Holve, MD

Applying Fluoride Varnish in a Pediatric Clinic

Starting in 2004, pediatric staff routinely applied fluoride varnish in the pediatric clinic for children seen at well child checkups (6, 9, 12, 15, 18, 24 and 30 months of age). Fluoride varnish is offered at each visit once the primary teeth erupt. Providers apply varnish at the conclusion of the visit. An oral health examination and education occur as varnish is applied. The procedure takes about three minutes.

The clinic intervention achieved a statistically significant 35% reduction of mean dmfs (from 23 to 15) for children who received four or more fluoride treatments compared to historical controls, even though many of the children in the 'successful' group still had extensive ECC. Access to dentists is very limited for young AI/AN children, but nearly all young children see pediatricians. It makes sense to involve pediatricians and approach ECC as a pediatric infectious disease that occurs in teeth, rather than a disease that is addressed only by dental staff.

Dee Robertson, MD, MPH

Applying 10% Chlorhexidine (CHX) Varnish to the Mother's Dentition: A Randomized Clinical Trial

Mother-child pairs were enrolled in a clinical trial in four tribal communities. Mothers received either active (10% CHX varnish) or placebo treatments. The children received only fluoride varnish at ages 12 months and 18 months. The outcome variables were caries increment over 18 months in the child and in the mother. More than 300 mother-child pairs had finished their clinical exams at the conclusion of the study in August 2009. For all children combined (active plus placebo) at age 24 (\pm 2) months, 57% had cavitated caries, with a mean d_2mfs of 4.3. At present, data are being cleaned and verified. The preliminary results of the unblinded data are expected in early 2010.

Cavity-Free in 2-0-1-3: A Multimodal, Community-based ECC Prevention Study

This study is being conducted in a South Dakota tribal community and involves a multifaceted approach to control of ECC, including: a) individualized oral health education, b) control of cariogenic bacteria for both mother and child using Glycyrrhizol A (derived from the licorice plant), and c) remineralization therapy (fluoride varnish) for the children every three months. In addition, the level of *S. mutans* is evaluated seven times during the study for both mother and child. Children ages 3–24 months are being enrolled, and each mother-child pair will be followed for 12 months. Mothers and children both utilize the licorice product twice daily for ten days, every three months. The study will conclude in 2011. The primary outcome variable is the level of *S. mutans* at the end of study, and secondary outcome variable is the level of caries compared to historical controls.

David Drake, PhD, MS

*Transmission of *S. mutans* in a Northern Plains Tribal Community*

This study of *S. mutans* transmission is recruiting 250 mother-child pairs. Plaque samples are being taken from mother-child dyads, and primary caregivers if they happen to not be the biological mothers to better understand when the child acquires the organisms. Comprehensive dietary and behavioral habits are also being collected. Other variables included the development of oral microbial communities and genotyping *S. mutans* isolates. This is the first study of its type in any AI/AN community. High levels of *S. mutans* are being found in some children as young as two months of age, long before the dentition erupts. Early establishment of *S. mutans* in the oral cavity increases the incidence and prevalence of caries.

Topic 7: Essential Cariology

Page Caufield, DDS, PhD

Factors likely to be Determinants of Early Childhood Caries in American Indian Children

Etiologies of ECC and severe ECC (S-ECC) are vastly different. There is evidence that S-ECC may be largely due to pre- and post-natal malnutrition. Teeth are developing during the first and second trimesters. Over only a few generations, AI/AN have changed their diet from high protein to high carbohydrate. *S. mutans* is only part of the story. There is a multi-cellular etiology, and the collective community of bacteria determines the risk for caries. There are problems with relying on antimicrobials to control S-ECC. Diversity of oral flora is good, but there is decreasing complexity in the microbiota transferred from mother to child. Whether it is reversible is unknown. In S-ECC, the diversity of the microflora decreases, which increases disease. A mother transmits microflora probably at birth. The cause, not just the symptoms, should be treated.

In low grade ECC, the host-parasite relationship follows the diet-bacteria-host model. With S-ECC, the relationship appears differently as DIET-bacteria-host. The protein to carbohydrate ratio is different. The challenge with currently available antimicrobial approaches is that they are not targeted. Most members of host biofilm are affected, not just the cariogenic bacteria. Key questions follow. CHX is nonspecific; what is the effect on the biofilm if we are using an antimicrobial that takes out the entire flora? What are the compliance and packaging issues? What about toxicity?

It is likely that the diversity within the oral microbiome will not be restored. Eliminating diversity is a concern, since lack of diversity (i.e., predominance of one or more species of cariogenic bacteria) is synonymous with disease. Koch's postulates⁵ do not work with indigenous bacteria. Are we making progress? We are still using the same paradigm from 1973—xylitol, fluoride, CHX and iodine for *S. mutans*.

Enamel hypoplasia (EHP) can result from malnutrition. A study looked at more than 1,300 chronically malnourished children, three to five years old, in Miyun, China. The mothers were malnourished during primary teeth formation. Those children with EHP had significantly higher colonization levels of *S. mutans* than non-EHP children. The more severe the EHP, the higher the counts of *S. mutans*. EHP also increases colonization of *S. mutans* mediated by post-natal malnutrition, resulting in S-ECC pattern caries. You can do fillings the rest of your life but you will never catch up with the ECC pattern.⁶

What can we do? The cause must be acknowledged and a plan formulated to educate and train healthcare providers for AI/AN communities. Explore the use of diamine silver fluoride (DSF) and atraumatic restorative treatment (ART) to alleviate and attenuate symptoms. Make an early diagnosis of EHP, modification of ecological colonization sites, pre- and post-natal intervention. DSF turned teeth black, but the caries did not progress. Primary teeth develop *in utero*. Interventions should start there, if ECC prevention paradigm is going to change.

Wenyuan Shi, PhD

Microbiological Tools to Assess Risk for Severe Early Childhood Caries

The oral cavity has a very complicated microbial flora. There are 100,000,000,000,000 bacteria/per mouth, with over 700 different species, but only about 12 species are cariogenic (the “dirty dozen”). At UCLA, Dr. Shi and colleagues have developed a method of detecting *S. mutans* in dental plaque with species-specific monoclonal antibody cell based detection. Selective culture:

- DNA based: PCR, Southern blotting
- Protein based detection: Antibody, Peptides

5 a. The bacteria must be present in every case of the disease; b. The bacteria must be isolated from the host with the disease and grown in pure culture; c. The specific disease must be reproduced when a pure culture of the bacteria is inoculated into a healthy susceptible host; d. The bacteria must be recoverable from the experimentally infected host.

6 Moore WM, Silverberg MM, Read MS. Nutrition, Growth and Development of North American Indian Children [monograph]. Washington, DC: Superintendent of Documents, U.S. Government Printing Office; 1972.

The monoclonal antibody (MAb) is created by the fusion of a normal B lymphocyte and a tumor cell (hibridoma). The *S. mutans* is detected in dental plaque using species specific monoclonal antibody, where detection is fluorescent only to *S. mutans* (fluorescence-activated cell sorter). Using saliva samples, diagnosis can be accurate down to a single bacteria in an assay that takes about 45 seconds. The plaque from a high caries risk person can be analyzed to determine the quality of the plaque. A MAb-based chair side test for *S. mutans* is in development.

From one U.S. population (Delta Dental patients), the distribution of *S. mutans* levels:

- > 2,000,000 *S. mutans* cells/ml ≈ 2%
- > 1,000,000 *S. mutans* cells/ml ≈ 5%
- > 500,000 *S. mutans* cells/ml ≈ 20%
- > 250,000 *S. mutans* cells/ml ≈ 40%
- > 100,000 *S. mutans* cells/ml ≈ 70%

Topic 8: Epidemiology of Pediatric Infectious Disease in Small, Crowded, “Closed” Communities

Jim Campbell, MD

The general knowledge of infectious disease epidemiology among AI/AN children is:

1. There is a disproportionately high burden of disease compared with similarly aged children in the general U.S. population.
2. There is a greater burden of pathogens (i.e., bacteria and viruses) circulating within these communities than outside these communities.
3. Children in these communities get disease at a younger age, and the risk of disease persists into older ages compared with what is seen in the general U.S. population.

The rate of pneumococcal disease among children less than 2 years of age is much higher for Navajo, Apache and Alaska Native children than among children in the general U.S. population. It is not fully understood why the rates are higher, but theories point to environmental and ecological conditions, such as smoke exposure by wood or coal burning stoves indoors, crowded indoor living conditions and high rates of other respiratory illnesses like viral infections. Genetic differences are not thought to be linked to the higher rates. Many AI/AN communities are generally a very young population

overall, with approximately 50% of the population on Navajo reservation being younger than 24 years old.

Topic 9: New Products for Early Childhood Caries Prevention

Wenyuan Shi, PhD

Glycyrrhiza uralensis (the licorice plant)

Disease occurs when acidogenic bacteria aggregate on the surface of the tooth, so preventing this aggregation will prevent caries. In Dr. Shi's lab at the UCLA School of Dentistry, hundreds of herbs were screened for the ability to kill oral pathogens, and he was surprised to find that an extract (Glycyrrhizol A) of the licorice plant kills cariogenic bacteria at a high rate—better than triclosan, which is an antimicrobial available in some commercial brand toothpastes.

Three in vivo studies have been completed with Glycyrrhizol A delivered in a 10 mg dose in a lollipop form. After 10 days, over 80% of human subjects had a five to 100 fold reduction in salivary *S. mutans* for 49 days after the intervention before the rate started to go back up. Even at 84 days, the counts are still much lower than original *S. mutans* count. Preliminary data from Head Start children show that the children with the highest levels of *S. mutans* got the most reduction in *S. mutans* levels from the Glycyrrhizol A.

Specifically Targeted Antimicrobial Peptides

Recently, an antimicrobial product has been developed that is selective only for *S. mutans*. This product is called “specifically targeted antimicrobial peptides” (STAMPs), and it contains a species-specific targeting domain molecule fused with a wide spectrum antimicrobial domain molecule. The result is that only the specific bacteria of interest (in this case *S. mutans*) is targeted. Once the fused molecule attaches to the *S. mutans* bacterium, the antimicrobial domain kills the bacterium almost instantly, without affecting any of the hundreds of non-cariogenic oral bacteria. The STAMPs is being developed as a commercial product.

David Drake, PhD, MS

1.0% Flavored Chlorhexidine (CHX) Gel

In collaboration with the University of Iowa College of Pharmacy, a 1.0% flavored chlorhexidine gel has been developed that can be used on a toothbrush. This CHX gel is alcohol free, which is unusual since the CHX molecule is frequently unstable unless there is alcohol. This product also has a pleasant raspberry flavoring

that was agreeable to essentially all children in a Head Start pilot study. Many flavoring agents destroy the molecule and inactivate the CHX, but this product has a high level of bioavailability of the CHX. In a pilot study a reduction of *S. mutans* levels was found in three to four year old children using a once a month dosing schedule.

Kathy Phipps, DrPH

Silver Diamine Fluoride (SDF)

The available data suggest that SDF may be a way to stabilize children (i.e., arrest existing active caries). In AI/AN communities, SDF could be very useful to delay caries progression until children are older and can have their caries restored without the need for general anesthesia. The product is reported to be going through the FDA approval process as a medical device (similar to the currently available brands of fluoride varnish) and not medication. This means that SDF will not require lengthy, expensive randomized clinical trials.

Topic 10: Existing Infrastructure for Early Childhood Caries Prevention in Indian Country

Jim Campbell, MD

Johns Hopkins Center for American Indian Health (CAIH) Research Program

The mission of CAIH is to support AI/AN communities in achieving: optimum physical, mental and social well-being, autonomy over community-based research and health service activities, and worldwide leadership in supporting other communities to overcome health inequalities.

Specific areas of past and current research include:

- Infectious diseases (both epidemiological and clinical prevention trials)—rotavirus and dehydration, *Haemophilus influenzae* type b (Hib), *Pneumococcus*, respiratory syncytial virus (RSV), Hepatitis A and B
- Behavioral health—suicide prevention, parenting skills/healthy families
- Training—courses during the Johns Hopkins University (JHU) winter and summer institutes, scholarship funds for graduate students, field staff training opportunities and mentoring

The Center's policy is to work only on diseases and conditions of disproportionate morbidity and mortality among AI/AN populations. Study types include disease

burden and risk factors, prevention and treatment, and ongoing monitoring. The center is currently investigating respiratory syncytial virus (RSV), *Haemophilus influenzae* Rapid Response Investigation (HIRRI), water quality, air quality, active bacterial surveillance and 13-valent pneumococcal conjugate vaccine (PCV13).

Jane Weintraub, DDS, MPH

Center to Address Disparities in Children's Oral Health at the University of California, San Francisco

The purpose of this NIDCR-funded Center (U54DE019285) is to reduce oral health disparities among children and their caregivers through research, training and dissemination with community partners. The current focus is on preventing and reducing ECC. Working with communities in several areas of California, the Center has conducted multidisciplinary, collaborative qualitative and quantitative research.

The Center has research activities and goals in these domains:

- Child and Family—improve parents' knowledge, attitudes, skills and behaviors to improve children's oral health
- Health care system—change providers' behaviors and practices (provide oral health counseling, fluoride varnish in primary care clinics and WIC programs, referral to dentists)
- Community and Environment—implement and evaluate caries prevention for preschool age children in non-dental settings
- Policy—disseminate findings of effective interventions and translate them into policy recommendations and clinical practice guidelines.

Current randomized clinical trials include: 1) comparing the efficacy of caries prevention strategies that include parental counseling and fluoride varnish with and without glass ionomer sealant on caries incidence and increment of three to six year olds in dental and non-dental settings in community health centers, and 2) determining the best way to reach one to three year old children from low-income families for fluoride varnish application. In this trial, primary care centers and WIC programs will be randomized to either deliver fluoride varnish on site or to refer the families to a dentist for their child's fluoride varnish application.

Terry Batliner, DDS, MBA

Center for Native Oral Health Research, Centers for American Indian and Alaska Native Health at the University of Colorado at Denver

Oral Health disparities exist in American Indian/ Alaskan Native (AI/AN) communities. Results from Indian Head Start Oral Health Surveys show ECC in AI/AN continues to increase. Compared to other children ages two to five, AI/AN children have more than three times the amount of untreated decay (19% vs. 68%). Long-term conditions that include limited economic resources, limited social and educational opportunities, and insufficient health systems contribute to poor health.

A new ECC prevention study is being initiated in a Northern Plains tribal community that uses motivational interviewing (MI) as the intervention. It involves a dialogue about current parenting practices and behaviors related to children's oral health—snack foods, oral hygiene, bottle and breast feeding, etc. At each session, a participant will be asked to assess the importance of a topic, confidence with the subject, and readiness to make a change. A participant will be assisted with developing an individualized "change plan."

Mothers will be randomized into one of two groups.

- Enhanced community services group—receives toothbrushes, floss, brochures and public service announcements that focus on risk factors for ECC
- Motivational Interviewing (MI) group—receives "enhanced community services" plus MI, including four MI home visits (one shortly after childbirth and the rest at 6, 12, and 18 months)

Both groups will receive three oral health assessments performed by calibrated dental hygienists. The first exam occurs shortly after teeth erupt; the second and third exams will be annually after the first one.

This center is also interested in looking at pilot studies using other ECC prevention modalities.

Dee Robertson, MD, MPH

Three Different ECC Prevention Models for Indian Country

1. Dental Clinic Model

Advantages

- Dental program is traditional advocate for oral health

- Focus is entirely on oral health, not competing with all other health concerns
- Staff are skilled in oral exams and procedures

Disadvantages

- Inadequately staffed for routine well child visits
- Staff not trained in the pediatric infectious disease model
- Best suited for episodic interventions (quarterly, semi-annual)
- Scarcity of effective episodic ECC prevention tools

2. Community Model

Advantages

- Head Start (age 3–4) is available in most tribal communities
- Early Head Start (age 6–36 months) is available in many communities
- Many children attend these programs (the proportion varies among different AI/AN communities)
- Head Start programs in AI/AN communities are very receptive to oral health issues
- Not dependent on dentists or physicians, who are frequently in short supply in AI/AN communities
- Ideal for interventions that require frequent repetition, such as daily applications for a prescribed duration

Disadvantages

- The children at highest risk often do not attend Head Start or Early Head Start even when these programs are available
- Many Early Head Start programs are home-based, rather than group settings
- Many Indian children will already have very severe ECC on entry into Head Start
- Limited number of prevention tools available

3. Pediatric Clinic Model

Advantages

- Well child clinics are standard in IHS
- Natural “home” for healthcare of young children
- Essentially all children are seen regularly for immunizations and assessments
- Focus is on age 3–24 months, which allows intervention before ECC develops

Disadvantages

- No pediatricians in many tribal communities
- Pediatric well child visits require attention to many other health concerns

- Pediatricians are not trained in oral health care
- Best suited for episodic interventions (quarterly, semi-annual)
- Scarcity of effective episodic ECC prevention tools

Topic 11: Expert Opinions on Promising ECC Prevention Research Strategies, including Risks and Benefits of Antimicrobials in Very Young Children

(Open session by Drs. Page Caufield, Norm Tinanoff, Wenyuan Shi and David Drake; contributing comments from Drs. Dee Robertson, Kathy Phipps, Jane Weintraub, Steve Holve, Patrick Blahut and Ms. Laura Baha)

There was a wide-ranging discussion on these issues, with pros and cons cited for many of the ECC prevention products and strategies found effective in prevention of caries in other populations. Certain salient themes recurred throughout the discussion including:

- ECC in AI/AN communities is a “*different disease*” from the usual “garden variety” of ECC found in other populations. ECC in these children is different in its onset, very aggressive and destructive course, extremely high levels of cariogenic bacteria in very young children and their mothers, and lack of response to the standard ECC prevention methods that have been found effective in other populations of children.
- Although the available evidence looks convincing for a major role of cariogenic bacteria as the cause of the severe ECC seen among AI/AN children, it is important to realize that most of the 700+ species of oral bacteria are either not harmful or actually helpful. Therefore, products and strategies should be identified that can eliminate the handful of known cariogenic bacteria (the “dirty dozen” in the words of Dr. Wenyuan Shi), while leaving the rest of the oral flora intact.
- There is no evidence that elimination of large portions of the oral flora with antimicrobials is harmful, but caution is warranted in using this approach with young AI/AN children.
- A potentially fruitful area of research includes whether dysnutrition (i.e., poor diet) early in pregnancy may contribute to defects in the tooth enamel of the fetus, leading to more susceptibility to colonization by cariogenic bacteria.

- There may be products available soon, such as silver diamine fluoride, that will arrest active caries to help “put out the fire” and reduce the need for emergent care.
- The best strategy of reducing the burden of ECC among AI/AN children involves a multimodal approach that should include: a) oral health education for the mother, b) antimicrobial therapy to reduce the level of cariogenic bacteria, and c) remineralization therapy to strengthen the enamel.

Topic 12: Metrics and Common Ground and Priorities for Future Research Directions

(Open session by Drs. John Zimmer, Norm Tinanoff, Page Caufield, Jim Campbell, David Drake and Wenyan Shi; contributing comments from Drs. Dee Robertson, Kathy Phipps, Jane Weintraub, Don Marianos, Terry Batliner, Steve Holve, Mark Crabtree, Patrick Blahut and Ms. Laura Baha)

The Symposium participants were challenged by Dr. Robertson to begin to develop a different and more appropriate measure of the disease burden from severe ECC (S-ECC) among AI/AN children. Dr. Robertson said that, in his opinion, the widely used practice of comparing mean dmft scores between different groups of children is inadequate and largely irrelevant. The dmft gives the same value (viz., ‘1’) to a tooth containing a single surface with a small, minor carious lesion as to a tooth with all surfaces destroyed by caries. Similarly, the mean dmfs score is of limited value unless it is used with a severity index. In any case, using either of these indices as mean values for a population of children is not at all useful for assessing the burden of disease from severe ECC for children in a community. Dr. Robertson suggested a new metric is needed that provides a measure of severity, such as one that utilizes a weighted index. An example could be assigning a numeric weight to each of the standard scores used in caries research to assess the extent of a carious surface (Table 1).

Table 1: ECC Classification

Weight	Designation	Description
1	d1	demineralization without cavitation
2	d2	cavitation into the enamel but not into the dentin
3	d3	cavitation into the dentin
4	d4	cavitation into the pulp

Other possible parameters of a new metric to describe the severity of ECC discussed were:

- Location of the caries (i.e., smooth surface or pits and fissures)
- Loss of function (e.g., pain eating or difficulty speaking)
- Age of the child (i.e., the same level of caries may have very different ramifications for a 2 year old compared to a 6 year old)

Regarding fruitful areas for future research on prevention of ECC among AI/AN children, participants agreed that any research or new interventions will need rigorous evaluation to determine the effectiveness in tribal communities.

Dr. Shi noted that many antimicrobial products are available that could be studied for their effectiveness. Because ECC is a *different disease* in tribal communities, the levels of effectiveness may vary from the results of trials in non-AI/AN populations.

Dr. Caufield noted that because ECC is an infectious disease with indigenous bacteria, the traditional methods of controlling exogenous bacteria may not be fully applicable to this disease, and any physiological insult in the first trimester can trigger enamel hypoplasia (EHP).

Dr. Robertson said that, if we are going to posit a high prevalence of EHP as the reason for a high prevalence of severe ECC, we should define how to identify and measure EHP and establish the prevalence of EHP among the population.

Dr. Blahut noted that if we plan to require that any new research or interventions have a rigorous evaluation of effectiveness, the same should be required of the interventions in which resources have been invested for many years, such as community water system fluoridation. The only evaluation of its effectiveness by IHS found a small, but not statistically significant, difference in the number of children who were caries free, but no difference in the overall level of disease as measured by dmfs.

Many of the Symposium participants offered thoughts on what we should be doing *now*, while waiting for more conclusive evidence of the effectiveness of specific or combined interventions.

A couple of participants recommended doing simple things like twice a day tooth brushing with fluoridated

toothpaste and improved oral health education. However, other participants countered that this is what has been done for the last few decades without any evidence of effectiveness.

Dr. Caufield recommended a program for sealing the occlusal surfaces of the primary dentition, but Dr. Zimmer stated that this has been done with no evidence of effectiveness from applying sealants to children younger than 18 months.

Dr. Marianos reiterated the experience and opinion of essentially all practicing IHS and tribal program dentists and pediatricians that there is very little chance of any significant improvements from only behavioral interventions. He further noted: "Just look at the microbiology of this issue. We see *S. mutans* values that are off the charts for both children and their mothers, that is what should be the priority."

Dr. Drake believes we have to utilize a multimodal approach, "As we have been saying all day, ECC in Indian children is a *different disease*. I don't believe having kids just brush twice a day is going to change things."

Next Steps

Again, most of the Symposium participants offered suggestions on the next steps to be taken:

Dr. Robertson reiterated a theme that was consistent throughout the meeting. No new activities should be recommended that cannot be evaluated for effectiveness.

Dr. Marianos recommended developing projects and studies in collaboration with the Johns Hopkins Center for American Indian Health because it has a long-established infrastructure for health research in several Southwest American Indian communities.

Dr. Batliner stated that the University of Colorado Oral Health Disparities Center is funded for seven years, and there may be some discretionary funds for ECC prevention research that is not limited to just behavioral interventions of the larger studies.

Dr. Caufield suggested that academic researchers like him need to work with the people on the front lines to alleviate the suffering. He felt that researchers from other countries, who are using ECC prevention modalities not available in the U.S. could provide the

benefit of their experience. He further recommended that the ADA should bring in experts for an in depth review and planning workshop to develop a plan to move ahead on the issue of controlling ECC among AI/AN children, and funding should be sought from private foundations (e.g., Gates and Kellogg Foundations).

The meeting ended with Dr. Mark Crabtree's statement that it is incumbent on us all to take our efforts at ECC prevention for AI/AN children to a higher and more effective level.

Conclusion

Many participants agreed that early childhood caries among AI/AN children may represent a *different disease* from that experienced by other populations of children in the U.S. It starts earlier, follows a more aggressive course, results in a much higher burden of disease for the children and their families, and has been refractory to many years of determined efforts to control it using intervention strategies found effective in other populations. Control of ECC among AI/AN children requires new approaches which are likely to be multimodal in nature and with an enhanced emphasis on the infectious etiology of the disease. ECC control will also require development of new metrics with which we can better characterize the disease and measure the effectiveness of new prevention approaches.

Appendix A

Agenda:

Symposium on Early Childhood Caries in American Indian/Alaska Native Children

ADA Council on Access, Prevention and Interprofessional Relations
in cooperation with
Indian Health Service

Arizona Biltmore Hotel, Phoenix
November 4, 2009

7:00	Registration and Breakfast
8:00	Welcome from U.S. Indian Health Service and American Dental Association Drs. Patrick Blahut and Mark Crabtree
8:10	Review Agenda, Format and Objectives Dr. Mark Crabtree
8:20	Participant Introductions Dr. Mark Crabtree <i>1–2 minutes each for participants to summarize their experience with Early Childhood Caries (ECC) and interest in ECC among AI/AN children</i>
8:45	Long-term Symposium Goals Drs. Patrick Blahut and Steve Holve <i>To reduce the burden of disease from ECC among Indian children:</i> <ul style="list-style-type: none">- Reducing the rate of symptomatic ECC- Reducing the life-long sequelae from advanced ECC
9:00	Background and Significance <ul style="list-style-type: none">- “This is a different disease” Dr. Dee Robertson- The epidemiology of ECC in Indian Country Dr. Kathy Phipps- Past and current IHS programmatic control efforts Dr. Patrick Blahut- ECC in Indian children: 20 years working at ground zero Drs. Stuart Holmes, James Singleton and John Zimmer- “There and back again” Dr. Don Marianos
9:45	Past and Current Research to Prevent ECC in Indian Country <ul style="list-style-type: none">- Tribal community member perspective on ECC-prevention research Ms. Laura Baha- Application of fluoride varnish in a pediatric clinic Dr. Steve Holve- Applying 10% CHX varnish to the mother’s dentition; Multimodal community-based research with interventions for mothers and young children Dr. Dee Robertson- Transmission of <i>S. mutans</i> in a Northern Plains tribal community Dr. David Drake
10:30	Break
10:45	Essential Cariology <ul style="list-style-type: none">- Factors likely to be determinants of ECC in Indian children Dr. Page Caufield- Virulence factors in cariogenic bacteria Dr. David Drake- Microbiological tools to assess risk for severe ECC Dr. Wenyan Shi
11:15	Epidemiology of Pediatric Infectious Disease in Small, Crowded, “Closed” Communities Drs. Steve Holve and Jim Campbell

11:30	New Products for ECC Prevention <ul style="list-style-type: none"> - <i>Glycyrrhiza uralensis</i> Dr. Wenyan Shi - 1.0% flavored chlorhexidine gel Dr. David Drake - Chlorhexidine varnish 1% & 10% Drs. John Zimmer and Dee Robertson - Silver diamine fluoride Dr. Kathy Phipps
Noon	Working Lunch—Existing Infrastructure for ECC Prevention Research in Indian Country <ul style="list-style-type: none"> - Johns Hopkins American Indian Health Research Program Dr. Jim Campbell - Oral Health Disparities Centers at the University of California at San Francisco Dr. Jane Weintraub and University of Colorado Dr. Terry Batliner
1:00	Three Different ECC Prevention Models for Indian Country Dr. Dee Robertson <ul style="list-style-type: none"> - Community based - Dental clinic based - Pediatric clinic based
1:30	Expert Opinions on Promising ECC Prevention Research Strategies and Risks/Benefits of Antimicrobials in Very Young Children Drs. Page Caufield, Norm Tinanoff, Wenyan Shi and David Drake <ul style="list-style-type: none"> - <i>The most fruitful new ECC-prevention research approaches and strategies</i> - <i>Risks vs benefits of using antimicrobials to control cariogenic bacteria in very young children</i>
2:00	Metrics Drs. John Zimmer, Norm Tinanoff, Page Caufield, Jim Campbell, David Drake and Wenyan Shi <ul style="list-style-type: none"> - <i>What is the best metric for describing and measuring the burden of disease for children most severely affected by ECC?</i> - <i>What is the best metric to assess the risk for developing severe ECC?</i>
2:45	Break
3:00	Common Ground and Priorities for Future Research Directions Dr. Patrick Blahut <p><i>What else do we need to know, and where do we need to put the most effort for the next few years:</i></p> <ul style="list-style-type: none"> - <i>Better surveillance of caries in very young Indian children?</i> - <i>Better surveillance of S. mutans?</i> - <i>Better risk assessment methods?</i> - <i>Better intervention products?</i> - <i>Better strategies to evaluate the effectiveness of any new ECC-prevention measures?</i> <p><i>What are the key researchable questions? Develop a consensus on the top five research priorities for making progress in the control of ECC in Indian children.</i></p>
4:00	What should we do now? Currently Recommended ECC Prevention Methods for AI/AN Children Dr. Patrick Blahut <p><i>Develop a consensus for ECC-prevention strategies that are reasonable to implement as public health practice while we await results of on-going and new research.</i></p>
4:30	Next Steps Drs. Patrick Blahut and Mark Crabtree
5:00	Adjourn Dr. Mark Crabtree

Appendix B

Panelists

Laura Baha	Study Director, Using Chlorhexidine Varnish to Prevent Early Childhood Caries, Whiteriver IHS Hospital
Terry Batliner, DDS, MBA	Clinical Associate Professor and Associate Dean for Clinical Operations and Patient Services, School of Dental Medicine, University of Colorado Denver
Patrick Blahut, DDS, MPH	Deputy Director, IHS Division of Oral Health
Bonnie Bruerd, DrPH	Region XI Head Start Oral Health Consultant
James Campbell, MD	Research Physician, Johns Hopkins Center for American Indian Health, Gallup Field Office
Page W. Caufield, DDS, PhD	Professor, Cariology and Comprehensive Care, NYU College of Dentistry
Mark Crabtree, DDS	Chair, ADA Council on Access, Prevention and Interprofessional Relations
David R. Drake, PhD, MS	Professor, University of Iowa, College of Dentistry
Stuart Holmes, DDS	Dental Director, Whiteriver IHS Hospital
Steve Holve, MD	IHS Chief Clinical Consultant in Pediatrics and Director of Pediatrics, Tuba City Regional Health Care Corporation
Donald W. Marianos, DDS, MPH	Consultant in Public Health
Kathy Phipps, DrPH	Oral Health Research Consultant
Gary Podschun	Manager, Community Outreach and Cultural Competence, American Dental Association
Dee Robertson, MD, MPH	Consultant in Pediatrics and Health Research
Shelli Ryczek, RDH	Study Director, Using Chlorhexidine Varnish to Prevent Early Childhood Caries, Tuba City Regional Health Care Corporation
Wenyuan Shi, PhD	Professor and Chair, Oral Biology and Medicine, UCLA School of Dentistry
James Singleton, DDS	Pediatric Dentist, Alaska Native Medical Center
Norman Tinanoff, DDS, MS	Chair, Department of Health Promotion and Policy, University of Maryland Dental School
Jane Weintraub, DDS, MPH	Lee Hysan Professor and Chair, Division of Oral Epidemiology and Dental Public Health, University of California, San Francisco School of Dentistry
John Zimmer, DDS	Pediatric Dentist, IHS Sisseton Health Center

