Rationale and Evidence for the International Caries Detection and Assessment System (ICDAS II)

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The International Caries Detection and Assessment System (ICDAS) presents a new paradigm for the measurement of dental caries that was developed based upon the insights gained from a systematic review of the literature on clinical caries detection system [Ismail, 2004a] and other sources [Chesters et al., 2002 ;Ekstrand et al., 1997; Fyffe et al., 2000; Ekstrand et al., 2001; Ekstrand et al., 2005; Ricketts et al., 2002]. That review found that while new caries detection criteria measured different stages of the caries process, there were inconsistencies in how the caries process was measured. The review also found that there is a gulf between European and American systems for caries detection and there were inconsistencies among the research criteria for measuring dental caries. By and large, especially in the USA, dental caries has been synonymous with presence of cavitation. In Europe, at least among the research community, the understanding of dental caries appears to be more advanced than the dichotomous approach used in the American criteria for measuring caries in that the clinical stages of the disease process which precede cavitation are acknowledged and often recorded.

The future of research, practice, and education in cariology requires the development of an integrated definition of dental caries and uniform systems for measuring the caries process.   The systematic review concluded that there is an urgent need to address the answers to the following questions: 1) what stage of the caries process should be measured; 2) what are the definitions for each selected stage; 3) what is the best clinical approach to detect each stage on different tooth surfaces; and 4) what protocols of examiners' training can provide the highest degree of examiner reliability? These were the initial questions that initiated the discussion of the ICDAS process.

In this paper, we will describe the philosophy of the ICDAS system, how the ICDAS answers each of the four questions, and whether ICDAS can serve as a basis and benchmark for clinical and epidemiological research and inform dental undergraduate and postgraduate teaching in cariology. At the outset it is important to define an important guiding principle of ICDAS. Members of the coordinating committee have attempted several times to include the largest input of the cariology community in the process of developing integrated criteria. The ICDAS committee was expanded to include a larger group of participants. Invitations were mailed to cariologists from Europe and the USA. The following document summarizes the discussions that took place during the Baltimore ICDAS II workshop which was held in March 2005. It should also be understood that the ICDAS committee explicitly acknowledges that the ICDAS approach is built on a foundation of evidence which dates back over the last hundred years to G.V. Black in the US and to many of the founding fathers of ORCA (the European Organisation for Caries Research) in Europe.

Historical Perspectives and the Need for an Integrated System

Developments in epidemiological caries measures

More than a decade ago concern was expressed about how the quality and comparability of caries data could best be safeguarded in order to achieve valid assessments of disease status at a time when significant service developments were accompanied by changes in both the pattern and distribution of dental caries [Pitts, 1993]. These issues are even more relevant today. There is a danger that key information and concepts are not being disseminated sufficiently well [Pitts, 1994], and many of the clear and established issues and challenges in this area are still not recognized in dental public health. There is, therefore, a need to continue work to bring together

the evidence base from research in the field of "cariology" (which is very robust in some areas, but more deficient in others) on the one hand and the national and international dental epidemiology, dental public health, and dental practice communities on the other.

Many of the concepts debated at least since the 1980s in cariology are still seen as "new" or as radical by many working in other fields. There are, however, some encouraging signs in the UK [Drugan, 2004], the European Association for Dental Public Health (EADPH), the American Dental Association (which supported the Baltimore workshop), and the Federation Dentaire Internationale. The new emphasis on caries measurement and management may indicate that the dental community worldwide has started to recognize that we need new approaches in caries detection, assessment, and management.

The ICDAS coordinating committee has been guided by the model depicted in Figure 1 which illustrates graphically the type of updated caries terminology now being recommended. This allows more clarity for lay and non-dental audiences as well as continuity with traditional measures, while also reflecting the current research evidence from cariology. Key changes are to carefully avoid the use of the misleading and widely misunderstood term "caries free" and to explicitly acknowledge whether or not initial lesions clinically confined to the enamel are included or excluded in examinations.

Developments in caries measures for clinical research

There have been several conferences held during the last five years that focus on caries detection and assessment. A recent issue of *Caries Research* reporting the peer reviewed proceedings of

the 50th Anniversary European Organisation for Caries Research (ORCA) Congress on *Cariology in the 21st Century* is a good start [Nyvad et al*., 2004]. The series of published proceedings from the "Indiana Conferences on Early Detection of Dental Caries" organised by Professor George Stookey and published by Indiana University also contain a wealth of detail of work in this area [Stookey, 1996; 2000; 2004]. In the field of randomized clinical trials of caries preventive agents, it has now been shown that by using clinical visual diagnostic criteria that include enamel lesions, it is possible to detect differences in treatment effect over a shorter period than using criteria relying only on the later stage caries changes extending into the dentin [Chesters et al., 2002].

An International Consensus Workshop on Caries Clinical Trials (ICW-CCT) was held with in 2002 involving 95 participants from 23 countries. The final Consensus Statements represent international agreement on where the evidence leads in the field of caries clinical trials [Pitts and Stamm, 2004]. The final agreed text includes:

➤ "There is some confusion with the terminology employed in the literature around *caries diagnosis* (which should imply a human professional summation of all available data), *lesion detection* (which implies some objective method of determining whether or not disease is present) and *lesion assessment* (which aims to characterise or monitor a lesion, once it has been detected)".

➤ "The understanding of the caries process has progressed far beyond the point of restricting the evidence for dental caries to the D2 (caries in enamel only) or D3 (caries in enamel and dentin) levels of cavitation".

- "For future clinical trials, recording only cavitated lesions as an outcome measure is becoming outmoded".

- The workshop participants also recommended that "in light of the evidence reviewed, both here and elsewhere, pertaining to modern caries definitions and measurement concepts – the participants supported a statement recommending that in future controlled clinical trials, caries measurement methods are employed which:

  1. Are capable of accurately capturing at any given point in time the manifestations of the caries process in dental hard tissues (enamel and dentin).

  2. 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 re- mineralization, or from variations attributable to the caries detection system(s) employed.

  3. When applied sequentially, can differentiate actual product effects in terms of group differences in lesion initiation and lesion behavior (progression, arrest and/or regression)".

Immediately following the ICW-CCT workshop (April 2002), the ad hoc ICDAS coordinating committee was formed by Drs. Pitts and Ismail. The goal of that committee has been to develop an integrated clinical detection and assessment system of dental caries for research and clinical practice. The development of new technologies and applications has the potential to supplement clinical caries detection, but these assessments will have to be clinically meaningful by providing measurements over and above the noise of arrested initial and sub-clinical lesions (Pitts and Stamm, 2004]. A major challenge in synthesising the developing evidence in the partially overlapping fields of caries epidemiology, clinical caries

research and clinical caries management is the incompatibility of the terminology, criteria and grading systems currently used across these three fields. This challenge, together with a number of the recommendations of the NIH Consensus Development Conference (2001) and the ICW meeting on Clinical Caries Trials, led an ad hoc group to start the development of the International Caries Detection and Assessment System – ICDAS.

ICDAS: The Committee – The ICDAS activities have been carried out under the supervision of and on behalf of an informal, unfunded, ad hoc and voluntary committee which was assembled in an attempt to advance some of the key recommendations in the area of caries detection and assessment criteria. After the first meeting in Dundee, Scotland, an invitation was mailed to cariologists from Europe and USA to attend a development workshop in Ann Arbor, Michigan. No attempt was made to exclude any researcher or individual. The founding committee comprised: from the Dental Health Services Research Unit, University of Dundee (DHSRU): Nigel Pitts, Christopher Longbottom, Gail Douglas (now University of Leeds), David Ricketts; from the University of Michigan: Amid Ismail (now Temple University, Philadelphia); from Indiana University: Domenick Zero; from Copenhagen University: Kim Ekstrand; from the International Dental Federation (FDI) Elmar Reich and from NIH/NIDCR: Rob Selwitz. At the first meeting there was helpful input from Andrew Forgie (Dundee) and Chris Deery (now Sheffield). From the second meeting the Committee was joined by David Banting (Ontario), Hafsteinn Eggertsson (Indiana, now Oregon) and Woosung Sohn (Michigan, now Boston) and the third meeting onwards the committee was joined by Andréa Ferreira Zandoná (Indiana). To this group an additional 10 individuals participated in the Ann Arbor workshop. This group comprised the ICDAS development committee in 2002.

ICDAS: Philosophy – the philosophy on which this truly collaborative initiative is based is one where the methodology from caries epidemiology meets that from caries clinical trials and practice and the whole is conducted according to the values of evidence based dentistry (EBD). There have been many systems devised over the years for grading dental caries which have been visually based and included non-cavitated lesions in enamel and all are fully acknowledged. The driving principles of the ICDAS committee are: integration, scientific validation, and utility of the criteria in different research and practice settings.

ICDAS: Development Meetings – Before the ICDAS II workshop, four development meetings were held - Dundee, Scotland in April 2002; Ann Arbor, Michigan in August 2002, where the ICDAS I criteria were developed; Indianapolis, Indiana in May 2003; and Bornholm, Denmark in April 2004. The ICDAS II workshop was held in Baltimore, MD, USA, to share the progress in the ICDAS criteria and seek the input of a wider international expertise. Invitations were mailed to large group of experts and those who accepted the invitation convened to review, revise as necessary, and agree on the ICDAS II version of the criteria. The invitations were mailed to over 60 cariologists and researchers in the field.

ICDAS: Concepts – The use of a standardized system based on best evidence should lead to better quality information to inform decisions about appropriate diagnosis, prognosis and clinical management of dental caries at both the individual and public health levels. A "wardrobe" of validated tools should allow users to select the best criteria and conventions for a specific use. Adoption of the system should, in the longer term, also facilitate the work of those who subsequently seek to systematically review published evidence in the three fields referred to

above. The concept is that the system will be an open one maintained on the World Wide Web and subject to peer review. Users of the system will have to: 1) specifically acknowledge the version of the system they employ and 2) specify which parts of the "ICDAS wardrobe" is being used.

Figure 2 summarises the following key features of ICDAS:

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> The **ICDAS caries detection criteria** have been piloted in various guises in Dundee, Detroit, Indiana, Copenhagen, Columbia, Mexico and Iceland. They are now ready for wider use and have been further peer reviewed in 2005.

> The **ICDAS caries activity criteria** are still part of an expanding research agenda. Preliminary caries activity assessment criteria have been developed using the ICDAS approach of relying on visual assessment and the use of the WHO/PSR probe. Further research is planned to validate the proposed criteria.

> The **ICDAS caries system** provides a vital step forward in giving a coherent framework of comparison against which the potential benefits and performance of existing and new aids to caries detection and diagnosis can be assessed against the optimised clinical visual method. Previous systematic reviews and consensus conferences have found considerable difficulty with the heterogeneous methodology and reporting in this area.

Caries diagnosis is an important part of the dentist's daily work. Caries diagnosis is a process, which can be considered as a three-step procedure: detection of the lesion, followed by an assessment of the severity of the lesion, which again is followed by an assessment of the activity

of the lesion [Ekstrand et al., 2001]. Caries risk assessment on the other hand is the assessment of the risk of getting new lesions in the near future [Bratthall et al., 1997].

Early in the discussions of the ICDAS coordinating committee it was recognised that lesion detection without assessment was of little clinical relevance. However, in reviewing the literature, it was found that there was insufficient current replicated evidence on the visual signs and symptoms of lesion activity to present an evidence-based system within the ICDAS criteria for lesion assessment. The limited evidence available, and previous criteria systems, were synthesised and used to develop draft criteria for assessing caries activity and during the ICDAS II workshop participants reviewed and modified these. These proposed criteria will be investigated and further revised if necessary.

Coronal Primary Caries Detection Criteria

Principles used to develop the criteria for Coronal Primary Caries

Dental caries is a dynamic process with cycles of demineralization followed by remineralization. The balance between the two cycles determines the stage of the disease as depicted in Figure 1. It is hard to categorize a complex disease like dental caries into a scale because the process is continuous and could be measured, if feasible, as stages representing minute loss of tooth structure that is currently not detectable using the current technology available for in vivo use. Clinically, we rely on visual signs (change in color, cavitation) which represent manifestations of a relatively advanced caries process.

To understand the measurement of caries it is important to review basic concepts. Sound enamel is translucent and microporous. After repeated demineralization challenges, microporosity of the

subsurface enamel increases. The increase in microporosity leads to a change in the refractive index of enamel. The first sign of carious change, hence, is a change in translucency and light refraction of enamel after it is dried for a short period. If demineralization continues and enamel microporosity and surface loss increases, further reduction occurs in the refractive index of enamel. As a result, early carious lesions are seen even when the surface is covered with saliva. This is a more advanced stage of dental caries.

Ekstrand et al. [1995] has correlated between the severity of carious lesions and their histological depth. White spot lesions, which require air-drying, are most likely to be limited to the outer ½ of the enamel. The depth of a white or brown spot lesion which is obvious without air-drying is located some place between the inner 1/2 of the enamel and the outer 1/3 of the dentin. Localized enamel breakdown due to caries, with no visible dentin, indicates that the lesion extends to the middle 1/3 of the dentin. In addition, a greyish, brownish or bluish shadow of the dentin shining up through apparently intact enamel also indicates a lesion extending to the middle 1/3 of dentin. Frank cavities with visible dentin indicate that a lesion has been extended to inner 1/3 of dentin.

The ICDAS I and II criteria (Appendix) incorporate concepts from the research conducted by Ekstrand et al. [1995, 1997] and other caries detection systems described in the systematic review conducted by Ismail [2004]. These systems indicate that measurement of non-cavitated carious lesions in enamel or dentin can be based on visual topography at the surface level. While such systems are not perfectly accurate; they have both content and correlational validity with histological depth of carious lesions.

As stated before, the ICDAS was developed to provide an international system for caries detection that would allow for comparison of data collected in different locations as well as at different points of time. The ICDAS system was developed to bring forward the current understanding of the process of initiation and progression of dental caries to the fields of epidemiological and clinical research. The coordinating committee also took into consideration developing a system that has wider utility for dental practitioners. If dental caries is classified using agreed upon criteria and systems, then comparison of findings by epidemiologists and clinicians from different countries would be feasible.

The ICDAS measures the surface changes and potential histological depth of carious lesions by relying on surface characteristics. The coordinating committees have discussed at extensive length the concept of measuring caries activity and have tested different clinical criteria systems [Ekstrand et al. 2005]. At the ICDAS II workshop in Baltimore existing activity criteria were modified to fit with the ICDAS approach for clinical detection of dental caries. The proposed caries activity system will be evaluated in future research projects.

The primary requirement for applying the ICDAS system is the examination of clean and dry teeth. The ICDAS examination is visual aided by a ball-ended explorer that is used to remove any remaining plaque and debris and to check for surface contour, minor cavitation or sealants. It is highly advisable that the teeth are cleaned with a toothbrush or a prophylaxis head/cup before the examination. The use of a sharp explorer is not necessary because it does not add to accuracy of the detection and it may damage the enamel surface covering early carious lesions (Ekstrand et al. 1987; Bergmen and Lindén, 1969).

The ICDAS criteria for coronal caries are described in the criteria document attached to this paper.

Caries Adjacent to Restorations and Sealants (CARS)

Rationale and terminology

When a restoration is placed in a tooth, the adjacent tooth tissue, which is vulnerable to caries, can be considered in two planes. There is the surface enamel and the enamel and dentin of the cavity wall. Secondary caries has classically been described as occurring in two ways: an "outer lesion" and a "wall lesion". The chemical and histological processes involved in "outer lesions" are the same as primary caries and it has been suggested they occur as the result of a new, primary, attack on the surface of the tooth adjacent to the restoration. A number of researchers have suggested that secondary caries is quite likely to be primary caries adjacent to restorations [Ozer, 1997; Kidd and Beighton, 1996].

Additionally, however, given the appropriate conditions, a "wall lesion" may start on the wall of a cavity in the presence of leakage or micro-leakage. Thus these lesions only occur secondary to the presence of a restoration. The definitions given to caries found in association with a restoration, or on a restored tooth, vary greatly in the literature. "Secondary caries", "recurrent caries" and "residual caries" are some of the terms commonly used. However, the same terms are used to describe different conditions by different investigators. Many of the definitions focus on the spread of caries at the enamel-dentin junction (EDJ) in a restored tooth. Other definitions include the failure to remove all diseased tissues in the deep part and/or at the margin of cavity

preparations, however, this is more commonly considered to be residual caries. In an epidemiological survey, the presence or absence of caries adjacent to restorations is recorded without differentiating between "new" and residual caries. The terminology used should reflect this and it is suggested that the term "caries associated with restorations and sealants(CARS)" may be suitable.

Principles used to develop the criteria for CARS

Since "outer" carious lesions adjacent to restorations are thought to be analogous with primary caries the broad principles applied to the criteria for primary caries are also applied to CARS where relevant. However, it should be noted that the scientific basis for doing so has not been established, and the literature in the area of secondary caries is far more limited than for primary coronal caries. Much of the work which has been conducted has been done under "ideal" conditions within the laboratory setting and even then most have found poor correlations between visual signs and the histological findings.

Although caries associated with restorations is histologically similar to primary caries, its features cause certain diagnostic problems, including difficulties in the differentiation among restoration margin discrepancies (marginal integrity, discoloration of the tooth at restoration margin), secondary caries and residual caries [Mjör and Toffenetti, 2000].

Sharp probing for signs of secondary caries has all of the limitations and drawbacks associated with its use for primary caries detection. In addition, probing restored teeth can be misleading as a probe may become impacted in a margin discrepancy that is not in fact carious. It has been

demonstrated that discoloration at the restoration margin is difficult to evaluate, as shown by a "moderate" inter-examiner agreement (kappa of 0.49) [Tobi et al., 1999]. In part this is due to the variety of causes of discoloration found next to amalgam in particular. It is not always predictive of secondary caries, as a large amalgam restoration or its corrosion products may discolor the tooth grey or blue without caries being present. It has also been suggested that slowly progressing lesions are darkly stained [Miller and Massler, 1962], probably from exogenous dietary sources such as tea or coffee. It is possible that lesions that are most obvious clinically because of their color may be the ones that are inactive, arrested, or slowly progressing [Kidd, 1989a and 1989b]. Although corrosion products are known to form around amalgam fillings and are dark colored, Kidd and co-workers [Kidd et al., 1994] found similar levels of staining around amalgam fillings to that found around tooth colored restorations.

A number of studies have been conducted to investigate the association between shadowing or grey discoloration and the presence or absence of caries, some concluding that there is a statistically significant association [Kidd et al., 1994; Rudolphy et al., 1995; Topping, 2001] whilst others found no such relationship [Kidd et al., 1995; Rudolphy et al., 1996].

In conclusion, therefore, it should be noted that whilst many studies have shown that grey discoloration or shadowing at the margins of restorations is statistically significantly associated with caries, recording this as non-cavitated dentinal caries is likely to result in an overestimation of the amount of disease. The confounding of shadowing due to restoration color means that there are likely to be more false positives than in unrestored teeth if discoloration or shadowing alone is used to predict the presence of caries.

Non-carious changes and CARS

A number of features of restored teeth, that are not necessarily associated with the presence of caries, may be worthy of recording. Although, some of these categories may ultimately be counted as "sound" it may be of some importance to be able to differentiate some states from that defined above. Such non-carious changes seen in restored teeth include discrepancies in the integrity of the tooth-restoration interface (marginal ditching) and fractured restorations (e.g. isthmus fractures as opposed to marginal discrepancies). If any feature were present concurrently with signs of caries then the appropriate caries code would take precedence over any "non-carious change code".

Many studies have concluded that secondary caries is poorly related to marginal discrepancy [Kidd et al., 1992; Kidd, 1989a and 1989b; Kidd et al., 1994; Elderton, 1989; Kidd and O'Hara, 1990; Boyd and Richardson, 1985; Hamilton et al., 1993; Topping, 2001; Ando et al., 2004]. Some studies, however, have reported that the wider the gap at faulty margins, the greater the likelihood of caries [Goldberg et al., 1981; Goldberg, 1990; Jorgensen and Wakumoto, 1968]. It may, therefore, be important in an epidemiological study to record the presence of marginal ditching as an indication of teeth with an increased caries risk.

The extent of marginal deficiencies will range from those barely perceptible on visual examination alone to those that will readily admit a ball-ended probe. Since an increased width of the marginal deficiency may be a risk factor for the likelihood of developing caries or not it may be important to have a threshold at which the deficiency is recorded as present or absent. If a ball-ended probe is part of the examination kit, two categories of ditching could be recorded according to whether or not the probe can be admitted into the gap between tooth and restoration.

The ICDAS criteria for CARS are described in the criteria document attached to this paper (Appendix).

Root Caries

Root Caries

A recent systematic review commissioned for the National Institutes of Health (NIH) Consensus Development Conference on Dental Caries Diagnosis and Management Throughout Life concluded that there is "insufficient" evidence on the validity of clinical diagnostic systems for root caries [Bader et al., 2001]. However, the review only included clinical studies that used histology to validate the clinical caries diagnosis. This inclusion criterion excluded the vast majority of the literature on root caries.

Surveys describing the clinical appearance of root caries began to appear in the literature in the early 1970's and many surveys and longitudinal studies on root caries were reported over the next two decades. Since the early 1990's, however, very few clinical studies on root caries have been conducted. These clinical studies primarily used diagnostic criteria proposed by several

investigators (Sumney et al., 1973, Hix and O'Leary, 1976, Banting et al., 1980; Katz, 1984; U.S Department of Health and Human Resources, 1987.)

Generally root caries lesions have been described as having a distinct outline and presenting with a discolored appearance in relation to the surrounding non-carious root. Many root caries lesions are cavitated, although this is not necessarily the case with early lesions. The base of the cavitated area can be soft, leathery or hard to probing. Probing of root caries lesions with a sharp explorer using controlled, modest pressure, however, may create surface defects that prevent complete remineralization of the lesion [Warren et al., 2003]. Therefore, for detection and classification of root caries utilizing ICDAS criteria, examiners are directed to use a Community Periodontal Index (CPI) probe [World Health Organization, 1997].

Root caries frequently is observed near the cemento-enamel junction, although lesions can appear anywhere on the root surface. Lesions usually occur near (within 2 mm) the crest of the gingival margin. The distinction between an active and an arrested lesion further complicates clinical detection of root caries. The color of root lesions has been used as an indication of lesion activity. Active lesions have been described as yellowish or light brown in color whereas arrested lesions appear darkly stained. However, color subsequently has been shown not to be a reliable indicator of caries activity [Hellyer et al., 1990; Lynch and Beighton, 1994].

Since the clinical signs of lesions are considered to be different for active versus arrested root caries and the clinical signs associated with lesion activity have yet to be validated, the criteria proposed within the ICDAS incorporate all of the reported clinical signs, and therefore consider both lesion detection and assessment together unlike the criteria for coronal caries.

The presence of cavitation (loss of surface integrity) associated with a root caries lesion does not necessarily imply lesion activity. Non-cavitated (early) root caries lesions almost universally are considered to be active. A cavitated lesion, however, may be either active or arrested. Lesion activity has been linked to lesion depth [Billings et al., 1985], but this clinical observation has not been verified.

The texture of a root caries lesion also has been linked to lesion activity. Active lesions have been described as soft or leathery compared to arrested lesions that have a hard texture. There is supporting laboratory evidence from a study that used microbiological indicators for lesion activity that "soft" or "leathery" lesions on root surfaces are more heavily infected with bacteria than are "hard" root surfaces [Lynch and Beighton, 1994].

Root caries lesions that occur closely adjacent to (within 2mm) the crest of the gingival are considered to be active whereas lesions that occur on the root surface more distant from the gingival crest are more likely to be arrested. There is microbiological evidence to support this clinical observation [Beighton et al., 1993].

The determination of root caries activity probably is more closely related to decisions regarding treatment or management than to the determination of the presence of caries on the tooth root. Published reports on the clinical measurement of root caries were consulted in developing the ICDAS criteria [Hellyer and Lynch, 1991; Banting, 1993; Banting, 2001; Leake, 2001]. Given the paucity and generally low level of the scientific evidence, the ICDAS Coordinating

Committee, recommends that the following clinical criteria be used for the detection and classification of root caries:

1.   Color (light /dark brown, black);

2.   Texture (smooth, rough);

3.   Appearance (shiny or glossy, matte or non-glossy);

4.   Perception on gentle probing (soft, leathery, hard); and

5.   Cavitation (loss of anatomical contour);

Additionally, the outline of the lesion and its location on the root surface are useful in detecting root caries lesions. Root caries appears as a distinct, clearly demarcated circular or linear discoloration at the cemento-enamel junction (CEJ) or wholly on the root surface.

The ICDAS criteria for root caries are described in the criteria document attached to this paper.

Principles used to develop the criteria for Coronal Caries Lesion Activity Assessment

While detecting caries lesion is important, it only represents part of the diagnostic process necessary to properly assess the caries disease status. A long sought after goal in cariology is to be able to accurately and reliably characterize the caries activity status of lesions. Is the lesion progressing, arrested or regressing? Two approaches have been considered. The first approach involves monitoring over multiple clinical examinations changes in the physical and/or optical properties of caries lesions. For this approach ICDAS severity scoring can be applied. The

second approach involves attempting to characterize caries lesion activity during a single clinical examination in real-time, and this is subject under consideration here.

The modern understanding of dynamic nature of the caries process, where lesion progression can be arrested at any stage of the process, supports the importance of clinically assessing caries activity status (Nyvad and Fejerskov, 1997). This is particularly important for non-cavitated lesions because they may self-arrest as part of the natural history of the disease or become arrested due to changes in the local environment (Backer Dirk, 1966). In older adults, arrested non-cavitated lesions may be scars from disease activity occurring years or even decades earlier; however, these scars do not provide useful information about the current disease status of an individual unless they reflect a recent documented change from an active lesion status. Some consider activity assessment to be the "Holy Grail" of cariology, because it can provide chair-side evidence of the caries disease process real-time. Furthermore, it may also prove to be best way to determine caries risk status and identify patients who require intensive preventive intervention (Zero et al., 2001). Clinical research is the other arena where caries lesion activity can and should play an important role. Caries assessment is necessary for identifying subjects that have teeth with active disease for studies designed to test treatments intended to arrest or reverse caries. Caries inactive lesions (scars) have a very low probability of progressing or regressing and thus mitigate the possibility of showing a treatment effect.

The assessment of the caries activity status of early lesions is currently very challenging as it relies on the clinicians ability to identify subtle changes in enamel by visual and tactile inspection. Clinical criteria for caries lesion activity assessment have been developed (Ekstrand

et al., 1997; Nyvad et al., 1999). The criteria are generally based on the physical properties of surface reflection and texture of early lesions, with chalky rough surfaces being active, and smooth, shiny surfaces being inactive. The color of the lesion can also be used to make the distinction between arrested and active, with arrested lesions acquiring internal brown pigmentation and surface stain, while active lesions retain their white appearance. The Nyvad criteria which combine severity scoring with lesion activity assessment have been recently validated (Nyvad et al., 2003). The validation was based on a three year longitudinal study involving daily supervised brushing with fluoride dentifrice (n=193) vs. control (n=80). The study evaluated the Relative Risk of transitions (progression or regression) of the test group in relation to control group. They found that the activity criteria were capable of reflecting their hypothesized fluoride effect (inhibition of lesion progression/enhancing lesion regression) and thus established construct validity. Predictive validity was established based on the finding that active non-cavitated lesions had a higher risk of progressing to a cavity than did inactive non-cavitated lesions.

A recent study (Ekstrand et al., 2005) pointed out the difficulty of trying to differentiate active lesions from inactive lesions in one single appointment without specific training or calibration. As with all clinical indices, a certain measure of uncertainty must be expected. Given the highly site-specific nature of caries, it is possible to have areas that are arrested and active on the same tooth surface. There is also the possibility of lesions being in a transitional stage, either going from active to inactive or inactive to active. The future holds promise for the development of clinically useful tools to assist dentists and researchers in making decisions about activity status of caries lesions. Currently available technology, such as Quantitative Light Fluorescence (QLF)

and DIAGNOdent may be useful for monitoring changes in lesion activity over time. QLF has the added potential for real-time assessment of caries activity status by measuring the pattern of fluorescence radiance change during dehydration (Ando et al., 2001; Al-Khateeb et al., 2002). The development of user-friendly technology to assist clinicians and researchers in real-time assessment of the activity of early lesions should be given the highest research priority.

Criteria for the ICDAS Caries Lesion Activity Assessment are largely based on the Nyvad et al. (1999) system for differentiating between active and inactive caries lesions both at the non-cavitated and cavitated levels. However, the ICDAS version differs in a number of ways from the original criteria: 1) In the original system (Nyvad et al., 1999), lesion severity and active status are determined as one combined score, whereas the ICDAS severity score and activity assessment are provided as two separate scores; 2) The Nyvad criteria are applied to initially plaque-covered teeth, while ICDAS exams are initiated on cleaned teeth which is why ICDAS includes plaque stagnation areas as a surrogate for the presence of plaque; and 3) the Nyvad criteria for texture are determined using a sharp probe, while for the ICDAS approach the use of a ball-ended probe is recommended to avoid unnecessary damage.

ICDAS I and Histological Validation

During the development of the ICDAS I criteria in August 2002, the participants in the workshop examined the occlusal surfaces of 57 extracted teeth. The consensus of all participants was used to define the clinical status of the occlusal surfaces. The teeth were stored in moist containers and were sectioned and examined under magnifying lens (10X). Each designated area was scored using the scale of Ricketts et al. [2002] into:

0 = No enamel demineralization

1 = Enamel demineralization limited to the outer 50% of the enamel surface

2 = Demineralisation (brown discoloration) involving between 50% of the enamel and 1/3 of the dentin

3 = Demineralization (brown discoloration) involving the middle third of the dentin

4 = Demineralization (brown discoloration) involving the inner third of the dentin

The histological scoring was carried out by two examiners concurrently. The two examiners re-scored 10 teeth and agreed the second time on 8 of the 10 scores. The percentages of tooth surfaces classified clinically with codes 0, 1, 2, 3, 4, and 5+6 and are seen on sectioning to extend into dentin are presented in Table 1. These data support the decision of the ICDAS II workshop to switch the original codes 3 and 4 (ICDAS I) to portray a sequential progression of dental caries.

The likelihood ratios that a tooth classified with codes 2, 3, 4, or 5+6 had dental caries into dentin, relative to a tooth classified with codes 0 or 1 are presented in Table 2. These ratios show that the ICDAS II (with codes 3 and 4 switched) has an ordinal sequence in terms of histological extension into dentin. These ratios are relatively high [Goodman 1989] compared with the likelihood ratio (LR) of standard medical signs and symptoms. For example, in relation to heart attacks, an elevation in the ST segmentation on an electrocardiogram (ECG) has a LR of 11.2; while radiating pain to both arms has a LR of 7.1 [Panju et al. 1998].

Ekstrand and colleagues also investigated the relationship between the ICDAS I seven point classification system when applied to the occlusal, free smooth and approximal surfaces of extracted posterior teeth. The results using the ICDAS I system are cross tabulated with the original histological scoring system (Ekstrand et al., 1997). A strong relationship was found between the two variables for occlusal, free smooth and approximal surfaces (Spearman correlation coefficients = 0.93, 0.95 and 0.94 respectively). Similarly for the second examiner the correlation coefficients were 0.87, 0.96 and 0.92 respectively. The LR+ ratio (positive likelihood ratio) that an approximal lesion classified with ICDAS codes 3-6 is in dentin is around 18.

Reliability of the ICDAS: Coronal Caries

Ismail et al. [2005] has collected data on training of examiners in the Detroit Dental Health Project. The study found good to very good inter-examiner reliability among dentists who were trained over a period of 1 week. The kappa coefficients for inter-examiner agreement ranged between 0.74 and 0.88. The intra-examiner kappa coefficients for the two main examiners were around 0.78. One secondary examiner had an intra-examiner reliability of 1.77 and a fourth secondary examiner who worked only on Saturdays had a intra-examiner kappa of 0.50. Details on reliability analysis using log-linear modelling are presented in a separate paper [Ismail et al., 2005]. For CARS, the inter-examiner kappa coefficient ranged between 0.33 for one examiner and over 0.80 for the two main examiners. The main examiners had an intra-examiner reliability of 0.80.

Ekstrand (unpublished) reported that intra-examiner kappa coefficients when examining extracted teeth using the ICDAS I was substantial (Kappa = 0.87). The inter-examiner reliability was around 0.80.

Data from various studies at Indiana University have shown the ICDAS criteria to be a reliable and effective tool for various applications. It has been successfully applied in different types of studies, in-vitro studies as well as clinical studies (validation study, secondary caries, epidemiology, study on caries risk factors, and clinical trial), in different dentitions (primary and permanent teeth), in different age groups (children, teenagers, young adults, adults), and by multiple examiners with different background as well as previous exposure and experience with the criteria.

Several training and calibration studies have been conducted in Indiana and co-operative sites. The reliability from various studies is presented in Table 3. The ICDAS criteria were used in a project in Mexico, where caries risk factors and indicators measured in five rural village populations were correlated with caries prevalence. Intra-examiner reliability gave weighted kappa of 0.93 (Cook et al., unpublished data).

ICDAS and the International Context

As the evidence underpinning caries detection and activity is international, so the ICDAS Committee has ensured that its search for evidence and its outlook is also international. In Europe, as part of the Community Action Programme on Health monitoring of the European Commission, a project on Health Surveillance in Europe ran from 2002-2005. This European

Oral Health Global Indicators Development Project has adopted ICDAS criteria for its proposed European-wide indicators of caries severity. The move recognizes that, as the focus of public health planning embraces evidence based healthcare, moves away from providing only restorative interventions (fillings) and moves towards the delivery and evaluation of preventive programs and services, oral health indicators are needed which can be used to document the need for and the degree of success achieved in controlling early stage decay through prevention as well as meeting a continuing need to assess the pattern of restorative care which is provided for decay which has progressed to the more severe stages of the disease process. The recommended indicator for dental caries severity now provides the necessary flexibility to record at different stages of the caries process, according to the public health and clinical need. DMFT can therefore now be recorded at the early clinical stage of decay, the enamel *and* dentine caries (at the D_1 level, as in the ICDAS Method), or where it is sensible to collect data which records only the later stages of decay, this is done using dentin-only clinical caries (at the D_3 level as in WHO Basic Methods). It should be appreciated that data collected at the D_1 threshold can be reported at either D_1 or the D_3 level. The ICDAS criteria are also supported by the Epidemiology Special Interest Group of the European Association for Dental Public Health (EADPH) and have been discussed by the Council of European Chief Dental Officers (CECDO). At the dental practice level discussions are on-going with the Federation Dentaire Internationale (FDI).

ICDAS I has already been piloted in a number of countries besides the USA and the UK. These include Copenhagen, Columbia, Mexico and Iceland (as part of a National Survey of child dental health).There are currently formal requests to use the ICDAS caries detection criteria from: Germany, Portugal, Italy, Thailand, Peru and Austria. As the problems of communicating

information about caries between epidemiology, research, clinical practice and education interests are truly global, the Committee hopes that the ICDAS methodology may find widespread applications.

The Future of ICDAS

The mission of ICDAS is to provide a foundation for inclusion of other social and biological measures of dental caries. This foundation allows researchers and clinicians to choose the stage of disease and characteristics for assessment. Using the World Health Organisation (WHO) "Stepwise" or STEPS approach, we have identified of indicators of dental caries that may be measured now or in the future (Figure 3). The STEPS approach allows a logical organization of the different and often disparate indicators used into a series of core indicators which can be used at STEP 1, 2 or 3 depending on the circumstances and local needs, preferences and resources. Importantly, this approach also documents how each STEP can be supplemented into an expanded form, when needed, and also identifies a series of standardised optional indicators that could be added as and when they are needed or can be afforded. This philosophy is entirely consistent with the wardrobe approach of ICDAS and its use would result in improved comparability of data collected nationally and internationally and thereby facilitates systematic reviews in the area. It would seem wise that in moving forward in the area of dental caries, the three elements discussed above relating to epidemiology/dental public health, to clinical research and to clinical practice should not be seen as competitive with each other, or with continuing public health initiatives being mounted "upstream" from individual patients at the population level. The future should be better informed by improved communication between these related fields of activity and by sound planning and evaluations based on valid epidemiological data. In

parallel, systematic reviews of high-quality clinical research should inform appropriate, evidence based, clinical practice and preventive care delivered to well informed and involved patients.

The future of ICDAS depends on acceptance of the concepts of integration and utility within a caries detection and assessment system. We cannot as a community and a scientific discipline rely on ad hoc and un-replicated methods of testing measurement systems. We cannot solely rely on clinically irrelevant "gold standards" such as histological validation. Hence, the future of ICDAS depends on adaptive confidence of the cariology community in critically researching and modifying a common system for measurement and on further research. The participants at the ICDAS II workshop in Baltimore identified the following research areas for the field of detection and assessment of dental caries:

1. Conduct multi-center studies to evaluate the validity and reliability of ICDAS, caries activity indicators, and other diagnostic tools.

2. Test the feasibility and reliability of using the ICDAS in detecting caries on primary teeth.

3. Investigate different methods for effectively cleaning and drying of teeth and their impact on the usability of ICDAS.

4. Develop and test new explorers to allow for the detections of surface roughness or "tackiness" of root surfaces without causing damage to the surface.

5. Define the appropriate time required to dry teeth to identify the first visible signs of dental caries.

6. Validate the decision tables for clinical, radiographic, and other detection tools that were developed at the ICDAS Workshop (Figure 4).

7. Define and validate the treatment decisions table (Figure 4) defined by the workshop participants.

8. Develop and test clinical and other measures to assess caries activity.

For root caries, the workshop recommends the following research agenda:

1. Demonstrate *in vitro* validity of the root caries criteria used in the ICDAS system.

2. Demonstrate *in vivo* reliability of the root caries criteria used in the ICDAS system.

3. Investigate the feasibility and reproducibility of dental examiners using a rounded probe to detect root caries and assess root caries activity. Comparison of the use of a rounded probe for root caries detection and assessment could be contrasted with the "gentle" use of a sharp probe or the application of visual detection and assessment methods only.

4. Establish the optimal time and method to be used for drying a tooth surface, while preserving lesion characteristics in the detection and assessment of root caries using ICDAS criteria.

Additionally, the participants identified the need for the following supporting resources:

1. A library of images to depict the different codes and conditions related to ICDAS.

2. Statistical protocols for analysis of reliability data as well as for analysis of the ICDAS system in clinical and epidemiological studies.

3. Standardized protocols and online simulations to train examiners to use ICDAS.

Finally, the ICDAS coordinating committee wishes that soon the dental community would be able to detect, assess, and decide on caries diagnosis and management using the most current scientific evidence. Figure 4 depicts the future integration of a wider range of detection and analysis systems. We hope that evidence will become available to complete the matrix.

Table 1. Percentage of tooth surfaces classified using the ICDAS by histological caries status.

Clinical code	Number of teeth	Percentage in dentin
0	2	0%
1	11	9%
2	18	50%
3	8	88%
4	13	77%
5+6	5	100%
Total	**57**	

Table 2. Likelihood ratios of a ICDAS-classified teeth having caries in dentin.

Clinical [ICDAS I]							
Histological	0	1	2	3	4	5	Number
0	1	0	2	0	0	0	3
1	1	10	7	1	3	0	22
2			8	3	7	1	19
3		1		1	1	1	4
4			1	3	2	3	9
Total	2	11	18	8	13	5	57
LR [0-1)			6.5	11.4	10.0	13.0	

Table 3. Reliability of ICDAS in various studies at Indiana University.

Study	Intra-examiner agreement		Inter-examiner agreement		Activity, Intra- ex	Training
	Kappa	WK	Kappa	WK	Kappa	
Calibration of occlusal caries, 5 examiners	0.62-0.81	0.62-0.90	0.50-0.62	0.64-0.74	n/a	2 days; didactic, extracted teeth, subjects
Additional calibration of the same group, 4 examiners	0.64-0.84	0.78-0.91	0.51-0.71	0.65-0.81	0.71-0.89	1 day; didactic, subjects
Calibration of 3 examiners, internal at OHRI	0.58-0.69	0.65-0.77	0.40-0.45	0.55-0.58	n/a	1 ½ days; didactic, subjects
Validation study, (primary caries in primary teeth)	0.72	0.81	n/a	n/a	n/a	n/a
Secondary caries	0.73	0.76	n/a	n/a	n/a	n/a
Dose-response study (occlusal surfaces)	0.61	0.75	n/a	n/a	n/a	n/a
In-vitro calibration of 30 faculty, graduate students, & students, 60 teeth*	0.61-0.69	0.80-0.84	0.34-0.38**	0.55-0.70**	0.62-0.65	3 hours; didactic, extracted teeth

* Scores are averages for each of three groups; WK = weighted kappa.

** Agreement of participants with histological evaluation

Figure 1. Updated caries terminology recommended to allow continuity with traditional measures while also reflecting the current evidence from cariology [Pitts 2004].
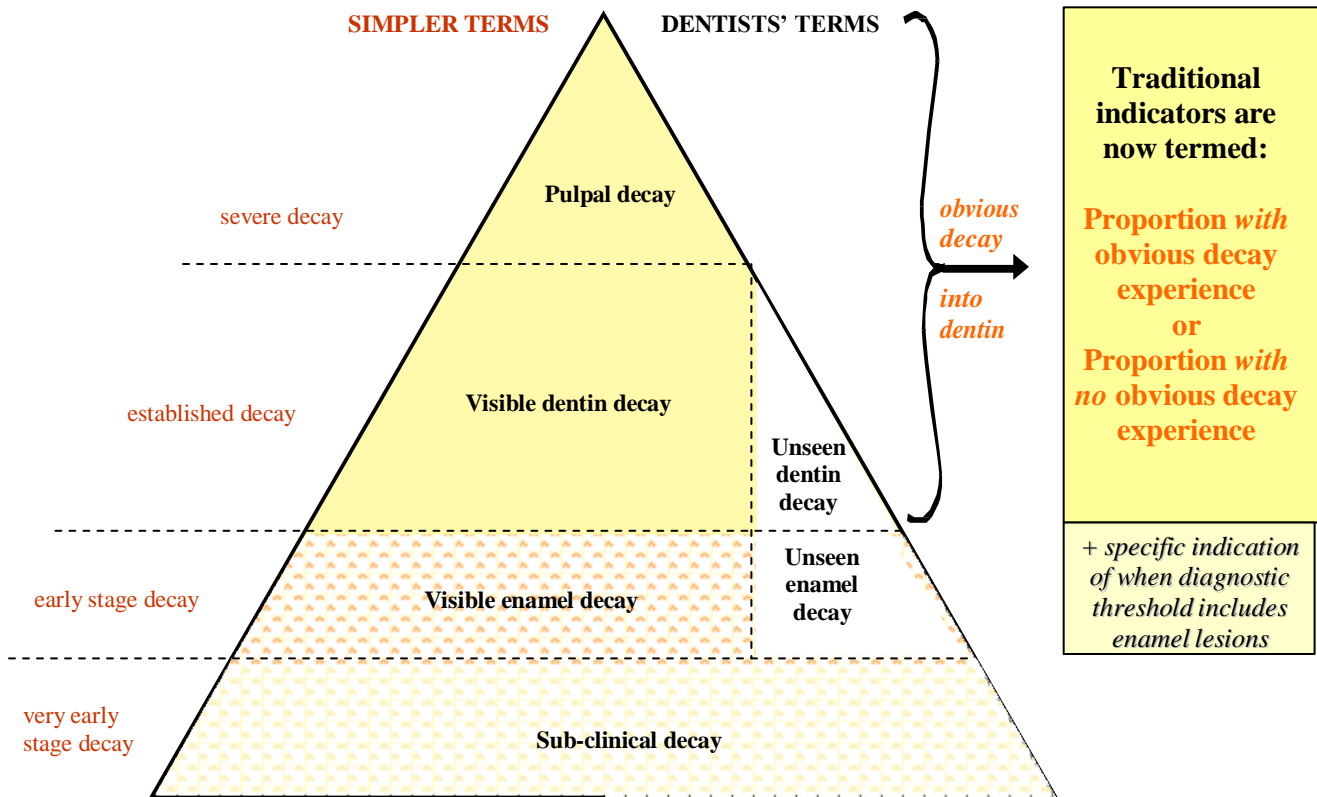
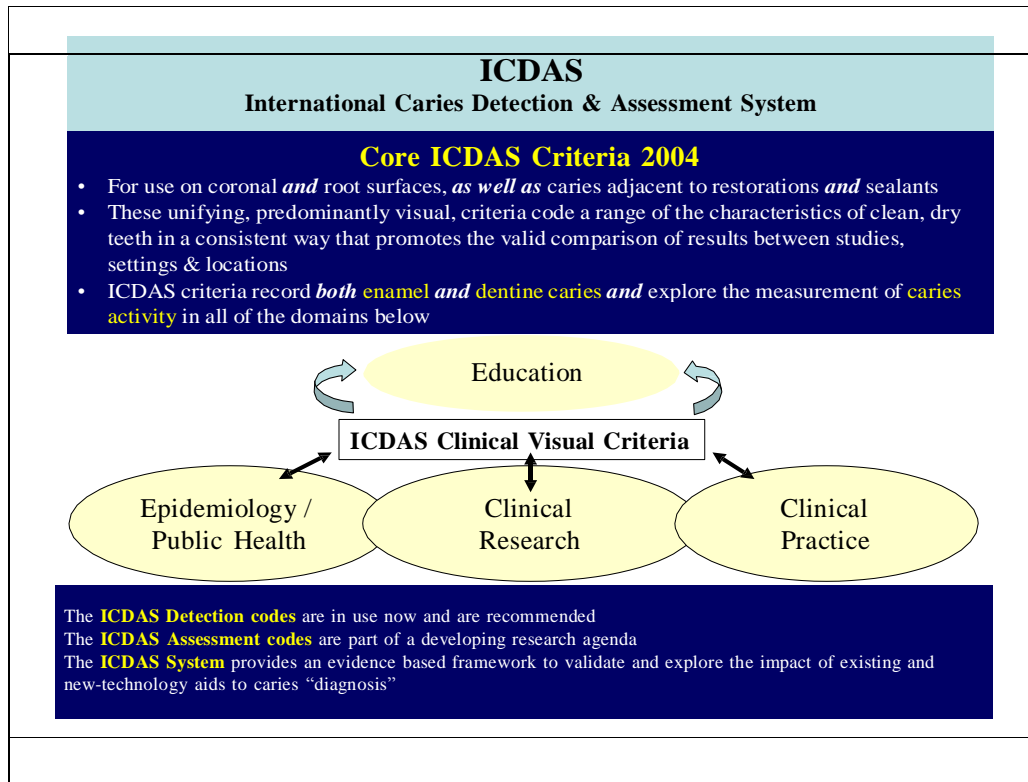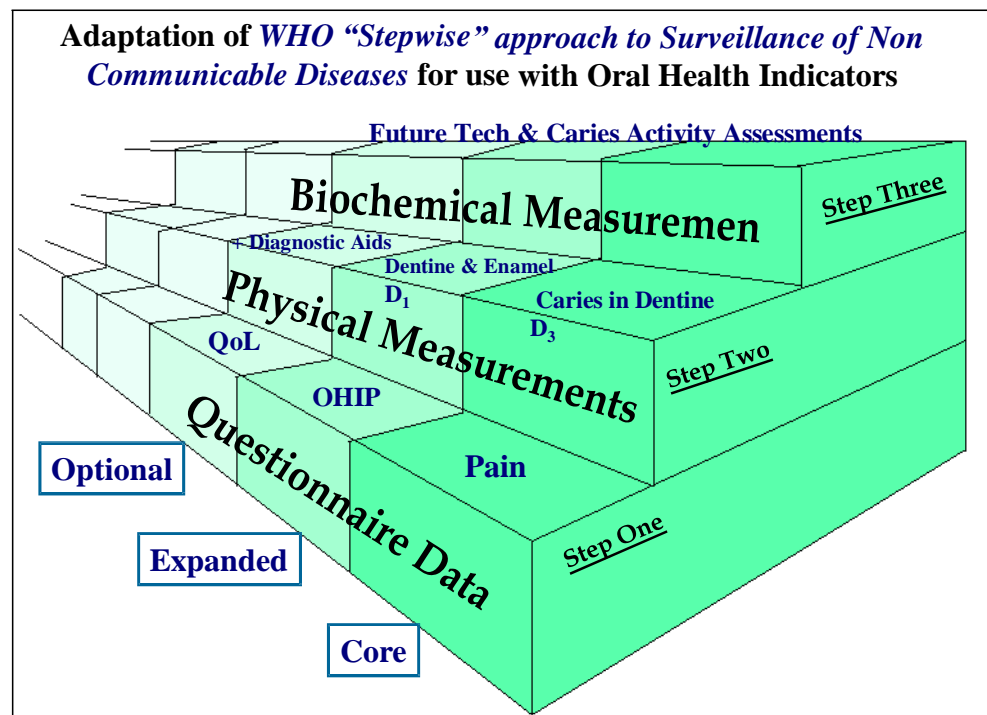**Figure 2. Overview of the development of the International Caries Detection and Assessment System – ICDAS.**

ICDAS
International Caries Detection & Assessment System

Core ICDAS Criteria 2004
- For use on coronal *and* root surfaces, *as well as* caries adjacent to restorations *and* sealants
- These unifying, predominantly visual, criteria code a range of the characteristics of clean, dry teeth in a consistent way that promotes the valid comparison of results between studies, settings & locations
- ICDAS criteria record *both* enamel *and* dentine caries *and* explore the measurement of caries activity in all of the domains below

Education

ICDAS Clinical Visual Criteria

Epidemiology / Public Health

Clinical Research

Clinical Practice

The **ICDAS Detection codes** are in use now and are recommended
The **ICDAS Assessment codes** are part of a developing research agenda
The **ICDAS System** provides an evidence based framework to validate and explore the impact of existing and new-technology aids to caries "diagnosis"

Figure 3. Adaptation of the World Health Organization (WHO) "stepwise" approach to surveillance of non-communicable diseases to enable an appropriate selection and integration of oral health indicators

Adaptation of *WHO "Stepwise" approach to Surveillance of Non Communicable Diseases* for use with Oral Health Indicators

Future Tech & Caries Activity Assessments

Biochemical Measuremen

Step Three

+ Diagnostic Aids

Dentine & Enamel D$_1$

Physical Measurements

Caries in Dentine D$_3$

QoL

Step Two

OHIP

Questionnaire Data

Pain

Optional

Expanded

Step One

Core

Adapted from Pitts, NB [2004]. ICDAS - an international system for caries detection and assessment being developed to facilitate caries epidemiology, research and appropriate clinical management. Community Dental Health, 21, 193-198.

Figure 4. Decision table for the ICDAS system.

ICDAS-II
Decision Table, Baltimore 2005

Epidemiology   Practice   Research   Education

←——— Clinical Visual Assessment ———→   ←—— Lesion Detection Aids ——→   ←—— Care Planning Aids ——→

Lay Terms	Dental Terms	Letter code	Number code	ICDAS activity	Bw	FOTI	Tech 1	Tech 2	Risk Status	Colour	Care Range
severe decay	Extensive cavity with visible dentin	X	6	p/a/r	-	-	-	-	h/m/l		PCA / OCA
severe decay	Distinct cavity with visible dentin	C	5	p/a/r	-	-	-	-	h/m/l		PCA / OCA
established decay	Non-cavitated surface with dentin shadow	N	4	p/a/r	-	-	-	-	h/m/l		PCA / OCA
established decay	Localized enamel breakdown	L	3	p/a/r	-	-	-	-	h/m/l	?	PCA / OCA
early stage decay *reversible/arrestible*	Distinct visual change in enamel	E	2	p/a/r	-	-	-	-	h/m/l		PCA
early stage decay *reversible/arrestible*	First visual change in enamel	V	1	p/a/r	-	-	-	-	h/m/l		PCA
Sound	Sound	S	0	p/a/r	-	-	-	-	h/m/l		App Care

Key: p = progressing, a = arresting, r = remineralizing; h = high risk, m = medium risk, l= low risk; PCA = Preventive Care Advised; OCA = Operative Care Advised.

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