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 Sumney et

al., 1973, Hix and O'Leary, 1976, Banting et al., 1980; Katz, 1984 and the 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 [gt1]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 0.77 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	