

# Conclusion Paper

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## Progress in Early Childhood Caries and Opportunities in Research, Policy, and Clinical Management

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**Abstract:** *The 2014 Early Childhood Caries Conference encompassed evidence-based reviews on the state of the science regarding early childhood caries (ECC) epidemiology, etiology, prevention, and disease management. The purpose of this paper was to discuss the work presented at the conference and identify opportunities in research, policy, and clinical management that may improve early childhood caries outcomes and lower costs of care. While great progress has been made since the 1997 ECC Conference, there remains a paucity of high-quality evidence from randomized controlled trials on what are the most effective means to prevent and manage ECC. Analyses of studies indicate that some approaches, such as chlorhexidine, iodine, and remineralizing agents, have not shown consistent findings in preventing ECC. However, evidence exists to yield recommendations in some areas. There are useful risk assessment indicators to identify preschool children at risk for caries. Fluoridated toothpaste and fluoride varnish currently are the most effective chemotherapeutic strategies to prevent ECC. Motivational interviewing, a form of patient-centered counseling, is effective for motivating oral health behaviors and shows promise for reducing caries. Additionally, evidence is emerging that shows the value of chronic disease management approaches and integrating ECC oral health care within medical care settings. Recommendations for future directions in ECC research and policy were also key outcomes of the conference. (Pediatr Dent 2015;37(3):294-9)*

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In the past two decades since the 1997 Early Childhood Caries (ECC) Conference was held at the National Institutes of Health, there has been extraordinary progress in the understanding of ECC regarding its etiology, demographic trends, prevention, and management. The proceedings of the 2014 ECC Conference highlight the extent of this progress. ECC is now widely recognized as a complex, multifactorial, and chronic disease that is preventable. It is significantly associated with diminished oral health-related quality of life and presents important social and economic burdens to families and to society. Importantly, preliminary findings from the 2011 to 2012 National Health and Nutrition Examination Survey (NHANES) survey suggest a decline in dental caries prevalence in the United States for two- to five-year-olds.<sup>1</sup>

However, despite the recent reductions in ECC prevalence in the United States, ECC remains an important problem, with significant differences in caries prevalence existing within particular subgroups. For example, in 2011 to 2012, 23 percent of United States two- to five-year-olds had dental caries in the primary dentition, while untreated caries in two- to eight-year-olds was twice as high for Hispanic and non-Hispanic African American children compared with non-Hispanic Caucasian children.<sup>1</sup> Among American Indians, Ricks and Bruerd reported that, despite extraordinary efforts over the past decade and the implementation of various innovative community-based interventions, American Indian children remain severely burdened with ECC, with a prevalence of 54 percent observed among one- to five-year-olds in 2014.<sup>2</sup>

The 2014 ECC Conference also highlighted the gaps in our knowledge and identified additional avenues for research. While the term “ECC” is now internationally recognized and there is general agreement on its case definition, differences in the diagnostic criteria and age range remain, especially between the United States and European researchers. These variations present challenges to surveillance efforts, our full understanding of the epidemiology of the disease, and the interpretation and generalizability of intervention studies that may use different definitions of ECC for both diagnostic criteria and clinical outcomes of interest.

While it is generally believed that ECC is a chronic condition that is both preventable and amenable to medical management, theoretical models that are currently being used as the rationale for both designing ECC interventions and program planning remain largely untested. Moreover, there remains a surprising paucity of high-quality evidence to support the effectiveness of any specific clinical, behavioral, or community-based interventions targeting children younger than six years

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old.<sup>3,4</sup> Much of our knowledge about ECC management appears to be inferentially drawn from evidence obtained from research with older children. Nevertheless, in 2014, following a review of the available evidence, the U.S. Preventive Services Task Force (USPSTF) gave a B grade to the evidence for the recommendation that: (1) primary care clinicians prescribe oral fluoride supplementation starting at age six months old for children whose water supply is deficient in fluoride; and (2) primary care clinicians apply fluoride varnish to the primary teeth of all infants and children starting at the age of primary tooth eruption. However, the USPSTF review also concluded that the available clinical trials of xylitol use were inconclusive regarding effects on caries prevention.<sup>5</sup>

The purpose of this paper was to systematically review the 2014 Early Childhood Caries Conference evidence regarding approaches to ECC management, identify those areas where sufficiently high quality evidence exists to yield recommendations, and identify key knowledge gaps for future research priorities. To this end, the conference's advisory committee proposed an agenda for future research and development of clinical guidelines and policy changes that has the potential to change the way ECC is managed in the future.

**Effectiveness of motivational interviewing on ECC preventive behaviors and risk.** There is conventional wisdom that patient communication and education are critical in improving ECC health outcomes, but data demonstrating success of these approaches are lacking. The meta-analysis presented by Borrelli et al. shows the potential of parent-targeted motivational interviewing (MI) in improving pediatric health behaviors and health outcomes.<sup>6</sup> MI is a patient-centered approach that focuses on building intrinsic motivation for change by exploring and resolving ambivalence. Their meta-analysis shows that parent-targeted MI is associated with significant improvements in pediatric health behaviors (e.g., oral health behaviors, diet, physical activity, and reduced screen time and access), pediatric health outcomes (body mass index and dental caries), and parent behaviors that affect children's health (smoking cessation and household smoking restrictions). While MI significantly outperformed comparison groups on pediatric oral health behaviors and management, the positive effect of MI on dental caries, while promising, should be viewed with caution because it is based on a limited number of studies.

A systematic review presented by Hieftje et al. also showed the value of electronic media interventions, such as video games, for health behavior change in youth. In their review, 17 of 19 studies reported a statistically significant change in health or safety behaviors, including those related to physical activity, nutrition, asthma, and sex.<sup>7</sup> While great potential exists in the use of video game interventions for altering health behaviors in youth, there continues to be a need for higher quality, rigorously evaluated interventions, especially regarding oral health behavior change.

**Value of caries risk assessment.** The review of caries risk assessment by Fontana has identified the value of clinical, environmental, and behavioral factors that should be considered when assessing caries risk in young children. Examples include: caries history; dietary habits (especially the frequency and amount of sugary food and drink consumption); social history (especially socioeconomic status); oral hygiene habits (e.g., use of fluorides); and medical history (e.g., emphasis on conditions that could affect salivary flow rate).<sup>8</sup> Furthermore, data show how factors associated not only with the child but also the parent/primary caregiver (e.g., parental oral health status and

parental deprivation) are important to consider. The use of structured forms may aid in the systematic assessment of multiple caries risk factors in practice and in objective record-keeping over time. However, there is limited evidence for their validity and prospective studies are needed.<sup>8</sup>

**Effect of fluorides on ECC prevalence.** The reviews by Li and Tanner and Twetman and Dhar each addressed conventional interventions considered in the ECC management. The role of community water fluoridation and topical fluorides as an anticaries agent is supported by systematic reviews. Specific data were presented, showing the efficacy of fluoridated toothpaste and fluoride varnish in reducing ECC. Systematic reviews have shown that fluoride toothpaste is effective in reducing dental caries in preschool children,<sup>9</sup> but the amount of fluoride that is swallowed must be controlled by limiting the amount of fluoride toothpaste placed on the toothbrush.<sup>10</sup> Additionally, there is consistent evidence from systematic reviews that 2.26 percent fluoride varnish is effective in reducing dental caries in preschool children when used at three- to six-month intervals.<sup>11,12</sup>

**Effect of antimicrobials on oral microbiota and ECC.** Chlorhexidine (CHX) has a long history of use in caries prevention trials.<sup>13,14</sup> Some reports show a significant reduction in mutans streptococci (MS) at an early stage of the intervention; however, after three months, the reduction was diminished.<sup>15</sup> Results from the systematic reviews presented in these proceedings show insufficient evidence to conclude that the daily use of CHX alone or in combination with fluoride application for an extensive period reduces the levels of MS or lactobacillus (LB)<sup>3</sup> or incident caries in young children.<sup>4</sup>

Povidone-iodine (PVP-I) is a stable chemical complex that is used as an effective broad-spectrum topical antimicrobial agent. PVP-I has been explored as a topical antimicrobial therapy in the prevention of dental caries in clinical studies. Few studies found that PVP-I temporarily reduced MS and LB counts.<sup>16</sup> A combination of PVP-I and fluoride varnish led to a greater reduction in caries incidence than the use of fluoride varnish alone.<sup>17,18</sup> However, most of the studies were performed on permanent or mixed dentitions and their effectiveness in ECC remains unknown.

**Effect of xylitol on oral microbiota and ECC.** The meta-analysis by Li and Tanner demonstrated that xylitol-based interventions have resulted in a significant reduction of MS colonization and caries in young children.<sup>3</sup> Additionally, xylitol interventions in mothers aimed at affecting MS levels and caries in their offspring show a marginal caries-protective effect compared with non-xylitol intervention.<sup>3</sup> However, a high degree of heterogeneity and risk of bias in some of these studies suggest that the reported reductions should be interpreted cautiously. The USPSTF and Cochrane reviews found that the evidence for xylitol's effectiveness is insufficient to recommend its use.<sup>5,19</sup>

**Effect of silver compounds on oral microbiota and ECC.** For centuries, silver has been known to exhibit antimicrobial effects due to its properties as a heavy metal. There currently is renewed interest in the therapeutic application of silver diamine fluoride, silver fluoride, nano-silver fluoride, and silver nitrate to arrest and prevent dental caries.<sup>3,4</sup> There are several reports of silver compounds used at very high concentrations (30 to 38 percent) to affect ECC progression, but published studies to date have a high risk of bias. Evidence from high-quality randomized clinical trials is necessary before the use of silver compounds become a recommended management approach for ECC.

**Effect of restorative dentistry on oral microbiota and ECC.** Full-mouth restorative treatment under general anesthesia is often used for children with severe ECC, particularly in those families with low socioeconomic status. The regimen is comprised of extraction of unrestorable teeth, surgical removal of carious lesions, and restoration of teeth with stainless steel crowns or intercoronal restorations. Significant reductions in cariogenic bacterial counts in saliva have been reported after such comprehensive treatment. However, the bacterial levels in saliva and plaque increased six to 12 months after the treatment, and relapse rates following full-mouth rehabilitation under general anesthesia were reported to be in the range of 22 to 79 percent.<sup>4</sup> Thus, the long-term effects of restorative care under general anesthesia, alone or in combination with antimicrobial approaches, remains questionable.

At present, there are no known studies on the use of pit and fissure sealants to prevent ECC. Based on the clinical recommendations from the American Dental Association, there is strong evidence of the effectiveness of sealants in permanent teeth; however, there is a lack of data to support the use of sealants in primary teeth.<sup>20</sup> The strong evidence of effectiveness of sealants in preventing fissure caries in permanent teeth suggests that sealants should be effective in preventing at least the fissure component of ECC.

There are also no known studies on the effectiveness of temporary restorations (often referred to as atraumatic restorative technique or interim therapeutic restorations) in the ECC management, although data are available for older children. Several studies have evaluated temporary restorations in primary molars in older children and reported high survival rates of these restorations and reductions in new cavitation, pain, and referral to the operating room.<sup>21</sup> Because some of these children received temporary restorations as a part of the disease management program, the effect of such restorations as an intervention was not separately evaluated. Additional clinical trials are needed to evaluate the effectiveness of temporary restorations in ECC.

The evidence on the effects of traditional restorative dentistry on overall or oral health-related quality of life (QOL), or on oral QOL, is limited and was assessed to be of weak quality.<sup>4</sup> Most of the included studies reported evidence of improvement in oral QOL, as reported by the parents. Although the current evidence supporting effectiveness of traditional restorative dentistry in ECC children is insufficient, elements of restorative care must remain an integral part of the management of the disease in children who have active caries.

#### **Effect of new clinical approaches on ECC management.**

The U.S. health care system is now undergoing explorations to address disparities and enhance the efficiency and effectiveness of clinical practice. The review by Ng and Edelstein suggests that effective patient-provider communication, patient self-management strategies, minimal invasive procedures, and preventive programs based on risk have produced improved outcomes for ECC management.<sup>22</sup> However, while promising, the existing evidence in support of such interventions remains limited. These interventions for ECC, coupled with results of chronic disease management demonstrations for asthma and diabetes, support the concept that chronic disease management may be an important approach to ECC.

Medicaid data presented by Douglass and Clark<sup>23</sup> regarding integrating oral health into overall health care to prevent ECC show that few one- to two-year-olds receive a preventive dental visit. This suggests that having a dental home by the age of one year has shown limited success, despite the recommend-

ations of the American Academy of Pediatrics, American Academy of Pediatric Dentistry, and Bright Futures.<sup>24-26</sup> While oral health preventive services have been successfully incorporated into primary medical care settings, currently few pediatricians refer children for early dental care, few dentists are comfortable treating children younger than two years old, fewer still provide restorative care, and many dentists do not accept Medicaid insurance. These realities mandate new strategies to meet the needs of children and families and effectively prevent and manage ECC. Additionally, cost savings are only likely to be realized if ECC prevention programs utilize support professionals, integrate disease management, and seek innovative reimbursement models from third-party payers.<sup>23</sup>

**Research.** One of the major findings from the first ECC conference in 1997 was that there were large gaps in our knowledge about ECC, especially regarding prevention and treatment. These gaps and the related recommendations for future research were succinctly enumerated by Horowitz in 1998.<sup>27</sup> Over the past 17 years, there has been substantial research activity about ECC, leading to a better understanding of the disease process, risk factors, prevention, and treatment. This research, as summarized in these proceedings, indicates caries prevention approaches that have not been shown to be effective (such as CHX, iodine, and remineralizing agents) as well as approaches that have positive results in preschool children (such as fluoride toothpaste and fluoride varnish, MI for the promotion of pediatric oral health behaviors, and caries risk assessment methods). Further studies are needed on nonsupervised toothbrushing with fluoridated toothpaste and fluoride varnish applications in community settings to understand the effectiveness of these products in daily practice with infants and toddlers.

Other approaches with encouraging results may be applicable in treating ECC. A number of clinical trials have examined the effectiveness of xylitol-containing products, some with positive results and others with no significant differences between treatment and controls. A 2015 Cochrane review concluded that “there is insufficient high-quality evidence to prove that xylitol prevents” caries.<sup>19</sup> It still needs to be determined whether xylitol-containing products are efficacious in preventing caries in preschool children. Silver fluoride is another product that has emerged as a potential preventive and treatment agent for ECC. However, rigorous clinical trials are needed to determine its effectiveness prior to community dissemination. There also is a need for studies on the effectiveness of dental sealants and use of temporary restorations in preschool children. While these have been shown to be effective in older children, their effect in younger children has not been established.

The weight of evidence indicates the need to go beyond traditional dentistry approaches and integrate prevention and other methods of disease management to ensure long-term success in preventing ECC and caring for ECC children. While the current evidence for medical ECC management may not yet be conclusive, it is promising. Our task as clinical scientists is to continue to answer these questions so that, over the coming decade, the aforementioned promising interventions can either be discarded or disseminated, depending upon the accumulated evidence.

**Clinical guidelines.** Clinical management guidelines and protocols provide for systematic and standardized approaches to diagnosis, prevention, and treatment of disease and are valuable tools for improving quality of care and health outcomes. Such guidelines are based on best evidence from the current

literature, the consensus judgment of expert panels, and the clinical experience of practitioners. Currently, there are several evidence-based guidelines for the screening, prevention, and treatment of ECC, such as the: American Academy of Pediatrics' Oral Health Risk Assessment Tool; guidelines for use of fluoridated toothpaste in children younger than six years old from the American Dental Association<sup>10</sup>; recommendations of the U.S. Preventive Services Task Force<sup>5</sup>; and guidelines on caries risk assessment and management for infants, children, and adolescents from the American Academy of Pediatric Dentistry.<sup>28</sup>

Such guidelines have the potential to promote implementation of best practices for pediatric oral health care in non-dental settings (e.g., pediatricians, family physicians) and dental settings by systematizing decision-making and fostering appropriate levels of preventive and restorative care. For example, a fluoride regimen for a four-year-old at low caries risk may be limited to simply brushing twice a day with fluoridated toothpaste; however, for a high caries-risk child, professionally applied fluoride varnish treatment would be added to this brushing regimen. Examples of chronic disease management in medical settings for children have demonstrated better and more cost-effective care for conditions such as diabetes and asthma. The goals of guidelines are to use the best available evidence to provide better care for individuals at a lower cost. However, additional efforts are needed to transfer evidence-based guidelines into clinical practice.

**Policy.** The cost of treating ECC in the United States is enormous. The U.S. Medical Expenditures Survey found that, in 2006, 19.4 percent of children younger than five years old had a dental expenditure total expense of \$729 million in that year.<sup>29</sup> Several studies of hospital emergency department visits also have reported high rates of non traumatic dental visits for preschool children.<sup>30</sup>

The payment models for provider reimbursement have been slow to adapt to scientific advances, including preventive procedures, caries risk assessment, and clinical guidelines. The main reimbursement method in dentistry remains the fee-for-service model that rewards procedure-based reparative treatment instead of management of the disease process.<sup>31</sup> Barriers to changing the payment system include purchasers of insurance programs, providers, and patients—all of whom may base their health care beliefs and desires on factors other than current evidence. Additionally, there is a requirement for training and education to implement evidence-based care and potential financing changes in order for providers to foster the changes into everyday practice.

Some studies in the medical arena aim to improve the quality of care and enhance efficiency.<sup>32,33</sup> Pay for performance models encourage adoption of evidence-based medical practice by aligning financial reward with improved outcomes. However, these models have not been widely adopted due in part to the challenges associated with measuring quality of care, practitioners avoiding high-risk patients, and the belief that performance-based payments ultimately would negatively affect practice outcomes. Novel payment models based on evidence-based and risk-based care that are acceptable to providers, third-payers, and patients are critically needed.

Other oral health policies, such as a dental visit by the age of one year old, need to be put into the context of evidence- and risk-based care. Several professional organizations, such as the American Academy of Pediatric Dentistry, American Dental Association, and American Association of Public Health

Dentists, recommend that all children have their first preventive dental visit during the first year of life, while one organization limits this recommendation to children who are at high risk for dental caries (American Academy of Pediatrics). There is general consensus that information about preventing dental caries and anticipatory guidance is important for all parents of young children. However, the unanswered questions are: (1) Do all children need to be referred to a dentist, or a pediatric dentist at age one year old? (2) Should only high caries-risk children be referred? (3) Can physicians, nurses, or other health care providers perform caries risk assessments and preventive oral health care that actually yields reductions in ECC incidence? (4) What are the measurable benefits and longer-term outcomes of such early childhood interventions?

We have seen over the past few years that Medicaid programs in almost all states are reimbursing physicians for some oral health interventions that may be performed during well-child visits. The growth in Accountable Care Organizations, fostered by the Affordable Care Act of 2010,<sup>34</sup> is likely to lead to greater integration of medical and oral health care services over time. Moving beyond the older models of separate dental homes and medical homes, perhaps the concept of a health home in which there is integrated oral health care by a physician/dental team may result in Berwick's aim of better oral health care for young children, better patient experience, and lower costs.<sup>35</sup>

## Conclusions

Based on the evidence-based reviews presented in these proceedings, other recent reports in the literature<sup>36</sup>, and the consensus opinion of the ECC Conference's advisory committee, the following conclusions can be made:

1. Currently, there are knowledge gaps in microbiological interventions, remineralizing approaches, and restorative care regarding early childhood caries management. Research, especially well-conducted clinical trials have improved and will continue to improve health care for children.
2. Existing effective management strategies for ECC include caries risk assessment, brushing with fluoride toothpaste, fluoride varnish applications, and certain behavioral interventions that affect preventive self-care practices.
3. Using clinical guidelines, science-based policies, and new strategies (e.g., chronic disease management and integrating oral health into overall health care) may yield better quality of care and improved outcomes for ECC at lower costs.
4. New outcomes-based payment models for oral health care services are likely to displace current procedure-based payment models as the U.S. health care system moves toward greater integration of health services and accountable care.

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