

2015 Symposium on Caries in American Indian and Alaska Native Children

Hood River, Oregon
August 21–22, 2015



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Note: The viewpoints expressed in this report reflect the opinions of the individual Symposium participants and should not be considered the official views of QUEST.

* QUEST in AI/AN Children is a 501(c)(3) organization whose mission is to convene and focus the expertise and resources necessary to elucidate the etiology of rampant caries in the primary dentition in American Indian and Alaska Native (AI/AN) children, and to identify optimal strategies to prevent and control it.

2015 Symposium on Caries in AI/AN Children

Summary

Background

This Symposium was the 5th in a series of meetings focused exclusively on defining, understanding and attempting to ameliorate the severe caries in the primary dentition (CIPD) experienced by many young American Indian and Alaska Native (AI/AN) children. The impetus for these symposia started in 2007 with the ADA-sponsored Summit on AI/AN Access to Oral Health Care. At that meeting, Dr. Lindsey Robinson, a private pediatric dentist who was then Chair of the CAPIR council of the ADA, invited a panel of speakers to do a presentation on the oral health status of AI/AN children. The energy and enthusiasm resulting from that presentation launched the subsequent efforts that continue to this day to improve the oral health status of AI/AN and other disadvantaged children.

In 2009 the first of three ADA-sponsored Symposia¹ was held in Phoenix, Arizona. It brought together a small group of tribal representatives, academic researchers, and health professionals with decades of experience in preventive and curative services for children in AI/AN communities. Several hypotheses were advanced about potentially unique etiological factors that result in the very severe expression of caries in the primary dentition (CIPD) that AI/AN children experience.

The 2nd Symposium on CIPD in AI/AN children was held in Rapid City, South Dakota, in 2010. At this meeting tribal representatives, Indian Health Service (IHS) career pediatric dentists, and 15 experienced U.S. caries researchers representing ten prestigious research institutions spent two days examining the best data available on the subject. The Symposium participants identified specific knowledge gaps in our understanding of this disease, categorized them into four topical areas—Epidemiology, Microbiology, Enamel Hypoplasia and New Products—and made recommendations on how these knowledge gaps could be closed.

Specific action plans were developed to address the knowledge gaps in the 3rd Symposium in Phoenix, Arizona, in 2012. Subsequent to this meeting, the organizers of the Symposium formed a 501(c)(3) organization called QUEST, whose name encompasses the mission of the

¹ Links to all the symposia can be found at: <http://www.ada.org/en/education-careers/events/symposium-on-early-childhood-in-american-indian-and-alaska-native-children>

organization: **Q**uantifying, **U**nderstanding and **E**liminating **S**evere **T**ooth Decay in AI/AN Children. QUEST was the organizer of this latest Symposium on the subject.

QUEST convened a 4th Symposium in 2013 which:

1. Reviewed the progress made in each topical area (epidemiology, enamel hypoplasia, microbiology and new products) toward the specific objectives set at the 2012 Symposium.
2. Proposed new activities that build on the knowledge and experience gained over the previous year.
3. Created a business plan that will support the activities identified as critical for moving forward.
4. Identified collaborations with organizations that have similar concerns about finding more effective strategies to reduce the morbidity from severe CIPD for disadvantaged children.

This most recent Symposium (the 5th) continued in the tradition of the prior four symposia, but with three important differences:

1. There was substantially more representation by career IHS and tribally-operated program dental and pediatric staff.
2. The sessions had more emphasis on measurable improvements in clinical outcomes, including reports of the results being achieved by clinical programs in the Pacific Northwest, northern tier states and Arizona.
3. QUEST received direct input and assistance from the IHS Division of Oral Health, which also expressed its interest in receiving recommendations from the Symposium participants on policy issues to build on the progress recently made.

PLENARY SESSIONS AND BREAKOUTS

Introductions and Welcome: Dee Robertson (Robertson Introductory Remarks.pdf²)

QUEST is a 501(c)(3) organization in the state of Washington. The mission of QUEST is to *Convene and focus the expertise and resources necessary to elucidate the etiology of rampant caries in the primary dentition in AI/AN children, and identify optimal strategies to prevent and control it.* This precisely describes what we are doing here today.

The primary purpose of Symposium V is to build on the work of the previous sessions by highlighting practical and achievable actions available to us now to improve the oral health status of American Indian and Alaska Native (AI/AN) children and other children at high risk for severe dental caries.

Historical context: In 1985 as the Maternal and Child Health Consultant for the Northwest region of IHS, on my third site visit to a Northeast Washington tribal community I was challenged by a public health nurse saying, “Dee, you review our program every year and make recommendations for us, but nothing ever changes.” Many career Indian Health Service (IHS) health professionals at this meeting can identify with that frustration—especially as concerns what is by far the largest health disparity for AI/AN, severe tooth decay in children.

The good news is that some things have changed recently, and for the better:

- We now have data from two community-based IHS oral health surveys (2010 and 2014). Before 2010 there was only clinic encounter data.
- The five-year IHS ECC Initiative was completed in 2014, and we will hear about it today from several IHS dentists who participated in this project.
- QUEST now has active institutional collaboration and support from the Indian Health Service Division of Oral Health, with a strong representation from the national, regional and local levels here in this meeting.
- Most importantly, for the first time ever, we have credible clinical outcome data from an innovative IHS demonstration project to control caries in young children, and there is interest by IHS in using such health outcomes data as the basis for formulating policy.

Our task today is to:

- Assimilate the large amount of new information presented on caries in children.
- Discuss various viewpoints on the practical implications of the new information.
- Consider ways QUEST and IHS can collaborate with various agencies and organizations.
- Attempt to reach general agreement on policy recommendations to be forwarded to the IHS Division of Oral Health that will further our common goal.

² Links to all the cited presentations are available on the ADA website

Keynote Address: ECC and America Indian/Alaska Native Children: Are We In a Seldon Crisis? Bob Weyant (Weyant Keynote Seldon Crisis.pdf)

“A couple of months ago, Dee called me, and I answered. This was my first mistake. Dee had previously asked if I would do the Keynote Address using the 1999 NIDCR panel report (Drury 2009) as the reference point. In jest, I had said: Do you want me to portray the current situation as a ‘Seldon Crisis,’ to which Dee said, ‘Yes!’ Next time I’ll know better.”

Hari Seldon was a leading character in Isaac Asimov’s *Foundation Trilogy*. He combined history, sociology and statistics to make a probabilistic analysis—which he called ‘psychohistory.’ *Convergence of internal and external threats* creates a Seldon Crisis. Dee believed (and I somewhat agreed) that the longstanding and current status of caries in the primary dentition in the most severely affected children is analogous to a Seldon Crisis:

- **External crisis:** Few people really know about the problem, and thus few resources are aimed at addressing it.
- **Internal crisis:** The people who do know about it have been trying to solve the problem largely by trying to do a better job of the strategies that appear to have worked somewhat with lower risk populations of children, but have never been shown to work in a clinically significant way for those at highest risk.

The Drury Report in 1999 addressed what is ‘ECC,’ case definitions, diagnostic criteria and terms to describe pattern. They concluded (inter alia):

- Caries in the primary dentition (CIPD) remains a major health problem in US.
- There is a lack of critical information on CIPD, and more research is needed in multiple dimensions of the disease.
- Results of clinical research and surveillance on CIPD should be stratified in 1-year age brackets through age 5 because the prognostic implications for children with any given number of carious teeth differ greatly over this age span.

The NIDCR panel issued a number of recommendations, of which the most relevant to those at highest risk like AI/AN children are that progress is being impeded by:

- The need for better epidemiology on prevalence and severity
- Lack of effectiveness of existing interventions
- Absence of clinical decision-making protocols
- Diagnostic criteria based on relevance to clinical outcomes for the child—i.e., outcomes that affect the child’s quality of life (QoL).

Put in the format of a Seldon Crisis:

Internal crisis	External crisis
<p>For this subset of children at the highest risk:</p> <ul style="list-style-type: none"> • Our current tools are not up to the job—neither for primary prevention nor early secondary prevention • Our measurement tools are also inadequate • Distributions matter: reports of statistical reductions in mean scores tell us little about how efficacious the same strategy is for the children who, absent the intervention, will have severe disease. 	<ul style="list-style-type: none"> • AI/AN children represent only a very small proportion of the U.S. population. Policy makers are likely focused on the ‘bigger picture’ of all U.S. children. • Insufficient resources have been aimed at finding a solution. • We don’t know that we are even asking the right questions. • Current state of intervention research for the children at the most risk is poor.

Given that QUEST's Overarching Goal is to reduce the burden of disease from CIPD in AI/AN children, we need to ask:

What would success look like?

- Immediate reduction of disease burden.
- Progressive reduction of the prevalence and severity to no greater than the US all races.

How could we accomplish these?

- First, we need to understand the etiologic factors better, and need to systematically assess the relative 'success' of all current and future interventions.
- Second, we need to learn the lesson from the past that traditional operative curative services provided to individuals are the least cost effective and present problems with sustainability—especially in communities with limited access to the clinical expertise needed.
- In the end, the most effective approach will need to be multi-faceted, locally adaptable, scalable and sustainable.

The IHS 2014 Oral Health Survey, Kathy Phipps (Phipps Oral Health of Preschool AI/AN Children. pdf)

The survey was a probability sample of local tribal and IHS health care programs, commonly called "Service Units." Children aged 1–5 years were screened in non-dental clinic settings such as Head Start, WIC and well-child clinics. Forty-nine percent of the 165 service units participated.

Overall Results

- In age-specific comparisons to the general US population:
 - On average AI/AN children have four times (400%) the number of decayed, missing and filled teeth
 - Likewise, these children are four times more likely to have untreated tooth decay than white children.
- In some AI/AN communities about 50% of the children have caries experience by their 2nd birthday, which increases to 95% by their 3rd birthday.
- There were no statistically significant reductions between 2010–2014 overall or in any age group.
- There are substantial disparities in the prevalence and severity of caries in children among the various IHS Areas. The region of IHS that had the lowest prevalence and severity in the 2010 survey reported the largest overall improvement from 2010–2014.
- The teeth at highest risk of caries in 1–5 year old children are mandibular 1st molars followed by maxillary central incisors.
- We need to think beyond primary teeth—the permanent teeth could last 90+ years. About 7% of AI/AN kindergarten children already have decayed first permanent molars. The available data indicate these children are erupting permanent teeth earlier than most other children.

Presentations of QUEST's Goals, Objectives, Activities, Accomplishments and Plans

1. Oral bacteria associated with severe dental caries in Canadian First Nations, Métis and Inuit and Native American children: A Pilot Project; Bob Schroth and Wenyuan Shi (Schroth & Shi Oral Flora of First Nations Children.pdf)

Research Question: What is the primary etiological factor resulting in high prevalence and severity of caries in Canadian First Nations children: Unique pathogens or known pathogens acting in a new way?

Study participants: Medically healthy First Nations children (n=50) living in the Winnipeg area.

Data collected: Demographics, overall health, breastfeeding, weaning, frequency of snacking, brushing, and yearly household income

Results: Data analysis in progress. We intend to submit an abstract for the upcoming International Association of Dental Research (IADR) meeting.

2. The SMILeS Study: Microbiology of Severe Early Childhood Caries in American Indian Children; David Drake (Drake SMILeS Oral Flora Study.pdf)

We followed the development of the oral flora of a group of American Indian children (n=235) from age one month to 36 months. Key findings were:

- The mean age of acquisition is earlier than is generally reported in the literature.
- Only about half of the children acquired their *S. mutans* from their mothers. There were many children who harbored specific genotypes of *S. mutans* not found in other family members
- Unexpectedly high levels of *S. sobrinus* were found in some children.
- Children who had both *S. mutans* and *S. sobrinus* had higher caries experience, but *S. sobrinus* by itself was not associated with higher caries.

Conclusions: We confirmed previous reports that many high risk children acquire cariogenic bacteria at an early age, and found an association between a child having both *S. mutans* and *S. sobrinus* and having a higher incidence of severe caries in the primary dentition.

3. Developing a sealant-like product to protect areas of enamel hypoplasia (EHP) in the primary dentition; Fred Eichmiller

With funding support from Delta Dental of Wisconsin, our objective was to work with Dr. Gary Schumacher of the Anthony Volpe [formerly Paffenbarger] Research Center to develop a product that could be applied like a sealant to hypoplastic smooth surfaces of the primary dentition, which are commonly encountered by IHS pediatric dentists. Products based initially on glass ionomers and subsequently based on acrylates were made and tested, but none had the required combination of adhesiveness and durability. This project has now been concluded.

4. QUEST Enamel Hypoplasia Field Guide Project; Margherita Fontana (Fontana QUEST Enamel Hypoplasia Project.pdf)

Our objective was to develop and field test a simplified set of diagnostic criteria for enamel defects suitable for use by IHS dentists. There are many different presentations of enamel hypoplasia, including both quantitative and qualitative defects. Enamel

defects have been associated with onset of caries in the primary dentition, and the mechanism is believed to involve preferential colonization by *S. mutans*. Hypoplasia in primary anterior teeth has been associated with prenatal smoking, excessive weight gain, low birth weight, and premature birth.

The project was delayed by our inability to get a sufficient number of high quality images for field testing. In recent discussions, we decided that we can use images of enamel defects in other populations of children besides those of AI/AN children. Our intent is to pick up where we left off and we expect to have the diagnostic guide ready for field testing by early 2016.

5. A Staging System for Caries in the Primary Dentition; Dee Robertson (Robertson New Caries Staging System.pdf)

When individuals are diagnosed with any particular disease, the first and most important thing they want to know is how it will affect the quality and duration of their lives. A large proportion of the young children in the U.S. have no caries in the primary dentition (CIPD); for many others it is a mild and asymptomatic condition—in short, it does not affect their quality of life significantly. Yet for many AI/AN children, CIPD substantially diminishes the quality of life due to symptoms of the disease itself and from the extensive restorative treatment needed.

As clearly stated in the 1999 NIDCR panel report that Dr. Weyant referenced in his Keynote Address, not all caries in children is created equal: the prognosis for a one year old with a tooth cavity is much different than that for a five year old with a single lesion. This was the driver for QUEST's efforts to develop a caries severity staging system. Our proposed severity metric is called the 'CIPD Level,' and it is based on the dmft (decayed, missing, filled teeth) score in the primary dentition *stratified by very small age brackets*: <18, 18–23, 24–29, 30–35, 36–47, 48–59, and 60–71 months. Our basic premise is that this system will demonstrate a correlation between the numerical CIPD Level scores and expected future morbidity —i.e., diminishment in the quality of life—for the child. A manuscript describing this system has been submitted for publication. The QUEST workgroup addressing this is actively seeking access to additional data sets with which to test our premise.

6. Using electronic health records for population-level research of pediatric caries in Alaska; Tom Hennessy (Hennessy Using Electronic Records for Epidemiology.pdf)

The children in this study are from the urban Anchorage area, with an annual AI/AN birth cohort of about 650. We did a retrospective chart review, and extracted data from the electronic dental record (EDR) system.

Results:

- By age 5, 70.9% of children had caries experience, with the mean dft=5.0
- 25% of children were treated under general anesthesia in operating room before age 6 (~50 times the U.S. all races rate).

We then used the data to evaluate the new Caries Staging System described above, and found that the CIPD Level categorization more accurately predicted adverse outcomes than the old ECC system.

Conclusions:

1. Electronic dental records can be used to:
 - a. Evaluate prevalence of caries in children
 - b. Link outcomes for individuals
 - c. Track outcomes over time.
2. CIPD Staging Scores:
 - a. Can be determined and tracked in a population using EDRs
 - b. Provide more discrimination than ECC classification
 - c. Appear useful for identifying high risk patients
 - d. Appear useful for evaluating populations over time.

7. Caries Status of Northern Plains Tribal Community Children; John Warren (Warren Caries in Northern Plains AI Children.pdf)

Methods: A prospective cohort study whose primary purpose was to evaluate the oral flora of the children and their mothers over a 3-year period:

- 235 Mother-Child pairs enrolled when the child was 1-month old.
- Children completed regular follow-up visits through age 36 months.
- Dental caries examinations of these children were completed at each visit beginning as soon as any teeth were present.

Results:

- There was an extremely high retention rate in this study. More than 98% of the children initially enrolled completed the full study.
- By 22 months of age, 49% of children had cavitated caries experience, mean dmfs=3.7
- By 36 months of age, 80% of children had cavitated caries experience, mean dmfs=9.6
- When non-cavitated “white spot” lesions were included, the prevalence was 95%
- The maxillary anterior and mandibular posterior primary dentition were the most highly affected.

Conclusion:

Both the prevalence and severity of dental caries in this group of children were remarkably high compared to even other groups of children who are considered to be at ‘high risk’ for caries. Although this was not an intervention study, it was clear that the primary and secondary interventions being done in this community had little protective effect on severe dental caries.

Agency and organizational priorities and activities to reduce the disease burden from caries in high risk children

1. Overview of issues and recommendations IHS and local dental directors; Facilitator: Patrick Blahut

The discussions of this group resulted in a consensus on issues that can be put into three categories:

Clinical interventions for prevention and treatment

The highest level of interest for this group was in the results of a demonstration project now being conducted at the Warm Springs IHS dental program, which IHS DOH is now referring to as the “Warm Springs Model.” The essence of this project is that when primary prevention fails and young children develop caries, the parents are offered a non-operative approach in which the active caries is treated using a protocol consisting of silver nitrate followed by fluoride varnish. Participants expressed support for:

- Replicating the Warm Springs Model at other IHS and tribally-operated dental programs to evaluate its feasibility and level of success.
- Assessing the long term benefits of using silver products as compared to using conventional restorations.

Data issues

- Increase understanding not only of Health Promotion and Disease Prevention, but also increase emphasis on getting data on clinical practice strategies that improve clinical results.
- New GPRA (Government Performance and Results Act) objectives are needed that generate data on clinical outcomes rather than just process measures.
- Analyze existing data in a timelier manner and provide greater depth and maintain transparency.

Policy and structural issues

- Let senior leadership know that innovative interventions need to be tried and supported.
- Utilize the existing structure created by the IHS ECC Collaborative (2010–2014) to support new activities.
- Need policy changes to support clinical efforts; for example, some Head Start centers are still frequently serving fruit juice.

Conclusions

- Organizational change does not occur as quickly as we might like, but individual providers are working continually and making a difference.
- IHS and tribal program dental clinicians need evidence-based new interventions that are proven to work in every day clinical practice for the extremely high-risk children they care for.
- Good ideas need to be translated into practice, which often requires courage to implement something new and patience to get it get done.
- As with other organizations, concern about the possibility of adverse publicity may have slowed the IHS adoption of the Warm Springs Model.

2. Overview of issues and recommendations from Symposium participants representing federal agencies, health insurers, academics and dental organizations; Facilitator: Bob Weyant

Policy

- Provider education is needed to facilitate innovative changes in clinical practice, this has to start with dental school education.
- Potentially multiple levers may be available to influence policy changes, but they depend upon the circumstances, and in the case of IHS, on the tribes or programs involved.

Structural

- Cost and reimbursement issues associated with a new intervention. Even when the actual products are inexpensive, the cost issue is more related to staff time, which needs to be tied to return on investment. Models need to be developed that allow innovative approaches.

Translation into practice

- Promote utilization of the increasing changes in technology in a timely, efficient manner.
- Assess the comparative effectiveness of new products or strategies, such as the silver nitrate model (used to treat children with caries at some IHS sites) with silver diammine fluoride and other approaches.
- Change the culture within populations at high risk for dental disease, so that the expectation is for good oral health instead of poor.

Program assessment

- The process measures used by the IHS and other agencies, such as the number or proportion of children receiving a specified treatment, are of limited value.
- Need to shift the emphasis toward evaluating health outcomes, including:
 - Increasing children's quality of life, including fear reduction and decreasing pain both from the disease and treatment.
 - Decreasing the incidence of new caries after interventions.
 - Decreasing the number and proportion of children receiving treatment for dental caries under general anesthesia.
 - Increasing the percentage of children who enter kindergarten caries free.

Day #2

Report on a group exercise on current treatment approaches for common presentations of caries in AI/AN children, and expected results

The intent of this exercise was to explore how a diverse group of respondents representing multiple roles and perspectives within the broad category of “oral health” perceive the best treatment approach for young children with dental caries. There was no intention to portray any particular approach as being right or wrong, but rather to highlight the extent of the variation—large or small—in how a young child with a common pattern of caries might be treated by different practitioners.

At the prior Symposium in 2013, a similar exercise was done in which a few common scenarios of presentations of caries in young AI/AN children were presented to four groups, who had been assigned to approach each clinical scenario from one of four different ‘personas:’ (1) Local community standard of care; (2) Traditional invasive (drill and fill) restorations that are still the standard of care for many U.S. dentists; (3) Non-invasive approach which emphasize initial treatment with ITRs rather than invasive restorations; and (4) A non-operative approach that for many children treats caries initially with a silver ion antimicrobial, such as silver nitrate solution or silver diammine fluoride. At that prior Symposium, many participants were surprised by the large amount of variation of approaches not only among the different assigned personas but even among different participants within a single persona.

Results

All groups agreed that at the initial visit the dental staff would:

- Conduct a history, assessment of the child’s environment, and a clinical exam.
- Ensure that the standard recommended prevention plan for the child was reviewed.
- Present treatment options to the parent, and agree on a plan.

Compared to the results of this same exercise two years ago, the most notable difference among the treatment options was that the participants seemed to be less likely to recommend that the hypothetical child be scheduled for invasive procedures in general, and restorations and extractions under general anesthesia in particular.

There was also discussion of what would constitute a “successful outcome” from the perspectives of the child, parent, dentist, and payer. Last, it was agreed that there is a need to understand the systems issues at the individual and community level that led to this hypothetical child developing caries in the primary dentition at such an early age, and would influence the longitudinal outcome.

Reports of recent (a) controlled research and (b) clinical practices that are using silver ion products in a non-operative approach for children with caries

1. Margherita Fontana

The University of Michigan School of Dentistry is getting ready to start a randomized controlled clinical trial focused on the use of 38% silver diammine fluoride (SDF) in the primary dentition. The final approvals are expected soon.

2. **Mike Kanellis** (Kanellis Silver Nitrate Clinical Trial.pdf)

In October 2014 we began a randomized controlled clinical trial in an Amish community treating children age 2–11 with caries using a silver nitrate (SN) followed by fluoride varnish (FV) protocol compared to the usual restorative standard of care. This study population of Amish children has high caries rates, little exposure to fluoride, often reporting infrequent brushing, and limited access to dental care due to transportation challenges. Inclusion criteria are that the child have at least one active, soft lesion with dentin clearly exposed. Exclusion criteria are silver allergies or the child is uncooperative. Each child will be followed for two years.

For the SN group, the study protocol specifies applications of 25% SN solution to all carious lesions in the primary dentition. There are three applications one month apart, with a five-second application of SN followed immediately by FV, using super-floss or soft pick to get SN on interproximal lesions. Children have a recall visit with radiographs every six months, at which time they receive a single additional application of the SN/FV.

Outcome measures include:

- The incidence of new caries
- Progression of treated lesions
- Presence of major or minor failures
- Parental and child satisfaction
- Child oral health related quality of life

3. **Introduction to the “Warm Springs Model”:** Using a non-operative approach to children with caries; Patrick Blahut

It was reported at the 2013 Symposium on Caries in AI/AN Children that Dr. Frank Mendoza, pediatric dentist at the Warm Springs IHS Dental Program, had recently begun offering to parents a new non-operative approach of treating their young children with dental caries utilizing a silver nitrate solution followed by fluoride varnish protocol. Over the next year Dr. Mendoza regularly updated the IHS Division of Oral Health (DOH) on the progress of this project, which was reporting highly favorable results. Dr. Gary Pannabecker, a senior IHS field program director, and I visited Warm Springs to review this project. We confirmed the favorable outcomes being reported. We were impressed with the positive emotional perspective of everyone involved with the project, including the children being treated, their parents, the clinical providers and the local IHS administration. Based on the findings of our review, the IHS Chief Medical Officer endorsed the continued utilization of this new ‘Warm Springs Model’ for children with caries, and recommended cautious expansion of this Model to three beta sites. Progress for all sites is reported below.

Frank Mendoza: IHS Pediatric Dentist, Warm Springs, OR (Mendoza The Warm Springs Model.pdf)

As mentioned by Dr. Blahut, our implementation of a non-operative approach to children with caries began immediately prior to the previous Symposium on Caries in AI/AN Children held in Hood River two years ago. As background, despite utilizing all the conventionally recommended prevention products and strategies for many years, about

90% of our Head Start kids have caries experience, with about 100 children annually requiring restorations and extractions under general anesthesia. Prior to our new intervention, there had been no discernible change in the disease prevalence or severity from our primary and secondary prevention efforts.

Before we began our project in September 2013, we did a careful consideration of the risk-benefit ratio and concluded that the possible benefits far outweighed any potential risks. We went through many levels of approval, including the Warm Springs Health and Welfare Committee, Portland Area Chief Medical Officer, the Warm Springs Service Unit CEO and Chief Dental Officer, presentations to the community, and informing the full medical staff at our facility of the protocol to be used.

With the assistance of Dr. Dee Robertson, former IHS pediatrician and President of QUEST, we developed a detailed Manual of Procedures that specified all aspects of this project, including inclusion and exclusion criteria, treatment and exam schedules, the informed consent process, and multiple levels of evaluation of the safety and efficacy of the project. The primary age group of interest is children less than age 6 years, though we kept the flexibility of treating older children on the basis of expert opinion on the child's best interests. Our principal exclusion criterion is that we do not treat children who are already symptomatic with pulpitis or infection. The treatment protocol consists of application of a very small amount of 25% silver nitrate solution directly to the carious lesions, which are then covered with fluoride varnish. We do not routinely apply the FV to the rest of the dentition at this time.

Note that this model is offered as an option to parents whose children have active caries; we clearly explain that it is not mandatory. Over the last two years only two of 158 parents have chosen traditional restorations instead of this non-operative alternative.

Recommended schedule of treatments and exams in the Warm Springs Model

Visit #	Purpose	Interval from 1st protocol tx	Comment
1	1 st exam and initial discussion with parent	n/a	This may be combined with the 1 st treatment in some cases, usually not.
2	1 st treatment visit	n/a	Usually within 1 month of 1 st exam
3	2 nd treatment visit	14 days	Brief inspection and treatment
4	3 rd treatment visit	1 month	Brief inspection and treatment
5	4 th treatment visit	2 months	Brief inspection and treatment
6	5 th treatment visit & 2 nd exam	3 months	Full surface-specific exam (optional) and treatment
7	3 rd exam	6 months	Full surface-specific exam
8	4 th exam	9 months	Full surface-specific exam (optional)
9	5 th exam	1-year	Full surface-specific exam
Additional full surface-specific exams are scheduled at 6-month intervals through year 4.			

Results:

After two years our overall impression is highly favorable:

- It is safe, fast, easy, inexpensive and highly efficacious in arresting active caries in the primary dentition.
- Our providers like it, the parents like it, and the kids love it.

2-year Clinical Outcomes for 158 children at Warm Springs

Parameter	numerator	denominator	%
# Children with extractions for pathology	1	158	0.6
# Children receiving SSCs	3	158	2
# Children receiving anesthesia			
Local anesthesia	2	158	1
General anesthesia (GA)	3	158	2
GA for progressive disease	0	158	0

Characteristics of restorations (n=87)			
Amalgam	0	87	0
Esthetic GI (glass ionomer) or resin	52	87	60
Functional GI or resin (e.g., food trap)	35	87	40
GI or resin for progressive caries	0	87	0

Overall Conclusion: After 32 years of being a pediatric dentist for American Indian children, I finally have found something that works!

Caveats: There are many things that we still don't know about this protocol—especially the long range outcomes. In addition, despite our remarkable success, since starting this project I have had to provide treatment in the operating room to over 100 children because many did not get into my care before their disease became symptomatic, at which point I had no other option. However, this is not a pediatric dentistry problem—it is a systems problem: Why didn't these children see me for care earlier before their disease progressed? We will work to understand these systems issues in the coming year.

Gary Pannabecker: IHS Dental Director, Blackfeet, Montana (Pannebecker Warm Springs Model at Blackfeet.pdf)

We participated in the IHS ECC Collaborative program from 2010–2014, including routine use of FV (which we actually had started in 1995), xylitol gum, extensive parental nutritional counseling, and use of sealants and ITRs as indicated. Despite all our efforts, we could not see any success. We seemed to be “just doing more work on the same kids.” About 65% of kids 0–5 years have caries, with about half that many having untreated caries. Caries is frequently noted immediately upon eruption of the primary dentition. For many years about 20% of our children have needed restorations and

extractions under general anesthesia, and this likewise has not improved despite our efforts at primary prevention.

After accompanying Dr. Blahut for the review of the new Warm Springs program at the end of 2014, I requested permission from IHS to adopt the same protocol at my site, and Blackfeet IHS became the first beta site for the Warm Springs Model in February of 2015. We use the same protocol of multiple applications of silver nitrate followed by fluoride varnish as Dr. Mendoza has used at Warm Springs.

Our overall perception is that the protocol has been well-accepted by patients and families. It is highly efficacious in arresting caries in the primary dentition. We have had no complications other than silver nitrate can stain hands and countertops. We are using the same database and tracking system as Warm Springs to document all treatments and outcomes. Our follow-up data is limited because the short duration of using this protocol, but after six months we have a uniformly positive impression. It should be noted that even if traditional restorative treatment is later needed, we feel the silver nitrate protocol gives us a great advantage just by delaying the need for treatment until the child is older and can cooperate better, or until all the primary tooth eruption is complete. This will decrease the number of children who require restorations under general anesthesia.

Conclusion: Using the Warm Springs Model silver nitrate protocol is a very valuable tool for our armamentarium against this disease.

Lori Snidow: IHS Dental Outreach Director, Cass Lake IHS, Minnesota (Snidow Warm Springs Model at Cass Lake.pdf)

Like the other sites, we have utilized all the previously recommended primary prevention strategies, but continued to see high levels of disease in young children. Because of the difficulty of getting young children into the dental clinic, four years ago we began using an outreach model in which we take the care to the children using a mobile dental program. Our team includes a dentist, a CDHC (Community Dental Health Coordinator) and a dental assistant. Depending on the space available at the location, we do everything except extractions and root canals with our mobile setup. In 2014–15, our outreach program saw over 1200 children at 11 different Head Start and school sites. From program inception in 2010 to 2014, the Basic Screening Survey scores of children served by our outreach project have decreased 25%.

After getting multiple levels of local approval, in June 2015 we become the first outreach implementation of the Warm Springs Model. Despite the many advantages of delivering care to the children by outreach, a concern is that we have only limited access to the parents. Therefore, we decided to initially use the silver nitrate followed by fluoride varnish protocol to treat only the children's posterior teeth until the community gets more comfortable with the staining of the carious dentition. We hope that this non-operative approach will have another benefit in that currently a major obstacle to getting children into the dental clinic is fear of the dentist by many parents, based largely on their own experiences as children.

Mary Beth Johnson: IHS Pediatric Dentist, Hopi Nation, Arizona (Johnson Warm Springs Model at Hopi.pdf)

Like Dr. Pannabecker, we have done all the recommended primary and secondary prevention measures for years, but have continued to experience a very high prevalence and severity of caries in the primary dentition of our patients. Some particular challenges for us have been that a high level of geographic isolation, complex family structures, many parents with uncontrolled disease, and limited access to specialty services. Although we concentrate on having more visits for children through age 2, still most of the children have caries experience by age 4, with extremely advanced levels of disease common in young children.

It took many weeks to obtain the multiple levels of local approval to begin to implement the Warm Springs Model at Hopi; at this point (August 2015), we have treated only a handful of children. However, the response from the children, parents and providers has been positive. We are using the same protocol, database and tracking system as Warm Springs and the other beta sites. In conclusion, we view this new approach as a promising new tool in our toolkit for trying to control caries in young children.

‘What Works?’: Discussion on the role of primary and secondary prevention in reducing the disease burden from caries in AI/AN children

A recurrent theme of all the IHS presenters has been that despite determined and sustained efforts by dedicated IHS dentists, including implementation of all the recommended strategies and products of the IHS ECC Collaborative from 2010–14, little or no progress has been documented or observed clinically. A multitude of explanations have been advanced as to why “proven strategies” found somewhat effective in studies of other populations have not been efficacious for AI/AN children. This session was intended to explore briefly some aspects of the question of "What Works" to control caries in very high risk children, and how we might systematically evaluate the available evidence.

What Works for Caries in AI/AN Children, Fred Eichmiller, (Eichmiller Assessing 'What Works'.pdf)

In recent decades there have been hundreds of published studies of caries prevention in children, with varying levels of success reported. As noted in the previous presentations, the IHS DOH now finds itself with needing to make policy decisions on how to address the disease of caries in the primary dentition, given the lack of effectiveness of the standard approaches. QUEST has developed a working model of a decision tree algorithm (Appendix A) that may be useful for IHS and others to assess evidence of effectiveness of published reports. This decision tree, and the discussion to follow, is intended as a first step in this process.

What is High Risk? John Warren (Warren What Does 'High Risk' Mean.pdf)

As mentioned by Dr. Weyant in his keynote address, the current “official” definitions of Early Childhood Caries (ECC) and severe ECC were originally developed in an NIDCR-sponsored panel (Drury, et al, J Public Health Dent, 1999). These were subsequently

adopted by the Academy of Pediatric Dentistry, Council on Clinical Affairs (2008). However, when discussing populations such as AI/AN children, one can question the relevance and validity of these definitions. It seems to be a matter of perspective, in which low risk for ECC is “no risk” and anything else is high:

Low risk = little to no caries experience

High risk = caries is present to any varied extent

But how would we describe a population of young children in which caries is almost universal? The first time I encountered this situation, after an afternoon of examining these children as part of a calibration training, I described it as “a different disease,” meaning that the severity was at a much higher level than I had ever seen.

To highlight the different levels of severity of caries in children, below are data from two groups, both of which are considered high risk: Iowa WIC clinic children and AI children:

Caries Experience by Age (months)

Prevalence	12m	16m	22m	28m	36m
WIC	0%	5.8%	9.3%	18.2%	40.0%
AI	14.9%	31.8%	49.6%	69.2%	80.2%
Mean dmfs	12m	16m	22m	28m	36m
AI	0.5	1.6	3.7	7.0	9.6
WIC	0	0.4	0.7	0.2	1.8

Another way to look at this is using the caries severity staging model (CIPD Levels) described earlier by Dee Robertson.

CIPD Severity Classification – American Indian (AI) Children and Iowa WIC sample: Children age 36-47 months

Implications of using these Two Models: there are vast differences in disease experience between these two ‘high risk’ groups of children. Therefore, we cannot assume that interventions somewhat efficacious for the WIC children will be equally efficacious for the AI children.

CIPD Severity Level	WIC – Iowa (n)	AI Children (n)
0	24	46
1	6	27
2	5	12
3	1	21
4	3 (8%)	129 (55%)

Interim Therapeutic Restoration (ITRs) for Children, Mary Beth Johnson (Johnson Effectiveness of ITRs in the Primary Teeth.pdf)

ITRs are one of the IHS-recommended strategies for the initial management of caries in children. The same procedure is also known as ART (atraumatic restorative therapy) in other places. The procedure was developed three decades ago in Tanzania as an approach to controlling caries in children when advanced operative dentistry was not available. The goal is controlling decay until something more definitive can be done.

The procedure (which I call “scoop and squish”) involves removing the soft carious dentin and then sealing the cavity with glass ionomer, which is fluoride-rich and rechargeable. Published research indicates overall 2–3 year survival rates for this procedure; however, in different populations results range from poor to good. The research is not conclusive—there are few randomized clinical trials.

My personal experience with ITRs as an IHS pediatric dentist is that I find healthier pulps when I have to crown teeth after ITRs have been used. I believe ITR can “buy time” until the child is older and a more definitive treatment can be done. But it needs good margins and a good seal, and is better with four-handed dentistry. To my knowledge, as a result of the emphasis by IHS to utilize ITRs, the number of children initially treated this way has increased in the last few years. However, I’m not aware of any significant reductions in caries severity because of using ITRs.

Clinical Effectiveness of Glass Ionomer Sealants, John Zimmer

Glass ionomers have a broad range of uses in dentistry—both as cements and restorative material. Less frequently, glass ionomer is used as a pit and fissure sealant material in the mixed and permanent dentition. The clinical effectiveness of glass ionomer with permanent molars is well documented, but there is little information in the literature on the value of using glass ionomer sealants on the primary dentition. In spite of the lack of evidence, I thought glass ionomer might prove useful as a sealant material in the primary dentition, and have been using it that way for several years. Below are the data I have collected:

- 57% retention rate overall
- 75% did not have molar decay at the first follow-up at about 10 months
- Of the children retaining all their sealants, 7% had decay at follow-up
- Of the children who retained 75-100% of their sealants, 15% had decay at follow-up
- In 2010 57% of our 3-5 year olds had molar decay, compared to 2013 when 30% of children with GIS had molar decay at follow-up.

Opinion versus Fact: I do not have conclusive data, but I do not believe there is a large benefit in using glass ionomer sealants in children 18-24 months—largely due to isolation issues and the anatomy impeding the performance of any sealant material.

Effectiveness of Silver Ion Products, Margherita Fontana (Fontana Effectiveness of Silver Ion Antimicrobials.pdf)

Silver ion products have been used as antimicrobials since the late 1890s, and continue to have multiple medical applications. I will focus on silver diammine fluoride (SDF), as this is where the more recent evidence is:

Effects of 38% SDF: On the positive side, it is an effective antimicrobial, low cost, easy to use, and has been demonstrated to have some effectiveness in arresting caries in preschool children. On the negative side, it turns carious lesions—but not healthy enamel—black, has a metallic taste, and can cause transient irritation if it comes in contact with the gingivae or mucosae. In the past 15 years there have been several high quality studies using SDF for caries control in young children:

- Chu (2002) found that SDF arrests carious lesions on the anterior teeth of 3–4 year old children better than placebo.
- Llodra (2005) reported that SDF 2x/year is better than placebo both in arrest of extant caries and prevention of incipient caries. The preventive fraction was higher in primary than permanent teeth (PF79% vs 64% respectively).
- Yee (2009) reported 38% SDF is more effective than 12% SDF
- Zhi (2012) found that annual application of either SDF solution or high fluoride-releasing glass ionomer can arrest active dentine caries, and increasing the frequency of application to every six months can increase the caries arrest rate of SDF.

Conclusion: The strength of evidence is limited because the best studies available have:

- Used different treatment application protocols.
- Studied different teeth in children of different ages.

However, on balance, it appears that application of SDF to active caries in preschool children is safe and has a beneficial effect. In clinical practice, it is unclear which children with which types of presentations of active caries are the best candidates, and how the longer range results compare to other strategies, including conventional restorations.

Phoenix Area IHS Experience with the ECC Collaborative, Dan Huber (Huber Results of the IHS ECC Collaborative.pdf)

As the Area Dental Officer for Phoenix Area IHS, I encouraged and supported participation by our clinical programs in the IHS ECC Collaborative from 2010–14. The primary objectives recommended by the Collaborative included increased utilization of fluoride varnish, sealants and interim therapeutic restorations. Recently I have reviewed the documentation of the success of our programs, and overall found good results on the process objectives:

- Doubled the use of ITRs
- Increased sealant usage by 4-5x
- Increased fluoride varnish (which was already strong) even higher.

Despite the above successes, the Phoenix Area results on the 2014 IHS Oral Health Survey showed that for children age 1–5 overall:

- The proportion with caries experience *increased* from 57% to 63%
- The proportion with untreated caries *increased* from 36% to 54%

Conclusion: It is obvious that increasing our level of performance on all these recommended caries control strategies did not actually make the disease worse. However, I believe this is a clear message that IHS needs to take a hard look at “What Works,” our surveillance process, and how we measure the benefits of what we are doing. If there is no benefit, we need to consider doing something different.

Useful outcome measures for interventions in preventing dental caries in AI/AN Children, Eugenio Beltrán

In defining outcomes, we need to stress three levels of impact: statistical level (p-value), clinical level (efficacy) and community level (effectiveness). Most trials focus on statistical significance, fewer on clinical significance and community impact. Another aspect is that our current recommendations for preventing dental caries are tailored as simple interventions when in fact the target is a complex disease. If we analyze only one

element at a time, we may remove the “reality” from the equation, so the results—though valid statistically—are not applicable to the populations most needing them. So what do we do now? (aka, “The art of making decisions in an imperfect world”) We need to provide services to people where information on clinical effectiveness is less than perfect. In this case, the best we can do is define what we mean by “success,” and also how we can measure success in a feasible and valid way in a reasonable timeframe.

Examples of Potential Measurements		
Normative	Self-Reported	Societal
<ul style="list-style-type: none"> • Klein’s DMFT • CAST • PUFA • ICDAS • Need for restorations • Biological outcomes 	<ul style="list-style-type: none"> • Utilization of dental services • QoL • Impact on daily performances 	<ul style="list-style-type: none"> • Need for emergency services • Need for complex restorations • Cost savings

Summary of Symposium Recommendations to IHS

A. Silver ion antimicrobial products

- Expand the demonstrated benefits of using silver ion antimicrobials to treat caries in children across IHS.
- Develop a training and certification module, recommended consent form, and templates of other documents such as parent and community education materials to facilitate and standardize implementation of a silver ion antimicrobials protocol.
- Develop a protocol appropriate for IHS dental programs to use silver ion products to treat young children with caries. This should include inclusion and exclusion criteria for this treatment, clinical technique, and a recommended dataset to be collected to demonstrate outcomes.
- Encourage guidance from CMS on reimbursement for using silver products for caries control.

B. Medical – dental collaboration:

- Emphasize referral of children to the dental clinic by age one by medical staff.
- To increase the proportion of young children with caries identified at an early stage, consider locating a dental professional (DDS or RDH) in the medical clinic at least part time to examine or screen and, if needed, provide treatment or referral.

C. Data issues (clinical outcomes, GPRA [Government Performance and Results Act measures], local access to data, etc.)

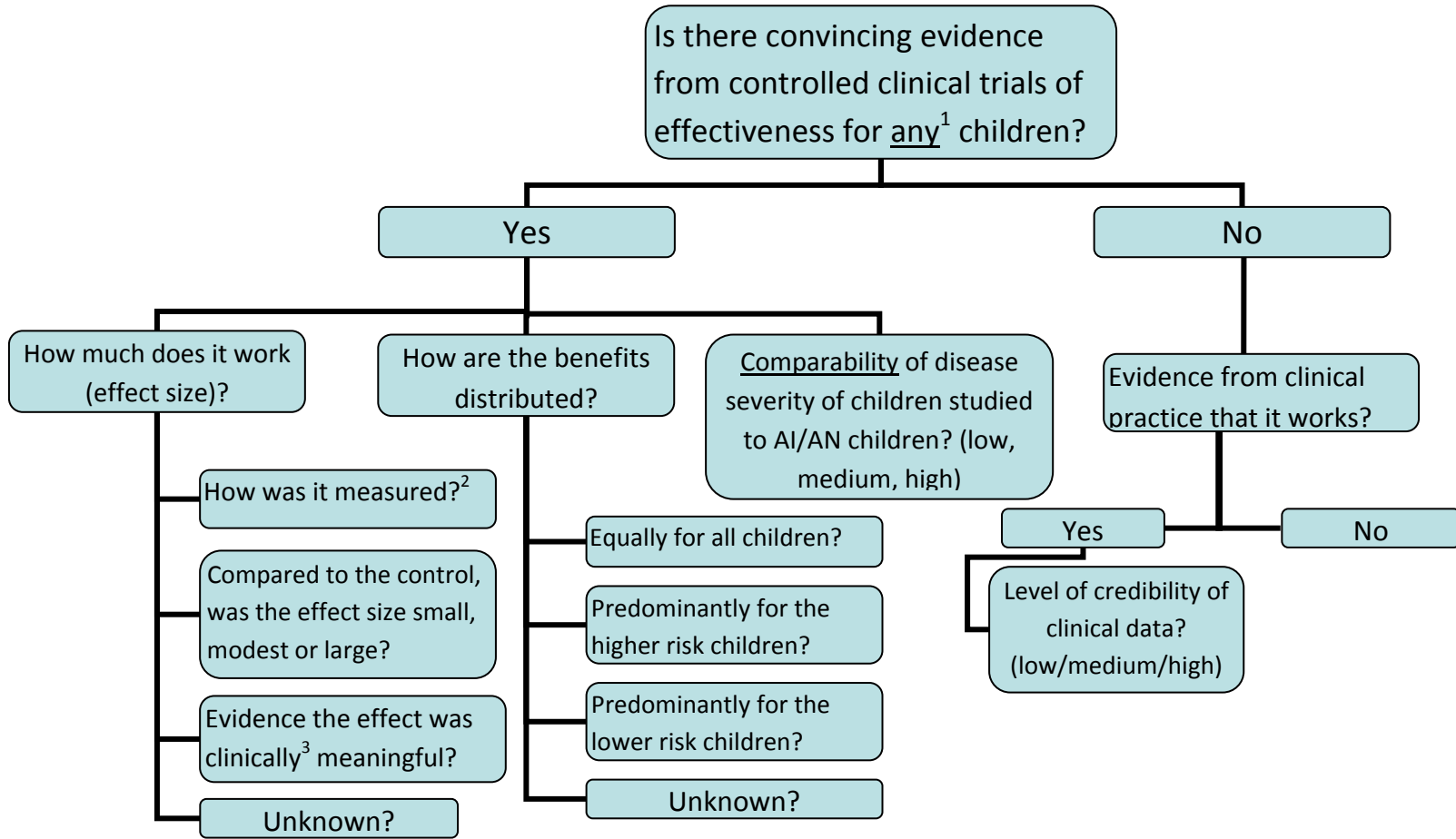
- Collect standardized data on the treatment of children with caries with a focus on outcomes.
- When silver ion antimicrobials are used, utilize the new CDT (D1354) code for treatment with an ‘interim caries arresting medication.’
- Develop clinical outcome measures to monitor the success of prevention and treatment efforts; these should not be used to penalize sites for not achieving the goals.
- Implement a standardized surveillance mechanism to track by IHS area the rates of treatment of caries in children ages 1–5 under general anesthesia.
- Demonstrate return on investment of caries control efforts by developing outcome measures supported by readily available data.
- Develop web-based tools so IHS and tribal staff at the local, regional and national levels can mine and analyze available data on caries in children.
- Over time, modify GPRA measures to support desired outcomes rather than process.
- For on-going NHANES surveillance, recommend oversampling of children <6 years of age to obtain valid data for these children stratified by age brackets of no more than 12 month intervals.
- Reconsider the utility of using prevalence and mean dmfs/dmft scores as the primary means of describing trends in dental disease in children.
- Standardize surveillance measures, and expand capacity for longitudinal patient data.

D. Workforce and Miscellaneous

- Consider alternative workforce models, including utilizing Dental Health Aides or other non-dentist members of the dental team, to expand access to care—especially for using non-operative approaches to treating children with caries.
- Consider the feasibility and effectiveness of using the Hall technique more often to treat children with caries.

This concluded the Symposium.

APPENDIX A: Decision Tree for “What Works?” for Caries in AI/AN Children



1. Not necessarily extremely high risk children like AI/AN
2. Mean NNCS, mean dmfs/dmft, prevented fraction, PUFA, proportion of GA cases, MID in QoL, % untreated caries, risk-benefit ratio, Bratthall's SiC Index, other?
3. Minimally important difference in improvement in symptoms and quality of life measures.

Symposium on Caries in AI/AN Children, August 21-22
Hood River, Oregon

APPENDIX B

Agenda QUEST Symposium on Caries in AI/AN Children¹ August 21–22, 2015

Day #1: Friday a.m.

Time	Item	Leader
7:00	Breakfast	
8:30	<ul style="list-style-type: none"> ▪ Welcome and Introductions ▪ Review of Symposium purpose, agenda and expected outcomes 	Robertson
8:45	<ul style="list-style-type: none"> ▪ 2014 IHS Oral Health Survey 	Phipps
Group breakout session #1		
9:00	Group A: Internal meetings of QUEST Workgroups (Epidemiology, Enamel defects, Microbiology, and Interventions) <ul style="list-style-type: none"> - Review progress toward 2015 goals and objectives - Draft objectives and work plan for 2016 	QUEST Directors
	Group B: Local dental program directors (IHS, tribal, non-profit) <ul style="list-style-type: none"> - Review of current IHS Division of Oral Health (DOH) programmatic priorities and constraints - Discuss the results of efforts by local dental directors to reduce the disease burden from caries in children 	Blahut
	Group C: Stakeholder interest groups and organizations <ul style="list-style-type: none"> - Status of on-going programs, activities and data collection related to caries control in high risk children - Where can progress be made? - What is needed to move forward? - Opportunities for coordination with QUEST 	Weyant

Friday p.m.

Time	Item	Leader
Noon	Catered lunch for all Symposium participants: informal discussions	
1:00	Introduction of afternoon sessions	Robinson
1:15	Keynote address: The 1999 NIDCR panel on caries in children: A Seldon Crisis of special relevance to QUEST and AI/AN children	Weyant
1:45	QUEST goals, objectives, activities, accomplishments and plans	QUEST Directors
3:00	Break	
3:15	Reports from the morning's discussions by Groups #2–3 on agency and organizational priorities and activities to reduce the disease burden from caries in high risk children	Blahut Weyant
Group breakout session #2		
4:00	Current treatment approaches for common presentations of caries in AI/AN children, and expected results	QUEST Directors

Agenda (continued)

Day #2: Saturday a.m. (plenary)

Time	Item	Leader
6:45	Breakfast buffet	
8:00	Summary of key issues from Day #1, and reports from group breakout session on common scenarios	Robinson
8:45	Reports of recent (a) controlled research and (b) clinical practices that are using silver ion products in a non-operative approach to children with caries (NOACC)	Robinson
10:30	Break	
10:45	<p>‘What Works?’: Panel discussion on the role of primary and secondary prevention in reducing the disease burden from caries in AI/AN children.</p> <ul style="list-style-type: none"> - How do we weigh the value of published controlled clinical trials vs data from clinical practice vs clinical experience only? - What short- and long-term metrics are most relevant? - What recommendations can QUEST and the Symposium participants make to the IHS Division of Oral Health for policies to control caries in AI/AN children? 	Eichmiller

Saturday p.m.

Time	Item	Leader
Noon	Catered lunch for all Symposium participants: informal discussions	
Group breakout session #3		
1:00	<p>Breakout groups to address policy and operational implications of the morning’s presentations for various interest groups:</p> <ul style="list-style-type: none"> - What new options (if any) have opened up for us? - What is needed to move forward? - What collaborations will be mutually advantageous? - How should we assess future changes in the oral health status of AI/AN children? 	QUEST Directors
3:00	Break	
Plenary session		
3:15	Reports from breakout groups.	QUEST Directors
4:00	Summary comments from agency and organization representatives	Robinson
4:30	Next steps—Who, what, when, and how to measure progress?	Robinson
5:00	Adjourn	

¹ Sponsored by QUEST—a 501(c)(3) organization in Washington State whose mission is to “Convene and focus the expertise and resources necessary to understand the etiology of rampant dental caries in AI/AN children, and identify optimal strategies to prevent and control it.”

APPENDIX C

Participants

Eugenio Beltran, DMD, MPH, DrPH	Oral Epidemiologist, Private Consultant, Atlanta, GA
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Participants (continued)

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