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ABSTRACT

Following the consideration of several recent systematic and other reviews, there is a growing professional and scientific consensus that caries measurement methodology in caries clinical trials (CCT) should be updated to reflect progress made elsewhere in cariology. In this paper, therefore, "modern" means accepted in contemporary dental research and dental practice on the basis of sound research evidence—not necessarily new or requiring the use of new technology. Caries measurement should be seen in the context of the objectives of modern clinical caries management and the continuum of disease states, ranging from sub-surface carious changes through to more advanced lesions. Measurement concepts can be applied to at least three levels: the tooth surface, the individual, or the group/population. All are relevant to CCTs. Modern clinical caries management can be seen as comprised of seven discrete but linked steps (Steps 2, 3, and 4 are directly concerned with measurement.): (1) 'Caries detection' represents a yes/no decision as to whether caries is present; (2) lesion measurement assesses defined stages of the caries process, taking into account the histopathological morphology and appearance of different sizes and types of lesion and the diagnostic threshold(s) being used; (3) lesion monitoring by repeated measures at a series of examinations is used when lesions are less advanced than the stage judged to require operative intervention (A comparison of serial measurements permits the efficacy of preventive care aiming either to arrest or to reverse the lesion to be assessed.); (4) caries activity measures would be very valuable, but are relatively poorly developed and tested at present; (5) diagnosis, prognosis, and clinical decision-making are the important human processes in which all the information obtained from steps 1 to 4 is synthesised; (6) interventions/treatments, both preventive and operative, are now routinely used for caries management; and (7) outcome of caries control/management assesses caries management by examining evidence on the long-term outcomes. A challenge for the future is to define a range of optimal caries measurement methods—in use or in development in recent trials, in clinical practice, and/or in caries epidemiology—that will best contribute to more efficient, modern caries clinical trials.

KEY WORDS: caries measurement, caries detection, caries monitoring, caries activity.

Modern Concepts of Caries Measurement

INTRODUCTION

This paper seeks to outline modern concepts of caries measurement and set these within the framework of contemporary, evidence-based, clinical caries management. This is in line with the first objective of the International Consensus Workshop on Caries Clinical Trials (ICW-CCT), which is to "critically review modern caries definitions and measurement concepts" and is of key importance in setting the scene for the design of appropriate, efficient, high-quality clinical trials of caries-preventive agents and procedures relevant to dental practice in the 21st century.

This paper builds on the findings of several recent systematic reviews conducted for the National Institutes of Health Consensus Development Conference on Dental Caries (Horowitz, 2004) and other purposes (Ismail, 1999) as well as other reviews, both pre-published (Ismail, 1997; Kingman and Selwitz, 1997; Pitts, 1997a,b, 2001) and undertaken for this Workshop (Featherstone, 2004; Ismail, 2004; Kidd, 2004; Stamm, 2004). These indicate that there is a growing professional and scientific consensus that caries measurement methodology in caries clinical trials (CCT) should be updated to reflect progress made elsewhere in the science of cariology and in clinical caries management.

DEFINITION OF TERMS

For the purposes of this paper and the ICW-CCT, terms are defined as follows:

"Modern" means accepted in contemporary dental research and dental practice on the basis of sound research evidence. It does not necessarily mean new, nor does it require the use of new technology. This is because several of the caries measurement concepts which have been developing and in use in other areas of dentistry for some years have not yet been adopted in the caries clinical trials (CCT) arena, which (in terms of core caries measurement methods) has apparently stagnated. There is a growing consensus that CCT methodology should be updated and refined to reflect these modern concepts and more recent, international, research evidence (Horowitz, 2004; Stamm, 2004).

"Concepts" of caries measurement should be seen as theoretical frameworks based upon both synthesized evidence and contemporary practice. These are framed in the context of the objectives of modern caries management and from the perspective of what is needed to fulfill the ICW-CCT mission—that is, to reach consensus about the designs of protocols for caries clinical trials, which are scientifically acceptable as pivotal evidence of the anti-caries efficacy of oral care products.

"Caries" has been defined in many ways in the literature. Modern evidence reveals that there is a continuum of disease states ranging from subclinical, subsurface changes through to more advanced, clinically detectable subsurface caries (with so-called "intact" surface layers), to various stages of more advanced lesion with microscopic and later macroscopic cavitation of enamel and significant involvement of dentin (Featherstone, 2004; Kidd, 2004). Therefore, dental caries is more than just a "cavity"; it is a disease process.

Caries **"Measurement"** has to do with looking at how defined stages of the caries process are quantified, graded, and recorded for results to be used in assessing the outcome of a Caries Clinical Trial. The measures have to be compatible with what is known of the caries process and the intrinsic limitations of the diagnostic modalities used. They should also be compatible with the objectives of modern clinical caries management.

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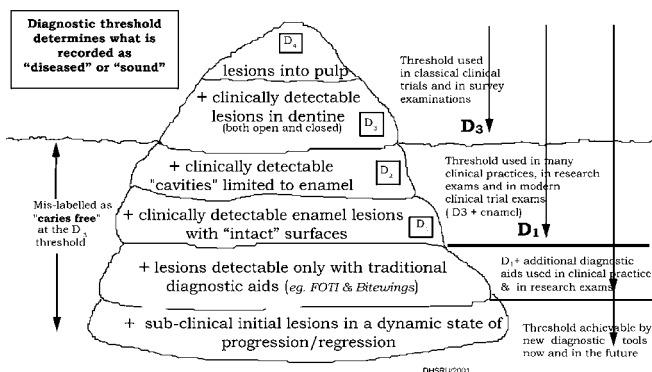


Figure 1. The “iceberg of dental caries”—diagnostic thresholds in clinical trials and practice.

CARIES MEASUREMENT IN THE CONTEXT OF MODERN CLINICAL CARIES MANAGEMENT

Caries management and measurement concepts can be applied to at least three levels: the tooth surface and the individual or the group/population level. All are relevant to CCTs. Traditionally, caries is recorded (and measured) at the level of the individual tooth surface or caries predilection site. This has logical advantage from the point of view of capturing as much information about changes in the caries process as possible during the trial, but only if this information is subsequently used fully in the analysis. Often, data on transitions between caries status over time measured in trials at the individual surface level seem not to have been used in final analyses of trial outcomes. Examination of caries outcomes by consolidating caries measures to the level of each individual has both clinical and statistical attractions and can help explain and describe the performance of interventions, while ultimately the result of the trial will depend upon appropriate measures being compared across randomly selected trial groups. (These aspects are considered further in other papers in the series).

For this paper, modern clinical caries management concepts can be seen as comprised of seven discrete but linked steps: (1) caries detection; (2) lesion measurement; (3) lesion monitoring by repeated measures; (4) caries activity measures; (5) diagnosis, prognosis, and clinical decision-making; (6) interventions/treatments; and (7) outcome of caries control/management.

Since caries measurement should be seen in the overall context of clinical disease prevention and management, each of these steps will be outlined below, but steps 2, 3, and 4 (which are directly concerned with caries measurement) will be considered in greater detail.

(1) Caries Detection

This is essentially a yes/no decision as to whether caries as a disease process is present in, for example, a particular tooth surface. The result obtained depends upon several factors, including: the true state of the tooth surface, the ultimate “detection potential” of the method used, the method’s accuracy and reliability in clinical use, and the influence of any detection threshold that has been chosen. Further detailed considerations, including the importance of validation, can be found in later papers in this series (Huysmans, 2004) and elsewhere (ten Bosch and Angmar-Månsson, 2000), but are beyond the scope of this paper.

(2) Lesion Measurement

This assesses defined stages of the caries process. Caries measurement methods must take into account an understanding of the histopathological morphology and appearance of different sizes and types of lesions (Featherstone, 2004; Kidd, 2004) and be explicit regarding the diagnostic thresholds (Pitts and Fyffe, 1988) being used.

‘Diagnostic threshold’ is a term that describes the cut-off level used in an arbitrary decision of what to classify as diseased and what to

classify as ‘sound’. This can be represented in the form of an ‘iceberg’ (Fig. 1). The peak of the iceberg represents gross or frank dentin caries (the so-called D_4 and more limited D_3 caries lesions) which rests on increasingly larger volumes of less extensive decay at the D_2 (enamel cavity) and more limited D_1 (white- or brown-spot caries lesions) levels of severity. These ‘D’ labels for lesion severity have been used for many years (WHO, 1979; Pitts and Fyffe, 1988) and make up standardized diagnostic criteria such as those in the Dundee Selectable Threshold Method (DSTM) (Fyffe *et al.*, 2000a,b). Such systems allow data to be produced at a variety of diagnostic thresholds (typically D_3 , caries into dentin only, and D_1 , caries of enamel and dentin), depending on the particular requirement.

As the iceberg metaphor reveals, the choice of diagnostic threshold used can have a profound effect on the magnitude of caries recorded, reported, and used in analyses (Rimmer and Pitts, 1991). It should also be appreciated that at the iceberg’s base there is a large number of initial lesions, only some of which can be detected with existing or new diagnostic aids.

Although traditionally used relatively rarely in pivotal analyses, clinical caries measures involving “pre-cavitation” lesions have in fact been reported in caries clinical trials since at least 1965 (Marthaler, 1965) and have been described and used in clinical research and practice for a very long time before that (Backer-Dirks *et al.*, 1951; Ismail, 2004). In recent years, in addition to clinical visual/visuo-tactile examinations, bitewing radiography and fiber-optic transillumination (FOTI), a range of newer technologies has also been used to produce (potentially) more sensitive measures with which to assess lesions.

The need for non-cavitated (or ‘pre-cavitated’) enamel lesions to be detected and measured has been set out many times over many years (*e.g.*, Backer-Dirks, 1961; Marthaler, 1984; Nielson and Pitts, 1991; Ismail, 1997; Pitts, 1997a,b, 2000, 2001; Fejerskov and Baelum, 1998). Caries measurement systems enabling this to be carried out, although diverse in their detail (Ismail, 2004), have also been available for many years (*e.g.*, Backer-Dirks *et al.*, 1951; Marthaler, 1966; Ismail *et al.*, 1997; WHO, 1979; Nyvad *et al.*, 1998; Ismail, 1999; Fyffe *et al.*, 2000b; Pitts *et al.*, 2000).

In most of these measurement systems, lesions have been graded on the basis of the depth of penetration of the caries through the tooth tissues. Recently, there has been a greater focus on grading both initial and more developed lesions on the basis of surface continuity (or so-called ‘macroscopic cavitation’). The methodological issues which need to be recognized when measurement methods are compared include: the ambiguity and incompatibility of some grading systems with regard to lesions around the enamel dentin junction, clarity as to the use of clinical (as opposed to histological) estimates of dentinal involvement, and defining clearly what constitutes ‘non-cavitated’ lesions in both enamel and dentin (Pitts, 1997a).

(3) Lesion Monitoring by Repeated Measures

This is used at a series of examinations when lesions are less advanced than the particular stage judged to require operative intervention. It should be noted that this stage is itself variable among dentists, systems, and countries. A comparison of serial measurements over time permits an assessment of the behavior of lesions to be made and thus allows the efficacy of preventive care aiming to either arrest or reverse lesions to be determined. Such monitoring can traditionally be made from serial standardized clinical examinations or serial radiographic examinations. There are numerous examples over the years of this approach of monitoring caries by repeated measurements made according to a standard scoring system (Hollender and Koch, 1969; Pitts, 1984a, 1985; Kingman and Selwitz, 1997).

Attempts at monitoring small changes in lesions over time led to a recognition of the need to measure such changes with objective and, it was hoped, more reproducible and quantitative methods (Pitts, 1984b; Angmar-Månsson and ten Bosch, 1987). Initial attempts to use computer-aided image analysis of serial radiographic images showed promise (Pitts, 1986; Pitts and Renson, 1987), but these still used

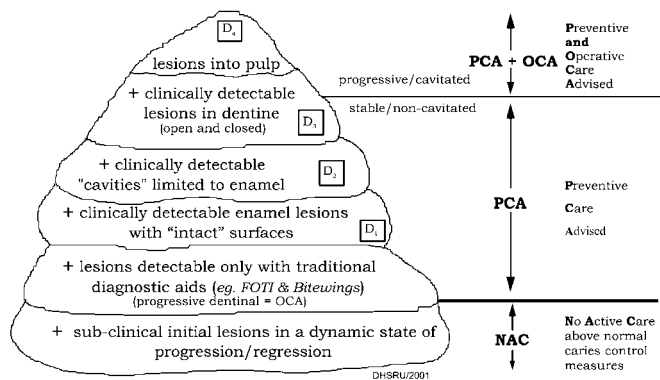


Figure 2. The "iceberg of dental caries" and contemporary treatment need/advice.

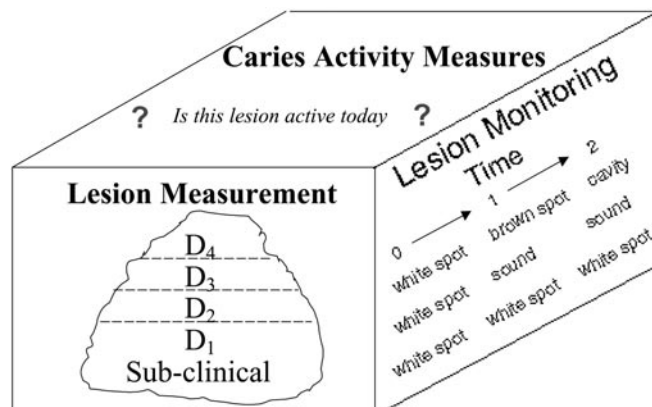


Figure 3. Three aspects of modern caries measurement.

ionizing radiation and were not developed commercially. The continuing need for new quantitative methods with which to make serial assessments of caries lesions has spurred a broad series of attempts to develop aids to the diagnosis and monitoring of lesions (these are referred to in later publications from the ICW-CCT).

(4) Caries Activity Measures

Although in comparison with the other aspects, this area has been relatively poorly developed and tested at present, clinicians ideally need to be able to measure the dynamic activity of each individual lesion to differentiate its current behavior from historical signs of past caries progression. Some promising modern criteria for clinical visual assessment include estimates of lesion activity from a single clinical examination (Nyvad *et al.*, 1998; Machiulskiene *et al.*, 2001; Ekstrand, 2002). Determination of caries activity from such assessments should be valuable in identifying lesions and patients suitable for inclusion in trials. At this stage, further validation is awaited with interest. This area should be seen as a direction for continuing research.

(5) Diagnosis, Prognosis, and Clinical Decision-making

These are the important human processes in which all the information obtained from steps 1 through 4 are synthesized. It should be emphasized that true diagnosis is not possible without such a synthesis and that there is continuing debate as to the combination of stage of lesion and patient circumstances which should translate into a restorative treatment decision. Individual patient factors and caries risk status are important considerations in these decisions. Although there are variations in the restorative thresholds used and recommended, there is a clearly apparent international trend in clinical practice for less surgical intervention and more prevention with preservation of tooth substance.

(6) Interventions/Treatments

Both preventive and operative treatments are now routinely used for clinical caries management. Since the aim of CCTs is to evaluate caries-preventive treatments, it is important to understand the clinical context in which successful products will be used. Fig. 2 shows an iceberg of contemporary treatment need and advice. In this illustration, the iceberg once again represents the continuum of the caries process, while the actions on the righthand side illustrate the type of care usually appropriate for the grade of severity of lesion depicted (Pitts and Longbottom, 1995).

The very small, background, subclinical lesions which are in overall balance between de- and remineralization need no active care (NAC) over and above normal caries control measures. A sizeable proportion of the iceberg is amenable to preventive care, and this is what is advised (PCA), while the status of existing lesions is monitored over time to assess the success of combined professional and self-care. For larger lesions which extend into dentin and are progressive and/or cavitated, typical care advised will consist of both preventive and operative elements (PCA + OCA). This is because without modification of the original etiological factors driving the caries process, restorations

can never be considered as effective in the long term, since the caries process will continue to be active.

Although this approach to clinical caries management, encompassing both primary and secondary prevention, is thought of by some as new (SIGN, 2000) and is often termed 'modern', it has in fact been advocated and used for very many years by numerous authorities and dentists in a variety of countries (see Pitts, 1992, 1997a,b; Pitts and Longbottom, 1995; Verdonshot *et al.*, 1999; Ismail, 2004).

Changes in disease presentation, particularly on occlusal surfaces (Kidd *et al.*, 1993), provide an increasing challenge to the detection, measurement, and diagnostic steps in the modern caries management process. Similarly, the beneficial effect of the more widespread use of pit and fissure sealants means that new methods are needed to make consistent and reliable assessments of surfaces that become sealed (Deery *et al.*, 2001). Changes in dental epidemiology and public health are also reflecting the modern methods of measuring and controlling dental caries at the population level. Epidemiological data collected for African and Chinese populations over a decade (Manji *et al.*, 1991; Luan *et al.*, 2000) show that monitoring clinically detected enamel lesions over a long period is feasible and generates useful new knowledge about lesion behavior in populations, as well as for caries management in individuals. In Denmark, national statistics collected at the D₁ measurement threshold have been used to show the total burden of disease in the population (Poulsen and Sheutz, 1999).

(7) Outcome of Caries Control/Management

Increasingly, dentists, dental associations, 3rd party payers, governments, and patients' groups are seeking to assess the success of caries management by examining evidence on the long-term outcomes. This includes success in arresting and reversing initial lesions as well as in preventing the development of cavitated dentinal lesions. Clinical trial outcomes must respond to the changes that have taken place in wider society if they are to continue to be valid and useful.

INTEGRATING THREE ASPECTS OF MODERN CARIES MEASUREMENT

From the above, it can be seen that modern caries measurement concepts now embrace three complementary domains, shown diagrammatically in Fig. 3. The three sides of this measurement rectangle show: direct lesion measurement according to the grades of severity (represented by the icebergs) on the facing surface, which is what can be detected and graded at each clinical trial examination; lesion monitoring by repeated measures at a series of examinations, shown on the side surface, where changes (transitions) in lesions over time are assessed within a trial; and caries activity measurement at a given time point (shown on the top), a process that is less well-developed, but indicates a complementary direction of travel for the future.

INCORPORATING THE BEST EVIDENCE ON CARIES MEASUREMENT INTO MODERN CARIES CLINICAL TRIALS

A challenge for the Workshop is to define a framework for identifying and utilizing optimal measurement methods that will best contribute to more efficient, modern caries clinical trials. These may be in use (or in development) in recent clinical trials, in clinical practice, and/or in caries epidemiology.

To develop a basis for consensus on the issue of caries measurement concepts in line with the ICW-CCT Mission (to reach consensus about the designs of protocols for caries clinical trials, which are scientifically acceptable as pivotal evidence of the anti-caries efficacy of oral care products) and its first Objective (to critically review modern caries definitions and measurement concepts), the following draft consensus statement is proposed:

"In light of the evidence reviewed, both here and elsewhere, pertaining to modern caries definitions and measurement concepts, the participants support a statement recommending that, in future CCT protocols, caries measurement methods are employed which:

- *are capable of accurately capturing at any given point in time the manifestations of the caries process in dental hard tissues (enamel and dentin);*
- *when applied sequentially, can monitor definitive changes in manifestations of the caries process over time, over and above any background 'noise' from normal levels of de- and remineralization, or from variations attributable to the caries detection system(s) employed; and*
- *when applied sequentially, can differentiate actual product effects in terms of group differences in lesion initiation and lesion behavior (progression, arrest, and/or regression)."*

This consensus statement on caries measurement systems, refined by discussion at the Workshop, will need to be integrated with those reached later during the meeting which relate to: (a) current and future diagnostic methods and requirements, (b) modern trial designs, and (c) statistical methods to provide pivotal evidence of anti-caries efficacy, to formulate key elements of protocol(s) for shorter and more efficient modern caries clinical trials and a framework for validating them.

Continuing research to optimize the specification and performance of caries measurement frameworks for assessing lesions in the Caries Clinical Trial environment is needed. Such systems may, in some cases, be different in detail from those meeting the clinical needs of dentists. These frameworks should, however, still be compatible with beneficial clinical outcomes for patients.

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