

*NIH Consensus Statement*  
***Diagnosis and Management of  
Dental Caries Throughout Life***



Volume 18, Number 1  
March 26–28, 2001  
National Institutes of Health  
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## About the NIH Consensus Development Program

NIH Consensus Development Conferences are convened to evaluate available scientific information and resolve safety and efficacy issues related to a biomedical technology. The resultant NIH Consensus Statements are intended to advance understanding of the technology or issue in question and to be useful to health professionals and the public.

NIH Consensus Statements are prepared by nonadvocate, non-Federal panels of experts, based on (1) presentations by investigators working in areas relevant to the consensus questions during a 2-day public session, (2) questions and statements from conference attendees during open discussion periods that are part of the public session, and (3) closed deliberations by the panel during the remainder of the second day and morning of the third.

This statement is an independent report of the consensus panel and is not a policy statement of the NIH or the Federal Government. The statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge of the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research.

## Reference Information

For making bibliographic reference to this consensus statement, it is recommended that the following format be used, with or without source abbreviations, but without authorship attribution:

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## Disclosure Statement

All of the panelists who participated in this conference and contributed to the writing of this consensus statement were identified as having no financial or scientific conflict of interest, and all signed conflict of interest forms attesting to this fact. Unlike the expert speakers who present scientific data at the conference, the individuals invited to participate on NIH consensus panels are selected specifically because they are not professionally identified with advocacy positions with respect to the conference topic or with research that could be used to answer any of the conference questions.

# Abstract

## Objective

To provide health care providers, patients, and the general public with a responsible assessment of currently available data regarding the diagnosis and management of dental caries throughout life.

## Participants

A non-Federal, non-advocate, 13-member panel representing the fields of dentistry, epidemiology, genetics, medicine, oral biology, oral radiology, pathology, periodontics, public health, statistics, surgery, and including a public representative. In addition, 31 experts in these same fields presented data to the panel and to a conference audience of approximately 700.

## Evidence

Presentations by experts; a systematic review of the dental research literature provided by the Agency for Healthcare Research and Quality; and an extensive bibliography of dental caries research papers, prepared by the National Library of Medicine. Scientific evidence was given precedence over clinical anecdotal experience.

## Consensus Process

Answering predefined questions, the panel drafted a statement based on the scientific evidence presented in open forum and the scientific literature. The draft statement was read in its entirety on the final day of the conference and circulated to the experts and the audience for comment. The panel then met in executive session to consider these comments and released a revised statement at the end of the conference. The statement was made available on the World Wide Web at <http://consensus.nih.gov> immediately after the conference. This statement is an independent report of the panel and is not a policy statement of the NIH or the Federal Government.

## Conclusions

This Consensus Development Conference, the first sponsored by the NIH on dental caries, provided an excellent venue to describe the great success that has been achieved in reducing caries prevalence. More importantly, it provided a public forum to review both the strengths and weaknesses of current dental caries research and clinical procedures. Effective preventive practices, such as the use of fluoride, sugarless products, and dental sealants were reconfirmed and clinical studies to identify more conservative but more effective nonsurgical and surgical approaches are to be applauded. However, it was evident that current diagnostic practices are inadequate to achieve the next level of caries management in which noncavitated lesions are identified early so that they can be managed by nonsurgical methods. Some new and sensitive diagnostic approaches were presented to the panel, but concern was raised about the use of histological confirmation of caries presence as an appropriate gold standard. The resolution of these issues requires that surrogate markers, validated by histological confirmation, be developed. Once these surrogate markers of dental caries activity are validated, rapid advances in our understanding of the caries process are certain to follow.

In spite of optimism about the future, the panel was disappointed in the overall quality of the clinical data set that it reviewed. Far too many studies used weak research designs or were small or poorly described, and consequently had questionable validity. There was a clear impression that clinical caries research is underfunded, if not undervalued. Moreover, incomplete information on the natural history of dental caries, the inability to accurately identify early lesions and/or lesions that are actively progressing, and the absence of objective diagnostic methods are troubling. Several systematic reviews of the literature presented at the Consensus Development Conference concluded that the majority of the

studies were inadequate, and it is clear that a major investment of research and training funds is required to seize the current opportunities.

This is not to say that the diagnostic, preventive, and treatment techniques currently used do not work, but rather that earlier studies to support their efficacy do not meet current scientific standards. Indeed, given the dramatic improvements in reducing dental caries prevalence in the past 30 years, both consumers and health professionals should not depart from the practices which are likely to have contributed to this oral health improvement, including the use of a variety of fluoride products, dietary modification, pit and fissure sealant, improved oral hygiene, and regular professional care. In addition, pending new data, clinicians should apply both preventive and therapeutic interventions in the manner in which they have been studied. When solid confirmation of the effectiveness of promising new diagnostic techniques, nonsurgical treatments of noncavitated lesions, and conservative surgical interventions for cavitated lesions are obtained, dental health professionals and the public should embrace them rapidly in anticipation of attaining still higher levels of oral health. None of these anticipated advances will be achieved, however, in the absence of a progressive, third-party payment system that acknowledges its responsibility to compensate providers adequately to ensure that the next generation of conservative therapy can be enjoyed by the American people.



## Introduction

There has been remarkable progress in the reduction of dental caries (tooth decay) in the United States over the past 30 years. The existence of children with no dental caries, a rarity in the past, is no longer unusual. The use of fluoride in public water supplies, in toothpaste, and in professional dental products, improved oral hygiene, and increased access to dental care have played major roles in this dramatic improvement. Nevertheless, dental caries remains a significant problem. Nearly 20 percent of children between the ages of 2 and 4 have detectable caries, and by the age of 17 almost 80 percent of young people have had a cavity — a late manifestation of dental caries infection. In addition, more than two-thirds of adults age 35 to 44 years have lost at least one permanent tooth due to dental caries, and older adults suffer from the problem of root caries. Moreover, there remain large segments of the population in which the disease remains a major problem. These health disparities, detailed in the Surgeon General's Report on Oral Health, tend to be clustered in minority children, the economically underprivileged, older persons, the chronically ill, and institutionalized persons — the very populations with the lowest access to dental care.

It should be noted that dental caries is an infectious, communicable disease resulting in destruction of tooth structure by acid-forming bacteria found in dental plaque, an intraoral biofilm, in the presence of sugar. The infection results in loss of tooth minerals that begins on the outer surface of the tooth and can progress through the dentin to the pulp, ultimately compromising the vitality of the tooth. During the past few decades, changes have been observed not only in the prevalence of dental caries, but also in the distribution and pattern of the disease in the population. Specifically, it has been observed that the relative distribution of dental caries on tooth surfaces has changed, and the rate of lesion progression through the teeth is relatively slow for most people. These changes

have important implications for diagnosis and management of incipient lesions, predicting caries risk, and conducting effective disease prevention and management programs for individuals and populations.

In order to make continued progress in eliminating this common disease, new strategies will be required to provide enhanced access for those who suffer disproportionately from the disease; to provide improved detection, risk assessment, and diagnosis; and to create improved methods to arrest or reverse the noncavitated lesion while improving surgical management of the cavitated lesion.

In an effort to optimize the identification of improved caries diagnostic, prevention, and treatment strategies, and to assess the quality of the data on existing diagnostic and treatment paradigms, the National Institutes of Health commissioned a Consensus Development Conference (CDC) on Diagnosis and Management of Dental Caries Throughout Life. The CDC explored these issues in a public forum on March 26–28, 2001, so that health care providers and the general public can make informed decisions about this important public health issue.

During the first day-and-a-half of the conference, experts presented the latest dental caries research findings to an independent, non-Federal Consensus Development Panel. After weighing the scientific evidence the panel wrote a draft statement that was presented to the audience on the third day. The consensus statement addressed the following key questions:

- What are the best methods for detecting early and advanced dental caries (validity and feasibility of traditional methods; validity and feasibility of emerging methods)?

- What are the best indicators for an increased risk of dental caries?
- What are the best methods available for the primary prevention of dental caries initiation throughout life?
- What are the best treatments available for reversing or arresting the progression of early dental caries?
- How should clinical decisions regarding prevention and/or treatment be affected by detection methods and risk assessment?
- What are promising new research directions for the prevention, diagnosis, and treatment of dental caries?

This conference was sponsored by the National Institute of Dental and Craniofacial Research (NIDCR) and the NIH Office of Medical Applications of Research. The cosponsors included the National Institute on Aging and the U.S. Food and Drug Administration.

## **What Are the Best Methods for Detecting Early and Advanced Dental Caries (Validity and Feasibility of Traditional Methods; Validity and Feasibility of Emerging Methods)?**

Observations and studies during the past two decades have indicated that diagnostic and treatment paradigms may differ significantly for large, cavitated lesions versus early, small lesions and demineralized areas on tooth surfaces. The essential anatomic-pathophysiologic problem is that the carious lesion occurs within a small, highly mineralized structure following penetration through the structure's surface in a manner which may be difficult to detect using current methods. Additionally, carious lesions occur in a variety of anatomic locations, often adjacent to existing restorations, and have unique aspects of configuration and rate of spread. These differences make it unlikely that any one diagnostic modality will have adequate sensitivity and specificity of detection for all sites. The application of multiple diagnostic tests to the individual patient increases the overall efficacy of caries diagnosis. Existing diagnostic modalities require stronger validation, and new modalities with appropriate sensitivities and specificities for different caries sites, caries severities, and degrees of caries activity are needed.

A systematic review, based on predefined criteria, concluded that studies of reliability and reproducibility of existing diagnostic modalities, which included visual-tactile, radiographic, and electrical conductance examinations, were not strong. The most significant problems with these studies were weak study designs; variability of examiner calibration; differences in criteria for lesions; lack of standards for histological validation; lack of adequate numbers of studies on several modalities and types of caries; and the sensitivity and specificity of caries detection. Also, given the acceptance criteria of the systematic review, which excluded all studies without histologic confirmation, the results regarding the validities of the examined modalities were ambiguous.

A number of studies excluded by the systematic review were also addressed. The use of sharp explorers in the detection of primary occlusal caries appears to add little diagnostic information to other modalities and may be detrimental. Studies employing receiver operating characteristic (ROC) analyses have shown radiology to have acceptable diagnostic efficacy in detecting larger cavitated lesions in numerous *in vitro* and *in vivo* studies. There was agreement that the literature is weak in the areas of diagnosis of caries on root surfaces and adjacent to existing restorations. The problems of assessing the microbiological load of demineralized dentin adjacent to or beneath existing restorations, and differentiating between residual and secondary caries, are substantial and important. Digitally acquired and post-processed images have great potential in the detection of noncavitated caries and in the diagnosis of secondary caries. Promising new diagnostic techniques are emerging, including fiber-optic transillumination and light and laser fluorescence. These new modalities and developing digital imaging systems require robust laboratory and clinical evaluation.

Existing diagnostic modalities appear to have satisfactory sensitivity and specificity in diagnosing substantial, cavitated, dental caries; specifically radiographic methods are essential in diagnosing interproximal carious lesions. However, these modalities do not appear to have sufficient sensitivity or specificity to efficaciously diagnose noncavitating caries, root surface caries, or secondary caries. There is currently no diagnostic modality which can differentiate between microbiologically active caries and demineralized dentin without caries activity beneath a restoration. This is a critical weakness in view of the significant percentage of restorations inserted to replace existing restorations. The need for the identification and clinical staging of the presence, activity, and severity of dental caries is of paramount importance in the deployment of treatment strategies that employ increasingly important nonsurgical modalities, such as fluoride, antimicrobials, sealants, and no treatment. Some diagnostic modalities are currently in various stages of development and testing; these modalities will need to be evaluated, using rigorously controlled clinical trials. Such studies will promote true staging of carious lesions, based on highly sensitive and specific diagnoses, followed by appropriate, linked, treatment-planning decision algorithms.

## What Are the Best Indicators for an Increased Risk of Dental Caries?

Recent decades have seen a remarkable decline in dental caries in the United States. The level of caries incidence, however, is not evenly distributed in the population. Overall, 20 percent of the population bears at least 60 percent of the caries burden while fewer than 5 percent of adults are caries-free. Thus, effective dentistry requires early identification of children at high risk for extensive caries so that they may receive early and intense preventive intervention, as well as those at low risk so as to reduce unnecessary care and associated expenditures. Caries incidence changes in adulthood and in geriatric populations, and risk and risk indicators may differ due to changes in host and environmental characteristics. Accurate caries prognosis throughout the life span, however, can support an appropriate, individualized level of care for each patient and a more effective use of health care resources for the individual and for the population. In addition, as dentistry moves towards earlier detection of lesions and a more preventive rather than restorative orientation, good risk assessment will be essential for improving the predictive values of new screening and diagnostic methods by preselecting at-risk subpopulations.

Numerous risk indicators, that is, characteristics or measurements that assist in the prediction of caries, whether or not they are involved in caries causation, have been suggested for children. Unfortunately, more of the supportive data come from cross-sectional correlations with accumulated caries experience than from prospective, protocol-based incidence studies. The prospective studies employed different combinations of potential predictors in a variety of populations, varied considerably in sample size and quality, and have not produced a broadly applicable index or set of criteria for risk assessment. More and higher-quality comprehensive, longitudinal, multifactor studies of implicated risk indicators are needed to obtain firm support for their associations with caries incidence, to clarify the strengths of these associations in differing populations, and to reveal

the extent to which the risk indicators provide independent as opposed to redundant information. In addition, although the nature of the disease process suggests that many of the proposed indicators may well be appropriate throughout life, validation studies in adult populations are largely absent or incomplete. Nevertheless, in practice there are several readily determinable indicators that together provide helpful guidance when dealing with otherwise healthy persons and some well-validated medical or disability conditions that place individuals at heightened caries risk.

Thus far, the most consistent predictor of caries risk in children is past caries experience. In addition, there is evidence of matrilineal transmission of mutans streptococci in early childhood. Hence, the presence of caries in the mother and siblings increases risks for the child.

Regular brushing of tooth surfaces using a fluoride-containing dentifrice, reduces caries risk. Conversely, inadequate exposure to fluoride confers increased risk. Conditions that compromise the long-term maintenance of good oral hygiene are also positively associated with caries risk. These include certain illnesses, physical and mental disabilities, and the presence of existing restorations or oral appliances.

Fermentable carbohydrate consumption fuels acid formation and demineralization and is associated with caries, particularly in the absence of fluoride. The amount, consistency, and frequency of consumption determine the degree of exposure. Long-term regular doses of medications containing glucose, fructose, or sucrose may also contribute to caries risk.

Medical conditions such as Sjögren's syndrome, pharmacological agents with xerostomic side effects, and therapeutic radiation to the head and neck, lower salivary flow rate to pathological levels and dramatically elevate a patient's risk of caries. This suggests that normal salivary flow rate is protective against caries. Some studies indicate that low buffering capacity, low salivary IgA, and low salivary calcium and phosphate are weakly linked to increased caries as well.

Mutans streptococci is an established etiologic agent for caries, and its presence clearly indicates the potential for cariogenic activity. However, its presence alone is no more than weakly predictive of clinical caries activity.

While some of the risk indicators known for children may well be applicable across all ages, some may differ across ages in the way they act or in their degrees of importance, while other risk indicators must be considered distinctive for adult and elderly populations. Thus, the inability to maintain good oral hygiene and xerostomia are risk factors of special significance among the elderly, and gingival recession uniquely increases the risk of root caries in elderly populations by exposing previously protected root surfaces to cariogenesis.

Low indices of socioeconomic status (SES) have been associated with elevations in caries, although the extent to which this indicator may simply reflect previous correlates is unknown. Low SES is also associated with reduced access to care, reduced oral health aspirations, low self-efficacy, and health behaviors that may enhance caries risk.

Caries is an etiologically complex disease process. It is likely that numerous microbial, genetic, immunological, behavioral, and environmental contributors to risk are at play in determining the occurrence and severity of clinical disease. Assessment tools based on a single risk indicator are therefore unlikely to accurately discriminate between those at high and low risk. Multiple indicators, combined on an appropriate scale and accounting for possible interactions, will certainly be required.

# What Are the Best Methods Available for the Primary Prevention of Dental Caries Initiation Throughout Life?

In the last 30 years a number of community- and individual-level strategies for preventing caries, notably water fluoridation and the use of fluoridated toothpastes, have been highly successful. This Consensus Conference did not evaluate the evidence for effectiveness of water fluoridation. This question has been the subject of public debate. It is widely accepted as both effective and of great importance in the primary prevention of dental caries. In light of this remarkable accomplishment, this portion of the report focuses on interventions that may provide additional benefit in the primary prevention of dental caries in individual patients.

Some of the evidence on which this report is based addressed the effectiveness of interventions when used in populations not specifically selected on the basis of having high risk for dental caries. Almost all of the relevant studies involved populations of children between 6 and 15 years of age. The interventions included application of acidulated phosphate fluoride gel (APF), fluoride varnish, chlorhexidine gels, pit and fissure sealants, and the use of dentrifices and other products containing noncariogenic sweeteners.

*Acidulated phosphate fluoride gel (APF):* Evidence for the efficacy of APF gel applied 1–2 times per year was consistently positive.

*Fluoride varnish:* The evidence for the benefit of applying fluoride varnish to *permanent* teeth is generally positive. In contrast, the evidence for effectiveness of fluoride varnish applied to *primary* teeth is incomplete and inconsistent.

*Chlorhexidine gels:* The evidence for the use of chlorhexidine gel is moderately strong, although many of the studies demonstrating its effectiveness used concomitant preventive measures.

*Pit and fissure sealants:* Pit and fissure sealants have been demonstrated to be effective in the primary prevention of caries, and their effectiveness remains strong as long as the sealants are maintained.

*Products containing noncariogenic sweeteners:* Noncariogenic sweeteners have been delivered to teeth as constituents of chewing gum, hard candy, and dentifrices. The evidence for both sorbitol and xylitol is positive, although the evidence for xylitol is stronger. Almost all studies of these agents included other interventions, such as fluoridated dentifrices, dietary modification, and oral hygiene instruction.

*Combination interventions:* There is reason to believe that preventive strategies may be more effective when they are combined than when they are administered individually. Numerous combination interventions have been studied. These include combined fluoride interventions, chlorhexidine plus fluoride, chlorhexidine plus sealants, and chlorhexidine plus xylitol. All studies included instructions in dietary modification and oral hygiene and instructions for control and experimental groups. In general, these combination treatments have been shown to be effective in preventing caries in children.

Consistent positive evidence was found for the effectiveness of all reviewed preventive interventions in unselected populations of children. Furthermore, the effectiveness of these interventions appears to increase as baseline DMFS (decayed, missing, and filled surfaces) scores increase, suggesting that they may be particularly effective in high-risk populations while raising questions about their cost-effectiveness in low-risk populations.

When review of the evidence is confined to studies aimed at high-risk individuals, there is a relatively small number of methodologically strong, sufficiently large studies specifically addressing the effectiveness of primary prevention interventions, with the exception of fluoride varnish, for which there is fair evidence of effectiveness. For these reasons, the panel concluded that carefully designed studies with adequate power and sufficiently long follow-up may be necessary to select the best intervention or combination of interventions that should be applied to selected groups.

The panel makes no comment on primary prevention of secondary caries, or on primary prevention of either occlusal or interproximal caries in adults, as no evidence was available to address these questions. Evidence regarding primary prevention of root caries is also very limited. Additional studies will be required to define optimal preventive intervention strategies for these conditions.

## What Are the Best Treatments Available for Reversing or Arresting the Progression of Early Dental Caries?

The caries process is endemic and potentially both preventable and curable. The latter can be achieved by identifying and arresting or reversing the disease at an early stage. Although more research is needed, clinical strategies to do this already exist. These strategies include application of fluorides, chlorhexedine, sealants, antimicrobials, salivary enhancers, and patient education. Fluorides and chlorhexedine can be delivered as varnishes, rinses, or gels. Many of these same strategies are also appropriate for primary prevention.

A number of the above treatment methods have been tested in clinical populations. However, the quantity and quality of the data vary by treatment.

1. *Fluoride*. The research data on fluorides in water and dentifrices support their efficacy. The data also support the use of fluoride varnishes. For rinses and gel applications the evidence is promising but not definitive.
2. *Chlorhexedine*. For varnishes and gels, the data are promising. Research data showing effectiveness of chlorhexedine rinses are lacking.
3. *Sealants*. The use of pit and fissure sealants is supported by the data.
4. *Combinations*. Combinations of chlorhexedine, fluoride, and/or sealants are suggestive of efficacy.
5. *Antimicrobials*. Although mutans streptococci is recognized as part of the pathology of caries and therefore an antimicrobial approach would seem reasonable, current data are inadequate to support antimicrobial treatments other than chlorhexedine and fluorides, both of which have antibacterial properties.

6. *Salivary Enhancers*. Although there are indications that pathologically low salivary flow, as a consequence of Sjögren's syndrome or as an effect of head/neck radiation treatment or xerostomic medications, is associated with caries, there is no evidence that low normal salivary flow produces a similar outcome.
7. *Behavioral Modification*. Most interventions require patient adherence, and current data provide some support for the efficacy of office-based behavioral interventions.

While there has been considerable progress in dealing with dental caries, it is still epidemic, particularly among vulnerable groups. The detection and treatment of early carious lesions by nonsurgical measures has considerable potential to further the reduction of this burden. Although more research on early dental caries is needed, data on primary prevention are sufficient to make some recommendations for dental practice. Practice would be further enhanced, however, by further research that addressed caries in the adult population, secondary caries, and root caries.

In the development of caries treatment, dentistry has moved historically from extraction to surgical restoration. Identification of early caries lesions and treatment with non-surgical methods, including remineralization, represent the next era in dental care.

This stopping and reversing of caries is dependent on early and accurate diagnosis, which remains a developing field. If maximum benefits are to be obtained, improved diagnosis is essential.

## How Should Clinical Decisions Regarding Prevention and/or Treatment Be Affected by Detection Methods and Risk Assessment?

At this time the panel senses a paradigm shift in the management of dental caries toward improved diagnosis of early noncavitated lesions and treatment for prevention and arrest of such lesions. Restorations repair the tooth structure, do not stop caries, and have a finite life span. They are themselves susceptible to disease. With the defining of caries as a multifactorial, multistage process extending from infection to demineralization and cavitation, clear diagnostic and staging criteria as well as a clear understanding of risk and prognosis are needed to determine dental treatment options. Evidence suggests that there are nonsurgical options for prevention and arrest and reversal of early noncavitated lesions. The decision not to treat, or to prevent, arrest, reverse, and/or surgically treat, are choices based upon these factors. Risk indicators also are considered in estimating future disease. Thus, diagnostic techniques and the influence of risk indicators need to be evaluated for all teeth surfaces and patients of all ages.

Although the evidence shows that many diagnostic methods are less than desirably accurate, current diagnostic interpretations still must be used until new, more sensitive, techniques are available and validated. The evidence-based reports supported previous caries experience and pathologically low salivary flow rate as indicators of significant risk. Most studies from the systematic reviews involved children and excluded root caries, adults, and anterior teeth. Therefore, the clinician must extrapolate reportedly successful preventive and arresting/remineralization techniques from children to adults, root caries, and anterior teeth. In the absence of clear evidence on adequately sensitive diagnostic methods for detecting early noncavitated lesions and risk assessment indicators, clinicians need guidelines for treatment.

Because research is still evolving in these areas, a series of guidelines created by consensus groups using currently available information is needed for patient treatment. In the absence of definitive evidence, choices must come from highly probable information. Selection of interventions and evaluations of known risks need to be guided by quality studies and literature.

Other reviews of literature and higher quality clinical studies are needed to contribute to these guidelines. From guidelines, appropriate treatment(s) can be chosen. Examples of such guidelines already exist.

Longitudinal studies with outcomes assessments are needed to determine the success of specific treatments. Long-term retention and functioning of treated teeth without recurrence of caries are essential outcome criteria. As evidence of better diagnostic methods, improved treatments, and clearer definition of risk indicators is established, treatment guidelines can be appropriately refined and individualized for the patient.

The dental profession has been successful in promoting caries prevention. Current information indicates that the opportunity now exists to extend prevention and treatment of caries to nonsurgical methods. These include further prevention, remineralization, and arrest of early noncavitated lesions. Controlled longitudinal studies that inform third-party payers can do much to support the adoption of more advanced diagnostic, preventive, and nonsurgical techniques into the practice of dentistry. Studies that explore a range of reimbursement options may be helpful in identifying reimbursement methods that both encourage and reward preventive nonsurgical dental treatment. Practicing dentists must have adequate incentives to apply these findings. Educational institutions and their curricula, state and national dental boards and board examiners, and accreditation agencies must also support the growing evidence for prevention and non-surgical treatment where indicated.

## **What Are Promising New Research Directions for the Prevention, Diagnosis, and Treatment of Dental Caries?**

In prefacing the listing of promising new research areas, it should be noted that the panel identified significant concerns about the nature of previous clinical research on dental caries. The science of clinical research design has advanced rapidly in the past several decades. However, the panel deemed that the design and execution of caries trials and epidemiological studies have not kept pace with the current standard. Many previous clinical caries studies were neither well designed nor well analyzed. They tended to be small, underpowered, improperly controlled, and incompletely described. Thus, when subjected to modern systematic review techniques, the overall quality of the database was judged usually to be in the range of poor to fair. Accordingly, NIDCR should expand significantly its clinical and research program to match the recent expansion in clinical training to promote improvement in the quality, size, and reporting of clinical dental caries studies and the number of well-trained clinical investigators. In the future, it will be imperative that markedly improved techniques be applied in each clinical study. In the interim, it would behoove clinical caries researchers to consult widely with clinical research methodologists and to ensure that their studies adhere to national and international criteria for reporting of studies as used in systematic reviews. In this manner, the successful exploration of the clinical opportunities listed below will be facilitated.

## Major Clinical Caries Research Directions

1. The *Epidemiology of Primary and Secondary Caries* needs to be systematically studied with population cohort studies that collect information on natural history, treatment, and outcomes across the age spectrum.
2. Research into *Diagnostic Methods*, including established and new devices and techniques, is needed. Development of standardized methods of calibrating examiners is needed.
3. *Clinical Trials* of established and new treatment methods are needed. These should conform to contemporary standards of design, implementation, analysis, and reporting. They should include trials of efficacy.
4. Systematic research on caries *Risk Assessment* is needed using population-based cohort techniques.
5. Studies of *Clinical Practice*, including effectiveness, quality of care, outcomes, health-related quality of life, and appropriateness of care are needed.
6. *Genetic Studies* are necessary to identify genes and genetic markers of diagnostic, prognostic, and therapeutic value.

## Conclusions

This Consensus Development Conference, the first sponsored by the NIH on dental caries, provided an excellent venue to describe the great success that has been achieved in reducing caries prevalence. More importantly, it provided a public forum to review both the strengths and weaknesses of current dental caries research and clinical procedures. Effective preventive practices, such as the use of fluoride, sugarless products, and dental sealants were reconfirmed, and clinical studies to identify more conservative but more effective nonsurgical and surgical approaches are to be applauded. However, it was evident that current diagnostic practices are inadequate to achieve the next level of caries management, in which noncavitated lesions are identified early so that they can be managed by nonsurgical methods. Some new and sensitive diagnostic approaches were presented to the panel, but concern was raised about the use of histological confirmation of caries presence as an appropriate gold standard. The resolution of these issues requires that surrogate markers, validated by histological confirmation, be developed. Once these surrogate markers of dental caries activity are validated, rapid advances in our understanding of the caries process are certain to follow.

In spite of optimism about the future, the panel was disappointed in the overall quality of the clinical data set that it reviewed. Far too many studies used weak research designs or were small or poorly described, and consequently had questionable validity. There was a clear impression that clinical caries research is underfunded, if not undervalued. Moreover, incomplete information on the natural history of dental caries, the inability to accurately identify early lesions and/or lesions that are actively progressing, and the absence of objective diagnostic methods are troubling. Several systematic reviews of the literature presented at the Consensus Development Conference concluded that the majority of the studies were inadequate, and it is clear that a major investment of research and training funds is required to seize the current opportunities.

This is not to say that the diagnostic, preventive, and treatment techniques currently used do not work, but rather that earlier studies to support their efficacy do not meet current scientific standards. Indeed, given the dramatic improvements in reducing dental caries prevalence in the past 30 years, both consumers and health professionals should not depart from the practices which are likely to have contributed to this oral health improvement, including the use of a variety of fluoride products, dietary modification, pit and fissure sealant, improved oral hygiene, and regular professional care. In addition, pending new data, clinicians should apply both preventive and therapeutic interventions in the manner in which they have been studied. When solid confirmation of the effectiveness of promising new diagnostic techniques, nonsurgical treatments of noncavitated lesions, and conservative surgical interventions for cavitated lesions are obtained, dental health professionals and the public should embrace them rapidly in anticipation of attaining still higher levels of oral health. None of these anticipated advances will be achieved, however, in the absence of a progressive, third-party payment system that acknowledges its responsibility to compensate providers adequately to ensure that the next generation of conservative therapy can be enjoyed by the American people.



# Consensus Development Panel

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