

ICCMS™ Guide for Practitioners and Educators

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On behalf of the Participating Authors of the International Caries Classification and Management System (ICCMSTM) Implementation Workshop, held June 2013**

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GCCM

Global Collaboratory for Caries Management



Directed by **ICDAS** and its **ICCMS™**

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**For a list of contributors from the ICCMS™ Implementation Workshop and development meetings since, please see Appendix A2.

Amid Ismail and Nigel Pitts are the co-Directors of ICDAS/ICCMS™ and are assisted by Stefania Martignon, the ICCMS™ Coordinator. Modifications, questions, and suggestions relating to the ICCMS™ Consensus Core resource document and this ICCMS™ Guide for Practitioners and Educators should be directed to Stefania Martignon (stefania.martignon@kcl.ac.uk) who also works with the current ICDAS coordinator Gail Douglas (g.v.a.douglas@leeds.ac.uk) as well as the ICDAS Coordinating Committee and the Global Collaboratory for Caries Management (GCCM), formed at King's College London under the supervision of Professor Nigel Pitts, with the aim of initiating comparative studies of the proposed systems and evaluate the process and outcomes of its implementation. Further details can be found in the webpages www.icdas.org and <a href="www.kcl.ac.uk/sspp/kpi/projects/healthpolicy/global-caries-management.aspx."

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Note: *ICCMS*™ is trademarked by the ICDAS Foundation in order that the International Caries Classification and Management System can remain open and available to all.

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Overview

The aim of this Guide is to describe the structure and facilitate the implementation of the International Caries Classification and Management System (ICCMS™), which the authors propose to be used in the daily handling of our patients for caries prevention and management and also in the teaching undertaken at dental schools around the world.

The ICCMS™ is a health outcomes focused system that aims to maintain health and preserve tooth structure. Staging of the caries process and activity assessment is followed by risk-adjusted preventive care, control of initial non-cavitated lesions, and conservative restorative treatment of deep dentinal and cavitated caries lesions.

There are four elements in the ICCMS™, the two key aspects are:

- Classification Caries Staging & Activity Assessment: this comprizes (i) staging of caries lesion severity ('initial'/'moderate'/'extensive') and (ii) caries activity assessment (likelihood of progression or arrest/reversal of lesions: 'active'/'inactive'). [Note that during the intraoral assessment phase information is also collected on oral risk factors; e.g. oral hygiene, dry mouth]
- Management Personalized Caries Prevention, Control & Tooth Preserving Operative Care: The dental team, together with the patient, devise a Personalized Caries Care Plan to manage the caries risk status of the patient as well as managing caries lesions appropriately. (i) Management of the risk status is based on both home care advice, as well as clinical activities; those with low risk getting general information on how to maintain teeth as sound, those with moderate and high risk with increasing focus on behavior changes and short periods between recalls to the clinic. (ii) The management of the lesions is related to the diagnosis of the individual lesions: 'initial' active lesions in general are managed with non-operative care (NOC) whilst moderate/extensive lesions are in general managed operatively with tooth preserving operative care (TPOC).

In order to devise an optimal Personalized Caries Management Plan, two other elements are also needed (please note that the chronological sequence and the method of integration of patient and clinical information may vary according to local preferences):

- **History Patient-level Caries Risk Assessment**: collation of risk information at the patient level (to be integrated with clinical and tooth level information).
- **Decision Making Synthesis and Diagnoses**: (i) classification of individual lesions combining information about their stage and activity (e.g. 'initial' active lesion), and (ii) an overall caries risk likelihood status combining information about presence/absence of active lesion/s and patient's risk ('low', 'moderate' or 'high' risk of getting future caries and/or of lesion progression).

The risk-based recall interval, including monitoring and review, then allows this caries management pathway to become a cycle, facilitating the achievement of optimal long-term health outcomes.

• Outcomes - are considered across: health maintenance, disease control, patient-centered quality metrics, as well as the wider impacts of using the ICCMS™ System.

The authors hope that this Guide will be useful in bringing the International Caries Classification and Management System - ICCMS™- to the attention of many more clinicians and educators around the world. We also hope that it will provide an indication of one way to operationalize the System. The characteristics of ICCMS™ are the delivery of effective, risk based caries care that prevents new lesions, controls initial caries non-operatively and preserves tooth tissue at all times.

The authors gratefully acknowledge the tremendous contributions of all the many parties who have contributed to both the ICDAS Foundation and to the development of ICCMS™.

Introduction

The International Caries Classification and Management System - ICCMS[™] - deliberately incorporates a range of options designed to accommodate the needs of different users across the ICDAS (International Caries Detection and Assessment System) domains of clinical practice, dental education, research and public health (see Figure 1). The ICCMS[™] system seeks to provide a standardized method for comprehensive caries classification and management, but recognizes fully that there are different ways for implementing such systems locally. ICCMS[™] builds on the evidence-based ICDAS system for the staging of caries. It also maintains the flexible approach of the ICDAS "wardrobe" which provides several approved options for categorising the disease according to local and/or specific needs, preferences and circumstances.

It must be appreciated that this Guide relates only to the use of the System in the domains of **Practice** and **Education**; there are a range of considerations and applications of ICDAS/ICCMS™ in Research and in Public Health that are important, but are beyond the scope of this Guide (see Figure 1).

The system outlined in this document is based on best evidence and consensus. The methodology used was wherever possible to use "SIGN" grading of the evidence with rapid reviews and then to use expert consensus to get recommendations based on the best available evidence. We hope that the expanding Global Collaboratory for Caries Management (GCCM) will provide a network to allow implementation of the ICCMS™ in ways that work locally. We also invite wider participation in the GCCM in order to secure continuous quality improvement as we implement, refine and localize this Guide.

For a long time, the field of caries detection, risk assessment, diagnosis, and management has been dominated by dogma and lack of translation of the best evidence into clinical practice¹. Therefore, over the last decade an international group of cariologists, epidemiogists and clinicians has worked to develop protocols for promoting appropriate management of caries based upon the best biological and clinical evidence.

The International Caries Classification and Management System - ICCMS™ - is linked to ICDAS. While ICDAS provides flexible and increasingly internationally adopted methods for classifying stages of the caries process and the activity status of lesions, ICCMS™ provides options to enable dentists and the dental team to integrate and synthesize tooth and patient information, including caries risk status, in order to plan, manage and review caries in clinical practice.

This document provides an international guide to the ICCMS™ System. The authors are aware of the need to focus on the key concepts and the cycle of caries management, but also to not be too prescriptive. We invite and anticipate local adaptation with flexibility which flows from the ICDAS "wardrobe" concept. The essential steps in delivering ICCMS™ are the four elements (specifically including the staging of lesions and assessment of caries activity) used to plan and deliver effective, risk based caries care that prevents new lesions, controls initial caries non-operatively and preserves tooth tissue at all times. Please note that a range of preferred risk assessment tools can be used with ICCMS™.

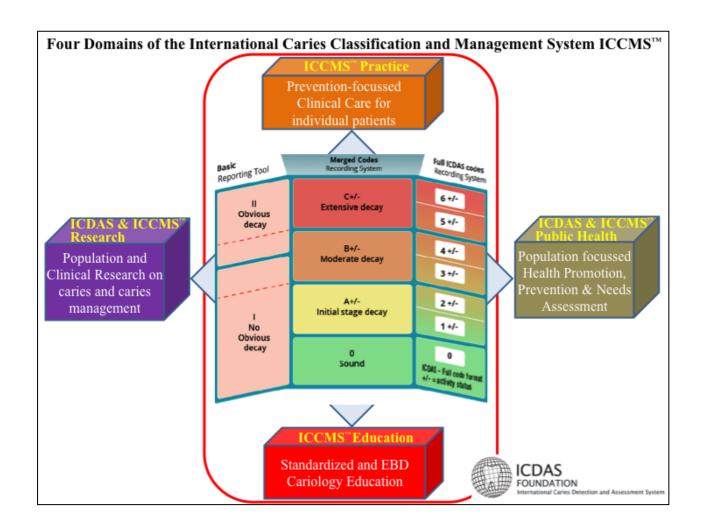


Figure 1. Identification of the ICCMS™ Practice and Education Domains relating to this manual (ICCMS™ Research and public health domains are beyond the scope of this manual).

The International Caries Classification and Management System - ICCMS™ is a health outcomes focused system that aims to maintain health and preserve tooth structure. Staging of the caries process and activity assessment is followed by risk-adjusted preventive care, control of initial non-cavitated lesions, and conservative restorative treatment of deep dentinal and cavitated caries lesions.

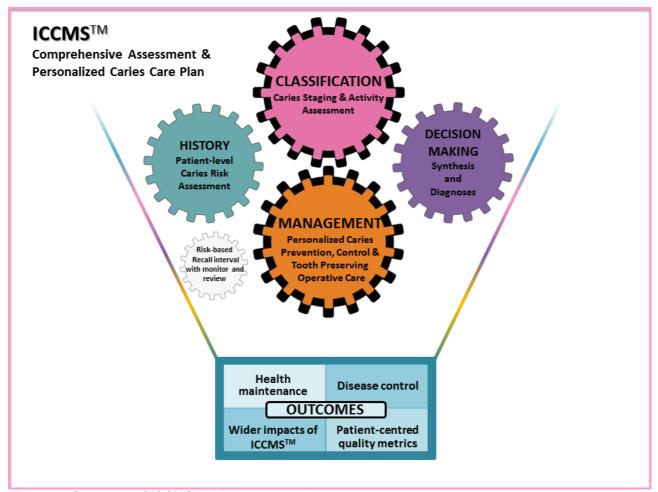


Figure 2. Overview of ICCMS™ Elements and Outcomes.

Figure 2 provides an overview of how ICCMS™ uses a simple form of the ICDAS Caries **Classification** model to stage caries severity and assess lesion activity in order to derive an appropriate, personalized, preventively biased, risk-adjusted, tooth preserving **Management** Plan. The ICCMS™ System is delivered as a cycle, which includes patient level Caries Risk Assessment along with Decision Making, which synthesizes both clinical and patient level information; it is then repeated according to risk-based recall intervals. The outcomes of using this systematic approach are assessed in terms of health maintenance, disease control, patient centered quality metrics as well as wider impacts away from individual patient care.

The ICCMS[™] development group have learned useful insights into routine clinical decision making and how to minimize unconscious diagnostic and treatment planning errors from Dr. Pat Croskerry (Division of Medical Education, Dalhousie University, Canada). His important work in this field began with researching decision making systems in emergency medicine, however his theories and teachings on heuristics are now being applied in many medical disciplines including caries diagnosis and management.

Heuristics are mental shortcuts that allow people to solve problems and make judgments efficiently in everyday life. They dominate our day-to-day clinical reasoning and are practical and effective, but can sometimes lead to cognitive errors in complex environments. (http://www.improvediagnosis.org/?CognitiveError). Most of the time clinicians (be they dentists, physicians or surgeons) use the so-called 'System 1' decision-making tactic.

System 1 is fast, autonomous, reflexive and inexpensive, but vulnerable to error. The experienced clinician devises set scripts and can move rapidly through routine repetitive tasks and arrive at good and appropriate decisions. However, he/she will recognize an atypical pattern when something doesn't quite fit and will then slow down and use 'System 2'. This is slow, deliberate, methodical but costly; it makes fewer errors and can allow the clinician to come up with a suitable care plan in complex or unusual cases.

In this Guide we have responded to this philosophy - Overview figures (with pink borders) show the key aspects of what should be done to deliver the ICCMS™ in 'System 1' type situations, which is typical of an experienced dentist working in a busy dental office or clinic. These figures communicate the key elements of ICCMS™. They can be viewed as a form of check-list. Detailed figures (with blue borders) are also provided and these show what is needed for situations where 'System 2' may be utilized and the clinician wants to slow down and move step by step through a more detailed pathway. The information summarized in the more detailed pathway diagrams is also useful for educators and for specifying outcomes. We hope that readers will use their judgment to choose which would be the appropriate decision making 'System' to use in different situations.

This document, named ICCMS™ Guide for Practitioners and Educators, focuses on the theoretical background that supports and facilitates the implementation of ICCMS™ and its practical applications in clinical practice and education. ICCMS™ has been developed by the ICDAS Foundation², with the help of a number of additional experts. It includes a comprehensive set of clinical protocols (drawn up based on the best available evidence) to support history taking, clinical examination, risk assessment and personalized care planning in order to enable improved long-term caries outcomes³.

1. History and Development of ICCMS[™]

The start point for the development of this system came in 2002, when groups of interested individuals from a number of international academic centers harmonized global evidence around caries detection and assessment to create the International Caries Detection and Assessment System (ICDAS). They have since maintained and developed the system with an increasing number of collaborators from around the world. The ICDAS Foundation was formed linking core centers in Dundee, Michigan, Indiana and Copenhagen. The current ICDAS foundation links many of the same core academic staff currently at the Universities of Kings College London, Temple, Indiana, Copenhagen, Dundee, Leeds, Michigan, Sheffield and many other academics and universities making up the ICDAS coordinating committee². The FDI World Dental Federation and researchers from the US National Institute for Dental and Craniofacial Research (NIDCR) have also contributed over the years. In recent years, the Alliance for a Cavity-Free Future (ACFF) and its chapters have also helped to promote ICDAS and ICCMS™.

The recognition of the then urgent need for a more standardized and robust method of classifying caries (with a focus on more than just the dentinal or cavitation stages of caries

as a threshold for making the decision to treat) came from an International Consensus Workshop on Caries Clinical Trials⁴⁻⁶.

The ICDAS Group recognized caries as an ever-changing challenge for both clinicians and epidemiologists/researchers. The group elected to merge a range of existing caries classification systems, which had been tested and reviewed by some of its members^{5,6}. These systems include a number of key papers linking clinical visual assessment of lesion extent and activity to histological validation^{7,8}, in order to produce an integrated caries classification system⁹. This system and the International Caries Classification and Management System (ICCMS™), which has been subsequently built upon it, has been the subject of a large number of peer reviewed papers from around the world².

The development of the ICCMS[™] system came through a series of international Workshops and symposia. It has been based on a contemporary understanding of the evidence on and around cariology¹⁰, international agreements on current caries terminology¹¹ and how best to advance tooth preserving caries management pathways¹².

The System has also been linked to the development and implementation of the European Core Curriculum on Cariology ^{13,14}. The FDI World Dental Federation serving as the principal representative body for more than one million dentists worldwide has published the FDI Caries Matrix which recognizes ICDAS in two of its three "levels" ¹⁵ (http://www.fdiworldental.org/media/11674/2011.ga.resolution.on.principle.of.caries.classification.and.management.matrix.pdf). Further, the FDI agreed (Hong Kong 2012) a policy statement on caries classification and management systems, which recommends that the elements of classification are kept distinct from those of management.

1.1 ICCMS[™]'s Goals for Caries Management

The mission of the International Caries Classification and Management System (ICCMS™) is to translate the current international understanding of the pathogenesis, prevention and control of dental caries in a holistic way through a comprehensive assessment and personalized caries care plan. This is in order to:

- prevent new lesions from appearing
- prevent existing lesions from advancing further
- preserve tooth structure with non-operative care at more initial stages and conservative operative care at more extensive caries stages

This should be done while managing risk factors through all of the elements in the caries management cycle and recalling patients at appropriate intervals, with periodic monitoring and reviewing.

The authors recommend that delivering these goals should be the driver for future remuneration systems and that outcome data should include these aspects.

A fundamental guidance statement relating to treatment decisions around operative intervention was agreed by all participants early in the development process and remains central to ICCMS™- this is to:

Preserve tooth structure and restore only when indicated.

Preservation of tooth structure in its widest sense drives all decisions in the ICCMS[™], as a patient-centered and biologically compatible system which is evidence-based (within the limitations of current knowledge), preventively oriented and safe for tooth structure. The system is focused on providing better care and better health at a lower cost and this philosophy has already shown some examples of important benefits in implementation¹⁶. Furthermore, the ICCMS[™] is compatible with modern International Educational conventions (such as the ORCA/ADEE Cariology Curriculum in Europe and the new CODA standards in the USA) which facilitates its implementation through undergraduate and continuing education. This approach has recently been demonstrated in the consensus on cariology teaching for undergraduate students achieved in the Colombian dental schools¹⁷ and progress being made across all dental schools in Malaysia.

1.2 Principles for Implementing ICCMS™

There are a number of key principles which underlie both the design and implementation of ICCMS™:

- 1. ICCMS™ aims to preserve tooth structure as there is a professional responsibility to avoid preventable removal of sound tooth tissue.
- 2. ICCMS™ aims to prevent caries from developing, to control the disease process if and when it occurs and to reverse existing lesions in order to limit the long-term damage to healthy sound tooth structure.
- 3. ICCMS™ maintains and improves the dental health "trajectory" of patients on a continuum of caries and dental health scale, with strong emphasis on both primary and secondary prevention across the life-course.
- 4. ICCMS™ is based around pragmatic and updated risk analysis and clinical risk management for the individual patient.
- 5. ICCMS™ is based around staging of the caries process and lesion activity.
- 6. ICCMS™ aims to prevent the development of new caries lesions and prevent existing initial caries from progressing.
- 7. ICCMS[™] care involves the use of caries lesion-defined preservative cavity preparations, cut only when operative intervention is clearly indicated and as a last resort. The guiding philosophy is to "preserve dental tissues first and restore only when indicated".
- 8. ICCMS™ care involves the use of regular and patient specific recalls based on the current risk status.

1.3 ICCMS[™] Caries Management Pathway

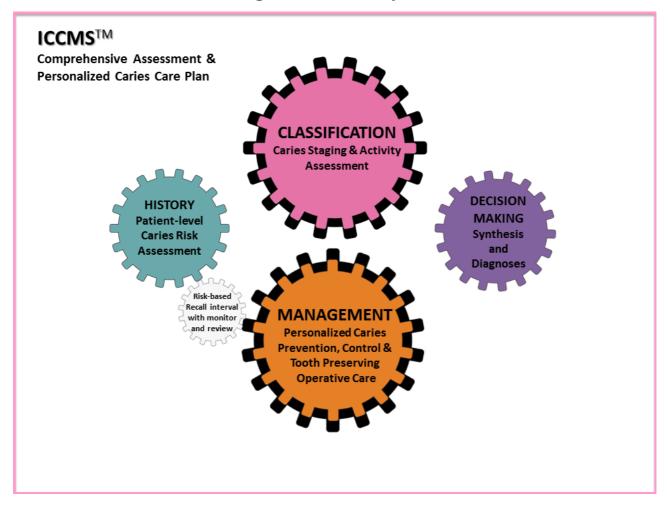


Figure 3. The Four ICCMS™ Elements, linked by risk-based recall.

The principles which the ICCMSTM is using are depicted in a cyclic format in Figure 3 and include four key elements. The **First Element** involves collecting a history from patients on their chief medical and dental complaints, past dental and medical history, history of present complaints, symptoms and preference for outcomes and then assesses the patient level risk factors. This step is integrated with the **Second Element**, the Caries Classification step, that starts with conducting an assessment of plaque on the teeth, followed by the clinical visual examination of the teeth, which focuses on determining the caries categories (sound, initial, moderate, extensive) on each tooth and tooth surface, assesses the activity state of each lesion, radiographic analysis (when available), and evaluates the caries experience (including number of restorations, state of previous restorative work, teeth extracted due to caries reasons, and dental sepsis), as well as other intraoral risk factors. The data collected from the interview and clinical examination are analyzed and synthesized in the **Third Element**, decision making, to synthesize and diagnose the risk of getting new lesions in the future and to diagnose each lesion in terms of whether or not they are active and if they are of initial, moderate or extensive severity.

To help in these procedures the ICCMS™ works with a matrix for Caries Risk and Likelihood at the patient level and information about staged caries severity & activity at the lesion/surface level (see 2.3.2). An important factor in developing a Patient Care Plan is the

patient's preferences in terms of the outcomes of different caries management options. The **Fourth Element,** management, is to develop a Personalized Caries Care Plan to prevent sound tooth surfaces from developing caries, prevent initial lesions from progressing to cavitated stages and manage "deep dentinal" and cavitated lesions following with Tooth Preserving Operative Care (TPOC), within an individual risk management plan that includes the recall interval, the monitoring of the status of caries lesions and the reviewing of the patient behavioral change plan (Figure 4).

Please note that the Caries Management Pathway is cyclical as each element follows on in turn. Additional detail is given in Figure 4 in order to demonstrate a recommended method of implementation. The cycle restarts after each risk based recall interval.

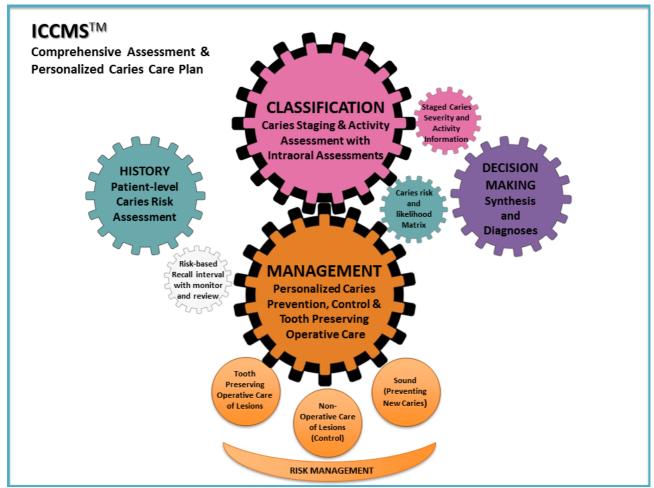


Figure 4. Detailed overview of ICCMS™ elements and their components.

2. ICCMS[™] Elements and the supporting evidence

The four elements of ICCMS[™] are described following the order in which the practitioner would typically proceed with the Caries Management Pathway. The classification and management Elements are distinctive and essential to ICCMS[™].

2.1 Element 1- History- Patient-Level Caries Risk Assessment

The evidence base describes risk factors, risk indicators and risk predictors, and there are specific definitions to support each of these. However for the purpose of this document, we will call all of these "risk factors". The authors are aware that, particularly for adults and older age groups, there are gaps in the evidence but hope that the Collaboratory will, in the future, provide better evidence in this area.

Prior to looking into the mouth, and having ensured that there are no urgent pain related issues, patient risk factors for caries are assessed (Figure 5).



Figure 5. Element 1- History- Patient-Level Caries Risk Assessment.

Listed below are the risk factors which may contribute towards an overall patient-level assessment of caries risk status. Further details and evidence can be found in Appendix C.

Patient level caries risk factors

Head and Neck Radiation

- Dry mouth (conditions, medications/recreational drugs/self report)
- · Inadequate oral hygiene practices
- Deficient exposure to topical fluoride
- High frequency/ amount of sugary drinks/ snacks
- Symptomatic-driven dental attendance
- Social-economic status/Health access barriers
- For children: high caries experience of mothers or caregivers

Box 1. Patient level caries risk factors.

Note: Risk factors in red denote a factor which will always classify an individual as high caries risk.

The patient-level risk factors are ascertained by taking a history to assess whether the patient has had radiation treatment, any use of medications, social background, dental attendance and to understand the patients diet.

2.2 Element 2- Classification: Caries Staging and Lesion Activity with Intraoral Caries Risk Assessments

This section describes the clinical caries assessment which stages caries severity and assesses caries activty (Figure 6). This step also includes the assessment of the intraoral caries risk factors.

Plaque assessment is essential for intraoral caries risk determination, but plaque has to be removed for accurate caries staging and lesion activity assessment. The assessment of caries will always be conducted by means of visual examination and when possible, combined with radiographic examination. This will lead to information about the stage of caries (in terms of initial, moderate or extensive) and its activity status at the lesion level (in terms of arrested or active).

The intraoral risk factors, together with the patient level risk factors will contribute towards the caries risk and likelihood matrix- see 2.3.2.

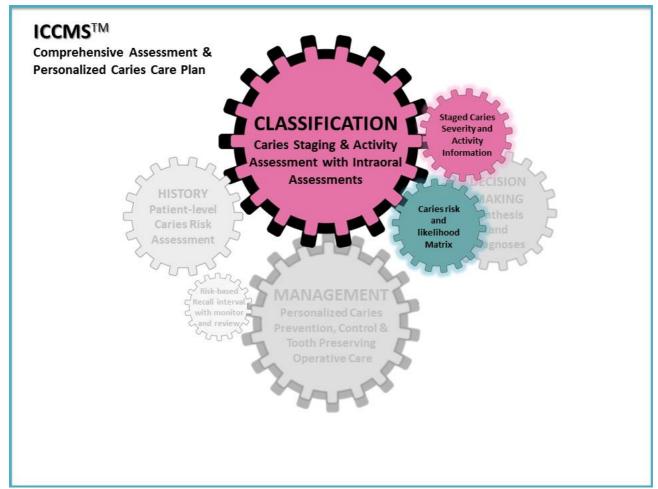


Figure 6. Element 2- Classification: Caries Staging and Lesion Activity Assessment with Intraoral Caries Risk Factors.

2.2.1 Assessment of Caries Risk Factors Intraorally

The ICCMSTM recommends assessing the following intraoral risk factors during the clinical examination of patients.

Intraoral level caries risk factors

- Hypo-salivation/Gross indicators of dry mouth
- PUFA (Exposed Pulp, Ulceration, Fistula, Absess) Dental sepsis
- · Caries experience and active lesions
- Thick plaque: evidence of sticky biofilm in plaque stagnation areas
- Appliances, restorations and other causes of increased biofilm retention
- Exposed root surfaces

Box 2. Intraoral level caries risk factors.

Note 1: Risk factors in red denote a factor which will always classify an individual as high caries risk.

Note 2. For child patients, prolonged nursing or bottle feeding is considered an increased risk of caries, as are erupting permanent molar teeth.

Further detail and evidence can be found in Appendix C.

The risk factors mentioned above correspond to those with higher association with caries risk status, and are to be considered for risk assessment. The dentist/dental team's hunch is also considered to be important on the basis of several studies¹⁸⁻²⁰.

As for how to calculate the caries risk status of the patient there are currently a range of diverse tests available, as well as computer-based systems for the individual assessment of caries risk, ranging from national or local forms to forms from professional organizations and others. ICCMS™ embraces the CAMBRA²¹ (Caries Management by Risk Assessment) philosophy for risk assessment.

Some other examples of caries risk assessment methods are listed below:

- Cariogram²²
- ADA²³
- University of Michigan / University of Indiana²⁴
- University of North Carolina 18,19
- Dundee Risk Assessment Model²⁰
- Caries Management book' risk form²⁵
- The ICCMSTM risk factors listed in this document.

They take into account different risk factors combining medical and dental health, as well as behavior and clinical data. While the evidence is still limited regarding which system to use, it is considered best clinical practice and best care for patients to assess individual caries risk taking into account local adaptations and age^{26,27}. Continuing research in this field is necessary, but until more complete evidence is available, existing methods should be used to support clinical practice according to local needs and preferences. Caries risk assessment systems typically assign three levels of risk, and the ICCMS™ development group (having reviewed the literature) defined low, moderate and high risk according to the criteria detailed in Table 1.

	Patient's Risk Status				
Low risk status Lack of any high caries risk factor (Box 1: red text) and other ranges (e.g. sugary snacks, oral hygiene practical fluoride exposure).					
Moderate risk status	A stage where the individual is not deemed to be definitely at Low risk or definitely at High risk of developing new caries lesions or of lesion progression.				
High risk status	Presence of any of the high risk factors in Box 1 or caregivers with very high caries experience or where the level of several of the lower risk factors in Box 1 suggests a combination likely to lead to a high risk status – the number and levels of these factors will vary according to geographical location and the prevailing socio-economic conditions.				

Table 1. Risk status of the patient

ICCMSTM considers that the likelihood of new caries lesions or the progression of existing lesions should result from the analysis of combining the patient's risk status (Elements 1 and 2) with the presence (or not) of active lesions. This combination is known as the Caries Risk and Likelihood Matrix. The outcome of this matrix can be used as part of the synthesis outlined in Element 3.

2.2.2 Staging lesions

The staging of caries lesions involves two steps of the caries diagnosis process⁴:

- Lesion detection (which implies an objective method of determining whether or not caries disease is present)
- Lesion assessment (which aims to characterize or monitor a lesion once it has been detected).

The summation and analysis of these will eventually lead to a third step, the caries diagnosis, which should imply a human professional summation of all available data. This will be considered in Element 3.

With the ICCMSTM system, following the ICDAS examination protocol²⁸, prior to the staging of caries lesions plaque should be removed in order to allow for an appropriate visual examination of the tooth surfaces (by means of professional prophylaxis, toothbrushing or cotton pellets) with appropriate light and the use of a ball-end probe (WHO probe).

At this point, the detection of lesions related to other conditions (different to caries) should be disregarded, such as developmental defects of the enamel- DDE (hypoplasia and hypomineralization), non-carious lesions (erosion, abrasion, abfraction), and the current status of the fillings (ditching, fracture) as these will not be considered in this document. Coronal primary caries will be fully described in this guide. For full definition of ICCMSTM categories see Appendix D. Root caries lesions will be described in Appendix E.

The examination should be conducted clinically, and where x-ray facilities are available together with a radiographic examination (in some countries radiographs could be assessed prior to the clinical assessment, depending on local regulations). Following this first step in staging lesion severity, the second step involves the activity assessment of the present lesions (see 2.2.2.4).

2.2.2.1 Staging coronal caries lesions clinically

For the purposes of this guide, the staging of coronal caries will include primary caries and caries associated with restorations/sealants (CARS) as one classification system. For the purpose of caries management, the ICCMSTM categorizes the lesions with the ICDAS merged codes (Table 2). For full definitions of ICCMSTM categories see Appendix D.

Definition of ICCMS™ Caries Merged categories Sound tooth surfaces show no evidence of visible caries (no or questionable change in enamel translucency) when viewed clean and after prolonged air-drying (5 seconds). Sound surfaces (ICDASTM (Surfaces with developmental defects such as enamel code 0) hypomineralization (including fluorosis), tooth wear (attrition, abrasion and erosion), and extrinsic or intrinsic stains will be recorded as sound). Initial First or distinct visual changes in enamel seen as a carious opacity or visible discoloration (white spot lesion stage and/or brown carious discoloration) not consistent with caries (ICDASTM clinical appearance of sound enamel (ICDASTM code 1 or Caries categories 2) and which show no evidence of surface breakdown or codes 1 and 2) underlying dentin shadowing. A white or brown spot lesion with Localized enamel **breakdown**, without visible dentin exposure (ICDASTM code 3), or an Underlying dentin shadow (ICDASTM **Moderate** code 4), which obviously originated on the surface being stage caries evaluated. (ICDASTM codes 3 (To confirm enamel breakdown, a WHO/CPI/PSR balland 4) end probe can be used gently across the tooth area - a limited discontinuity is detected if the ball drops into the enamel micro-cavity/discontinuity). **Extensive** A distinct cavity in opaque or discolored enamel with stage visible dentin (ICDASTM code 5 or 6). caries (ICDASTM codes 5 (A WHO/CPI/PSR probe can confirm the cavity extends and 6) into dentin).

Table 2. Definition of ICCMS[™] Caries categories (merged codes).

2.2.2.2 Staging coronal caries lesions radiographically

Radiographic information adds significantly to clinical findings in terms of finding lesions at different stages of progression²⁹⁻³². Radiographs help estimate the depth of caries demineralization into enamel and dentin. Depth is not always associated with the presence of cavitation, particularly on approximal surfaces.

Clinical investigations in a country with low caries progression rates revealed that, on average, 32% of radiographically visible lesions that extended into the outer third of the dentin manifested cavitation; in contrast, 72% of lesions extending into the inner 2/3 of the dentin were cavitated³³. Clinically cavitated lesions or lesions with obvious dentin radiolucency (deeper than the outer 1/3) on the occlusal surface are heavily infected in the dentin beneath the enamel dentin junction^{34,35}.

For establishing whether a lesion has progressed or not, two radiographs with a time lapse between are required.

If radiographs are available the first step is to grade coronal caries lesions on posterior teeth according to the scores in Table 3.

The ICCMS[™] classifies posterior tooth surfaces radiographically^{36,37}. Both the reproducibility and accuracy of this scoring system has been reported to be substantial³³ to excellent³⁷.

The evidence indicates that the radiographic penetration depth, at which one can reliably predict that the tooth surface is cavitated and dentin is heavily infected, is in the region of radiolucency deeper than the outer third of the dentin^{7,34,35,38-40}. This corresponds to scores 4, 5 and 6 in the ICCMS™ radiographic scoring system. With faster caries progression rates, cavity formation can also be expected in cases scored as 3 in the above system.

It must be appreciated that different conventions exist in different countries for classifying the severity of lesions where operative care is required. More evidence is needed to reduce international variation on this issue.

	ICDAS Radiographic scoring system						
	0	No radiolucency	M	No radiolucency			
	RA: Initial stages	RA 1		Radiolucency in the outer ½ of the enamel			
gories		RA 2		Radiolucency in the inner ½ of the enamel ± EDJ (enamel-dentin junction)			
ICCMS™ Caries Categories		RA 3		Radiolucency limited to the outer 1/3 of dentin			
ICCMS	RB: Moderate stages	RB 4		Radiolucency reaching the middle 1/3 of dentin			
	RC: Extensive stages	RC 5		Radiolucency reaching the inner 1/3 of dentin, clinically cavitated			
		RC 6		Radiolucency into the pulp, clinically cavitated			

Table 3. ICDAS/ICCMS™ radiographic scoring system.

2.2.2.3 Combining clinical and radiographic information

Eventually, both the radiographic (when available and for posterior teeth) and the clinical assessment of the lesion severity end up classifying the lesion into the categories of initial, moderate or extensive.

	Radiographic Categories (R)				
ICCMS [™] Categories (C)	R₀ ∰	RA ₁₋₂	RA ₃	RB (Si)	RC RA RA
C _{Sound}	Sound _{cr}	Initial _{CR}	Initial _{CR}	Moderate _{CR}	Extensive _{CR}
C _{Initial}	Initial _{CR}	Initial _{CR}	Initial _{CR} or Moderate _{CR}	Moderate _{CR}	Extensive _{CR}
C _{Moderate}	Moderate _{CR}	Moderate _{CR}	Moderate _{CR}	Moderate _{CR}	Extensive _{CR}
C _{Extensive}	Extensive _{CR}	Extensive _{CR}	Extensive _{CR}	Extensive _{CR}	Extensive _{CR}

Table 4. Combination of clinical and radiographic information.

Note- most lesions confined to enamel are not seen on radiographs.

Once again, it is important to recognize the variation between countries in defining lesion severity and radiographic equivalence. More evidence should help reduce this varietiation.

2.2.2.4 Lesion activity assessment

Currently it is clear that caries lesions can be detected and assessed at an early stage as initial lesions^{2,3,8}. These, and also lesions at a further stage of severity, can be progressing at the moment of the clinical examination. Therefore, the next step after the severity assessment of the caries lesions is to judge if these, irrespective of stage, are inactive or active.

While there are no current valid biological or clinical tools to assess caries activity and no single variable predicts whether a lesion is active or arrested, clinicians should rely on clinical indicators^{1,8,41-44}. Clinical observations to be taken into consideration for assessing enamel lesion activity are based on the modifications of the Nyvad et al.^{45,46} and the Ekstrand et al.⁴⁷⁻⁴⁹ caries lesion activity assessment criteria and include visual appearance, tactile feeling, potential for plaque accumulation and, for lesions located near the gingiva, the gingival health/disease status (Table 5).

It is known that some lesions are at an inactive stage; e.g. initial caries lesions located in the middle third of the buccal surfaces of primary molars that also show signs of white spot lesions and are smooth when gentle tactile assessment is conducted with a probe; initial caries lesions located in the occlusal surface of a bicuspid/molar tooth that also shows signs of brown spot lesions and are smooth to gentle probing.

Current available evidence since the work of Baker-Dirks in the 1950's⁵⁰ demonstrates that inactive lesions are less likely to progress than active lesions. This leads to the need to assess the activity status of lesions as part of determining the likelihood of progression. It is also important to link likely future progression with the intensity of care planned, in order for cost effective management of the disease (health economic studies in this area are needed, and some are underway).

Evidence in this field is scarcer than that on severity staging of lesions, however it is of importance to record activity. Therefore the best available evidence so far is presented below.

The scientific definitions and characteristics of active and inactive lesions have been defined in an international glossary (Appendix J) and are described below:

- An Active Lesion is considered to have a greater likelihood of transition (progress, arrest or regress) than an inactive lesion (there is an increase in dynamic activity in terms of mineral movement).
- An Inactive (arrested) Lesion is considered to have a lesser likelihood of transition than an active lesion (there is less movement of mineral and the lesion stays at the same stage of severity.)

ICCMS TM	Characteristics of Lesion				
Code	Signs of Active Lesions	Signs of Inactive Lesions			
ICCMS [™] Initial and Moderate Caries Stage	Surface of enamel is whitish/yellowish; opaque with loss of luster, feels rough when the tip of the ball-ended probe is moved gently across the surface. Lesion is in a plaque stagnation area, i.e. in the entrance of pits and fissures, near the gingival margin or, for proximal surfaces, below or above the contact point. The lesion may be covered by thick plaque prior to cleaning.	Surface of enamel is whitish, brownish or black. Enamel may be shiny and feels hard and smooth when the tip of the ballended probe is moved gently across the surface. For smooth surfaces, the caries lesion is typically located at some distance from the gingival margin. Lesion may not be covered by thick plaque prior to cleaning.			
ICCMS [™] Extensive Caries Stage	Dentin feels soft or leathery on gentle probing.	Dentin is shiny and hard on gentle probing.			

Table 5. Characteristics of lesion activity across the ICCMSTM coronal caries stages.

2.3 Element 3- Decision Making: Synthesis and Diagnosis

This element deals with the third step of the diagnosis process⁴ which involves the summation and analysis of information from the first two elements, regarding both the patient and the lesion level. The result will be the synthesis and diagnosis of the likelihood of new/progressing lesions in low, moderate or extensive risk status, and of each lesion in terms of whether or not they are active and if they are of initial, moderate or extensive severity.

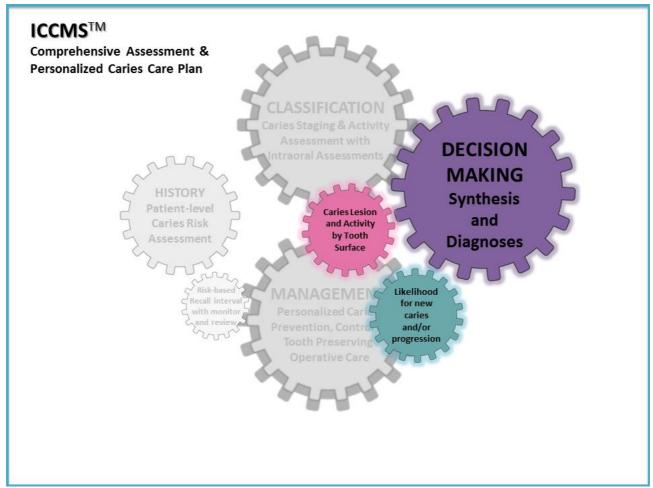


Figure 7. Element 3- Decision Making: Synthesis of information to reach Diagnosis and Risk Status.

2.3.1 ICCMS™ caries diagnosis

ICCMS[™] caries diagnosis is the result of the analysis of the combination of clinical and radiographic information (the latter when available) plus the lesion activity assessment. Table 6 shows the ICCMS[™] terminology for caries diagnosis. Please consider that as lesion activity can change, so can a recorded diagnosis.

ICCMS TM	Activity status		
combined Categories	Active lesions	Inactive lesions	
ICCMS [™] Sound	No lesion	No lesion	
ICCMS [™] Initial	Initial Active	Initial Inactive	
ICCMS [™] Moderate	Moderate Active	Moderate Inactive	
ICCMS [™] Extensive	Extensive Active	Extensive Inactive	

Table 6. ICCMS™ caries diagnosis (staging and activity status per lesion).

2.3 2 ICCMS™ caries risk analysis to assess likelihood of new lesions or caries progression

Recommendations based on best evidence²⁷ state that individual caries risk analysis is an important step in caries management and for achieving the best overall outcomes for patients. The ICCMS™ agrees, even though the evidence on the predictive validity of current assessment tools in many age groups needs to be strengthened further. The consensus view is that risk assessment should be conducted as an integral part of the personalized caries care plan. It is hoped that the collection of data and evaluations from the Global Collaboratory of Caries Management will provide new evidence and insight to develop the evidence base in this area, and on the effectiveness and utility of the ICCMS™ Caries Risk and Likelihood Matrix outlined below. As stated previously (2.2.1) it is acceptable for groups to choose a locally acceptable caries risk assessment method to use with ICCMS™.

ICCMS[™] caries risk analysis assesses the likelihood of new lesions or caries progression. It involves the stratification of individuals into low, medium, or high-risk status, irrespective of the tool used (Table 1), and the current caries activity status at the patient level.

These two aspects are combined into a matrix, shown as Table 7 below.

		Current Caries Activity Status at the Patient Level			
		No active caries lesions*	Initial stage active caries lesions	Moderate- or extensive-stage active caries lesions	
Risk status	Low risk	Low likelihood	Moderate likelihood	Moderate likelihood*	
	Moderate risk	Low likelihood	Moderate likelihood	High likelihood	
	High risk	Moderate likelihood	High likelihood	High likelihood	

^{*}Sound surfaces and/or inactive lesions

Table 7. ICCMS™ Caries Risk and Likelihood Matrix.

This matrix integrates three categories of current caries activity status at the patient level (none, initial, moderate/extensive) and the risk-status stratification (low, moderate, and high) into a likelihood matrix that stratifies individuals into low, moderate, or high likelihood of developing new caries lesions or the progression of existing lesions.

The current caries status at the patient level synthesizes whether or not there are any active lesions (sound and/or inactive caries), whether active lesions at the patient level are initial stage caries, or whether active lesions at the patient level are at a moderate and/or extensive stage of severity.

*Note- the top right cell in the matrix, at the intersection of Low patient risk status and the presence of moderate or extensive-stage active lesions in a patient, covers a wide range of possibilities. The number of lesions detected in a patient could potentially range from one active moderate or extensive lesion through to many such lesions. In either case, the likelihood of developing new lesions or the progression of caries is judged to be moderate, even if the patient level risk status is judged to be low. Specific variations may also be needed when dealing with young caries active children and some advocate assessing the cleansibility of lesions as well.

The way in which this matrix is generated and applied clinically can be understood further by reference to the Case Study outlined in Appendix L.

The core of the matrix represents nine color coded cells where the likelihood of new lesions or progression have been grouped into colors reflecting a traffic light analogy, green being associated with the lower likelihood of new lesions or progression, yellow a moderate likelihood of new lesions or progression, and red a high likelihood of new lesions or progression. For each of these likelihood categories ICCMSTM has defined evidence-based preventive and management strategies to either keep the risk of caries low, or to lower the likelihood of caries lesion development. This novel approach provides a link between caries risk status and management of risk.

The Global Collaboratory for Caries Management is developing a series of implementation tools to help operationalize this matrix. We will be making available software apps and paper-based tools to support the preventive and management aspects of this system. Updates and information will be made available through the ICDAS website (www.icdas.org)².

2.4 Element 4- Management: Personalized Caries Prevention, Control & Tooth Preserving Operative Care

After defining the individual patient's likelihood risk status and the diagnosis for each lesion, ICCMSTM presents a management element to build a comprehensive patient care plan (Figure 8).

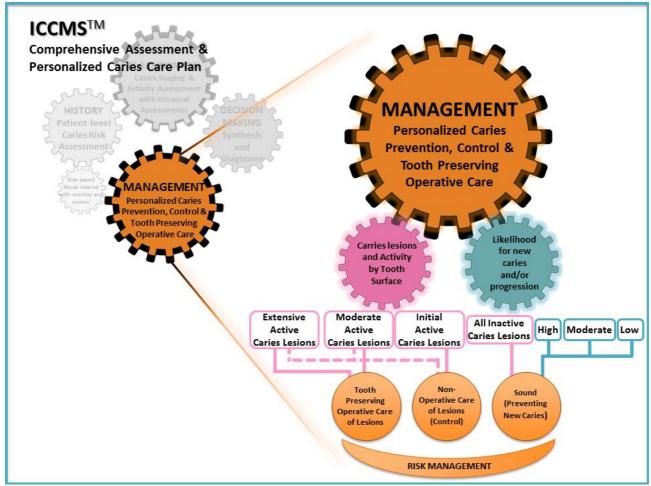


Figure 8. Element 4- Management- Personalized Caries Prevention, Control & Tooth Preserving Operative Care.

The Personalized Comprehensive Caries Care Plan involves and interconnects:

- Managing patient's likelihood for new caries and/or progression (risk status), whether low, moderate or extensive
- Managing individual caries lesions, with caries related treatment when they are active and defining different options according to their severity and taking into account if the dentition is primary or permanent for coronal caries.

The Management Element Includes:

- Preventing New Caries
- Non-Operative Care of lesions (NOC) (Control)
- Tooth Preserving Operative Care of lesions (TPOC),

As an integrated aspect, Risk Management applies to all of the above elements of the care plan.

Recall interval, Monitoring and Review will be considered at the end of this section. The risk-based review links to the start of the next cycle of the ICCMS™.

It is important to emphasize that if a patient presents with acute conditions and pain, these have to be managed as a priority before detailed care planning takes place.

The following subsections will describe the Comprehensive Caries Care Plan thoroughly, showing the best available evidence for recommendations.

2.4.1 Managing a patient's risk factors

The patient's caries risk factors management plan is tailored at the individual level and involves actions to protect sound tooth surfaces from developing new caries lesions, and all current active and inactive lesions from progressing. In addition, it aims to lower the risk status of the patient when moderate or extensive, and to maintain if low. A preventive plan should address both homecare and clinical interventions/approaches adjusted to the caries risk likelihood status of each patient. Based on the best available evidence, and depending on the caries risk likelihood status, ICCMSTM recommends the activities shown in Figure 9 (See Appendix G). Practitioners may choose from a package of preventive interventions based on caries risk likelihood status.

The intensity of the intervention is cumulative, so for patients with moderate caries risk likelihood all preventive interventions prescribed for patients with low caries risk likelihood should also be considered. Similarly for high caries risk likelihood patients all preventive interventions prescribed for low and moderate caries risk likelihood patients should also be considered in the patient's care plan. The ICCMSTM risk-based recall (re-care) interval for patients is described in subsection 2.5.

Note: Local adaptations may be required, for example according to varied levels of systemic fluoride concentration.

It is the ICCMSTM belief that prevention is an ongoing and dynamic process that involves engaging patients in reviewing their dietary and oral hygiene behaviors as well as clinical preventive care from the first dental visit.

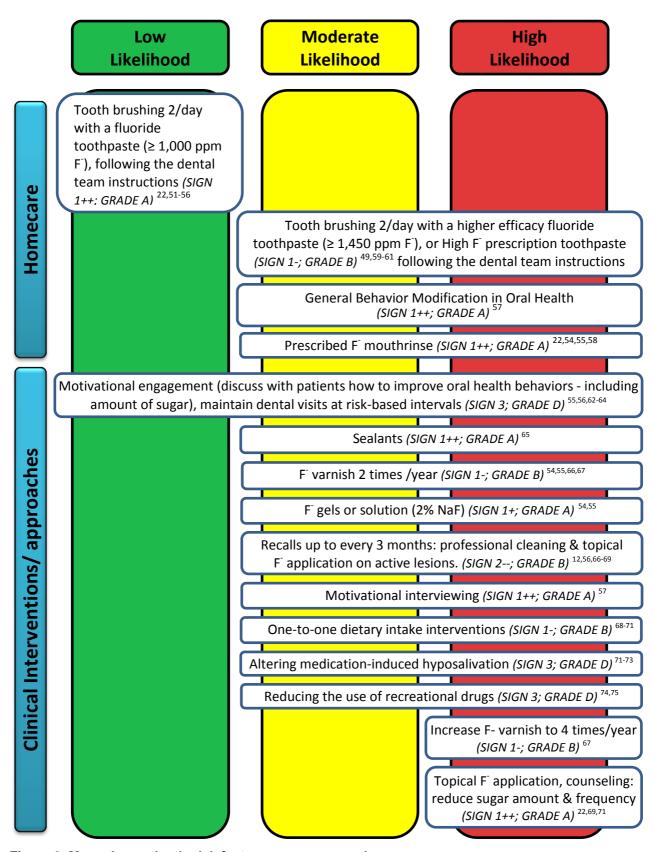


Figure 9. Managing patient's risk factors – core approach.

- Note 1: In some countries, chlorhexidine may be considered as a preventive treatment option.
- Note 2: This guide is provided as an overview for all age groups, however it is recognized that specific versions targeted for narrower age groups would be useful as later developments.
- Note 3: Local regulatory requirements and professional recommendations may modify fluoride concentrations in topical products.
- Note 4: Head & neck radiation, dry mouth hyposalivation, and PUFA signs, indicate the need for special care, including additional measures.
- Note 5: The frequency of preventive care should increase for the High Likelihood patients.

2.4.2 Managing Individual Lesions

The managing individual caries lesions plan is tailored at the lesion level. The ICCMSTM caries diagnosis (Table 6) is applicable to caries management decisions. The level of intervention depends on the clinical caries classification of the surface or tooth and the radiological extent (when information is available) of the lesion in enamel or dentin. The levels of clinical management recommended for active lesions are defined as follows:

M_{Initial}: Initial caries management stage (Non-Operative care (NOC) - control)

M_{Moderate}: Moderate caries management stage (in general TPOC)
M_{Extensive}: Extensive caries management stage (in general TPOC)

For sound surfaces and inactive lesions, risk-based prevention is recommended.

The only treatment decision suggested by ICCMSTM review of the best available evidence which can be considered as locally modifiable is where the clinical examination classifies the lesion as moderate but radiographically as RA3 (radiolucency reaching the outer one-third of dentin). The clinical options here may be either to manage these lesions non-operatively or by TPOC.

The ICCMSTM tooth preserving operative principles should guide decisions for all restorative care. Surgical restorative interventions are only used as a last resort. The shape and extent of the cavity preparation is dictated by the spread of the caries lesions and presence of infected or affected dentin. Caries removal from the pulpal aspect of the cavity should be carried out to remove soft infected dentin and prevent exposure of a vital pulp (assessment of pulp vitality is an important consideration prior to managing lesions which may be close to the pulp). It is acceptable to leave discolored carious dentin pulpally. In active extensive lesions where there is a risk of vital pulpal exposure, stepwise or partial excavation of caries should be carried out. Wherever possible, exposure of the dental pulp should be avoided.

With respect to Caries Associated with Restorations or Sealants (CARS) ICCMSTM recommends to either seal or repair defective or carious margins wherever possible. This also applies to defective or lost fissure sealants, which require maintenance/ repair only.

Based on best available evidence (See Appendix H) and depending on the caries category ICCMSTM recommends activities shown in Table 8 for permanent - and Table 9 for primary teeth, discriminating between surface type (See Appendix H for new evidence on individual lesions' interventions). Appendix E shows ICCMSTM recommended procedures for root caries.

Practitioners may choose from a package of non-operative care (NOC) and TPOC interventions. Sound surfaces and inactive (arrested) lesions are taken into consideration for risk management and inactive (arrested) moderate/extensive lesions for TPOC. ICCMSTM recall interval, monitoring and review of lesions is described in subsection 2.5.

For coronal caries in permanent dentition the caries management recommendations are defined as follows:

Surface				
Surface	Pits and	Mesial-distal (proximal) Free smoot		Free smooth
ICCMS™Stage	fissures			
M Sound	Risk-base	ed Prevention (Refer to Pre	evious S	Section)
	NOC: Clin	ically applied topical fluori	ide (SIGI	V 1) ^{67,76}
	NOC: Oral hy	giene with fluoridated den (SIGN 1) ^{51,66}	ntifrice (2	≥1000 ppm)
		echanical removal of biofi	lm (SIGI	V 3) ^{56,77}
M Initial Active	NOC: Resin- based sealants (SIGN 1+,2) 65	NOC: Resin-based		
	NOC: Glass ionomer sealants (SIGN 1) 65,79	sealants/infiltrants (SIGN 2) ⁷⁸		
M Initial Inactive	(GIGIV 1)	No lesion specific treatm	nent	
	NOC: Resin- based sealants* (SIGN 2+) 80-82			
M Moderate Active	TPOC (SIGN 1) ^{83,84}	Determine cavitation appropriate managem options (teeth separat recommended) (SIGN ^{33,85,86} . If no cavitation: N cavitation: TPOC (SIGN	nent tion (2+) IOC, If	TPOC (SIGN 1) ⁸³
M Moderate Inactive	No treatment or TPOC if the lesion become a stagnation area (SIGN 1) 83	TPOC - Esthetic reasons (SIGN 1) 83		
M Extensive Active	TPOC (SIGN 1) 83			
M Extensive Inactive	TPOC if the lesion is a PSA or esthetically unacceptable (SIGN 1) 83	TPOC (SIGN 1) ⁸³		

Table 8. Managing individual lesions in permanent teeth.

Note: The references here and the SIGN ratings are in the process of being re-checked.

For coronal caries in the primary dentition, caries management recommendations are dependent on the cooperation level of a child and time to exfoliation. The recommended management matrix is as follows:

Surface				
Sarrass	Pits and	Mesial-distal (proximal)	Free smooth	
ICCMS™Stage	fissures			
M Sound	Risk-based Prevention (Refer to Previous Table)			
	NOC: Clinically applied topical fluoride; fluoride varnish recommended for ≤ 6-yr. old children (SIGN 1) 67,76			
M Initial Active	NOC: Resin- based/glass ionomer sealant (SIGN 1+ / 1) 65,79	NOC: Resin-based sealants/infiltrants (SIGN 2) 87		
		ne with fluoridated dentifrice (≥ 1 first tooth erupts (SIGN 1) 51,66	000 ppm) when the	
	NOC: Supervision	on is recommended at least until (SIGN 1) ⁸⁸	the age of 8 years	
M Initial Inactive		No lesion specific treatment		
	NOC: Resin- based sealants* (SIGN 2+) ⁸¹		NOC: Resin- based sealants* (SIGN 2+) 81	
M Moderate Active	NOC: If sealant not feasible (teeth isolation difficulties) an option is a nontooth preparation preformed metal/strip crown (SIGN 1)83		NOC: If sealant not feasible (teeth isolation difficulties) an option is a nontooth preparation preformed metal/strip crown (SIGN 1) 83	
	TPOC: including placement of preformed metal or strip crowns (SIGN 1) 80,83,84	For appropriate management options determine cavitation status: Tooth separation (SIGN 2+) 67,79,80. If no cavitation: NOC. If cavitation: TPOC (including preformed metal/strip crowns) (SIGN 1)83	TPOC: including placement of preformed metal or strip crowns (SIGN 1) 80,83,84	
M Moderate Inactive	TPOC if the lesion is a PSA or the area is esthetically unacceptable (SIGN 1) 83			
	TPOC (including preformed metal/strip crowns) (SIGN 1) 80,83,84			
M Extensive Active	If restorative care is not possible, consider the Hall Technique or extraction (SIGN 1) 83			
M Extensive Inactive	TPOC if the lesion is a PSA or the area is esthetically unacceptable (SIGN 1) 83			

Table 9. Managing individual lesions in primary teeth.

Note: The references here and the SIGN ratings are in the process of being re-checked.

2.5 Recall interval, Monitoring and Review

ICCMSTM recommends that review and monitoring visits (conventionally referred to as recalls) should be adjusted based upon the age of the patient and their risk status. ICCMSTM defines Recall as the duration of the personalized intervals between visits to review and monitor a patient's caries status. The frequency range for recall could be as high as once every three months for a child (under than 18 years old) with high likelihood of developing caries, to a low of once every two years for an adult with low likelihood of developing caries. Please be aware that the frequency used may also be adjusted for other conditions such as periodontal or mucosal health. The recall interval range should be reconsidered and either modified or re-used, based on the findings of review and monitoring.

ICCMSTM differentiates between recall intervals set for overall risk management, for assessing preventive interventions and the monitoring of initial lesions (to check their progression status) and reviews of behavioral and oral hygiene change plans.

ICCMSTM recommends that at every dental visit (both treatment visits and recall visits) some level of review should occur. It is essential to evaluate the patient's progress (or lack thereof) on the behavior modifications recommended in regards to the risk management plan. Modification of patient behavior goals should be considered and discussed, as necessary. While investigating the status of behavioral changes it is important to also maintain patient autonomy (patient value of oral health and treatment choices). It may be helpful to create a written statement of newly designed behavior modification goals for the patient to take home. It is important to maintain good documentation of the review and to record future behavior goals.

"Monitoring" in this context is the evaluation of the clinical status of the dentition (including ongoing treatment) and ascertaining whether previously identified lesions have progressed, regressed or have become arrested (inactive). Monitoring must be done at recall visits and may also be completed at treatment appointments. All teeth/surfaces are evaluated and compared to previous ICCMSTM caries categories. Radiographs are interpreted to evaluate possible caries progression. Additionally, in areas where sealants or restorations were placed without complete caries removal, bitewing/periapical radiographs should be evaluated to determine both the size and depth of lesion transition (and apical changes if appropriate), or lack thereof. Also the full range of detection assessment methods such as patient symptoms (pain, swelling, etc.) and clinical evaluation (including detection and activity assessment devices, as appropriate) should be completed.

The Recall interval is based on age (eruption pattern and other milestones) and risk (based on lesion level as well as overall patient level). There is little evidence supporting a specific recall interval to prevent dental caries⁸⁹. Additionally a systematic review found that there is weak evidence to support one specific interval (i.e. six months) for all individuals⁹⁰. The recall intervals were agreed upon by a group of participants at "The Global Collaboratory for Caries Management" and are supported by several published recommended recall intervals^{68,70,91-94} (Note: level 1++ is the highest level of evidence in these six cited references). At the recall visit both Reviewing and Monitoring take place.

3. Outcomes of Caries Management using ICCMS[™]

Comprehensive patient care plans should, by design, focus on achieving health outcomes for patients. It is also implicit that health promotion outcomes are desired and this is an important aspect at both the patient and community levels. The outcomes should be value-focused and not value-blind. Plans should be designed and evaluated to assess potential outcomes in health maintenance, disease control and patient-centered quality metrics, as well as around the wider impacts of using the ICCMS™ (Figure 10). Locally relevant outcome measures should also be developed and added to these lists, as appropriate. Measures should be sensitive to change over time and tooth surface level information is therefore desirable.

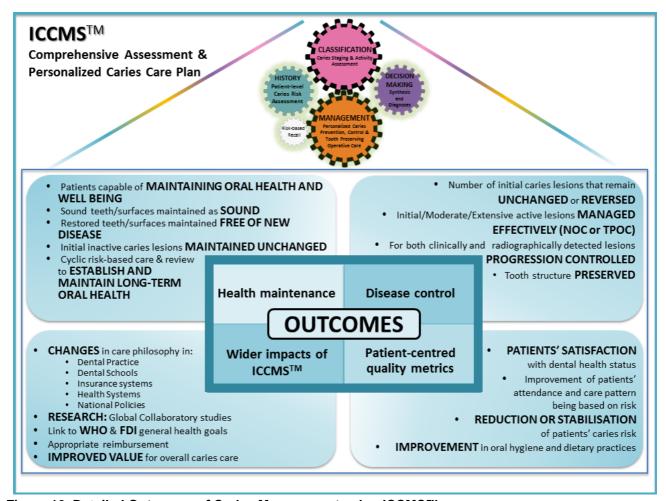


Figure 10. Detailed Outcomes of Caries Management using ICCMS™.

The use of this system should facilitate feedback on the success of care to patients and dental team as well as informing the reassessment and review of care. Outcomes data (and the recorded systematic use of the ICCMS TM) may also help dentists in many countries demonstrate "quality" and protect them in terms of legal liability and challenge.

Outcome information can also be used in research, evaluation and improvement of the ICCMS™. The analysis of the outcomes will also facilitate feedback to patients and to third-party payers.

4. ICCMS[™] in Practice

While there have been no studies that have evaluated the ICCMSTM system so far, a Global Collaboratory for Caries Management (GCCM) has been formed at King's College London (www.kcl.ac.uk/sspp/kpi/projects/healthpolicy/global-caries-management.aspx) to initiate comparative studies of the proposed systems and evaluate the process and outcomes of its implementation. There have been several short term and less comprehensive studies in the past of novel management methods of dental caries that preserve tooth structure. Mertz-Fairhurst et al. 95,96 have demonstrated that conservative enamel and dentin removal and sealing-in of caries can save tooth structure and have favorable outcomes. In addition to the scientific evidence that supports the different interventions proposed in this guide, additional evidence indicates that remineralization is not only limited to enamel but can also occur in dentin 97, An early childhood caries management approach that focuses on home care, prevention, and restorative care can result in positive outcomes.

In practice, implementation of the ICCMSTM will require introducing decision tools and education programs to increase the comfort level among dentists that the proposed system is pragmatic, practical, and worthwhile to implement. ICCMSTM manages caries holistically as a disease process and not as a lesion⁹⁸. It enables a clinician to go step by step through an evidence-based care pathway.

5. Related Developments

This section provides signposts to four aspects which will help to take ICCMS™ forward. The details are beyond the scope of this manual but users should be aware that regular updates will assess any impact on changes in the evidence base and emerging technologies. The research agenda, both for ICCMS™ and for global implementation will be developed incrementally over time. We hope that a series of integrated e-learning and software applications will assist ICCMS™ users in the fields of education and practice, and the Global Collaboratory for Caries Management will promote and monitor the implementation of ICCMS™ worldwide.

5.1 New Evidence on Current or Emerging Technology

A total of 70 studies on current and emerging technologies to manage caries were reviewed by two members of the Global Collaboratory for Caries Management Workshop and a research assistant with training in public health. The primary clinical outcomes considered were caries incidence and increments, percentage of children with progression and/or inactive caries, odds ratio progression of caries, fluorescence loss/mean fluorescence values, and changes in lesion area/volume and lesion depth. Studies that assessed both non-cavitated and cavitated carious lesions were selected for this review. Data were extracted independently by at least two reviewers and confirmed by a third. The quality of the studies was independently reviewed using criteria based on the SIGN (Scottish Intercollegiate Guidelines Network) guidelines⁹⁹. A single well-conducted systematic review or a large randomized clinical trial could support a recommendation for an intervention under the SIGN system. The evidence table was checked for consistency and corrections were

made based on consensus. The recommendation for any intervention was based on synthesis of the quantity, quality and consistency, applicability, generalizability and clinical impact. Strength of evidence and level of recommendation for each emerging technology were rated using the American Dental Association guidelines and the SIGN system, respectively (See Appendix B).

5.2 Research Agenda for ICCMS™ and the GCCM

Advancing the application of ICCMSTM in practice and education will require that several gaps in the knowledge base are addressed. The research agenda should include a focus on:

- 1) Implementation- Science Research around both understanding the barriers to and how to facilitate the adoption and improvement of ICCMSTM in Clinical Practice and Dental Education locally and globally.
- 2) Developing and evaluating valid and pragmatic methods for accurate assessment of caries risk in clinical practice.
- 3) Evaluating the validity and utility of the ICCMS™ Caries Risk and Likelihood Matrix in clinical practice.
- 4) Developing and evaluating new diagnostic aids to improve the accuracy of caries classification and activity assessment, especially the differentiation between stages of progression where non-surgical and surgical interventions are indicated.
- 5) Research on detection and management of active lesions on root surfaces and adjacent to restorations and sealants.
- 6) Research to evaluate the impact of using the holistic ICCMSTM Comprehensive Assessment and Personal Caries Care Plan on the future development of caries.
- 7) Developing and evaluating novel remineralising technologies that can inhibit the progression of initial caries lesions.
- 8) Research on restorative techniques and materials to preserve tooth structure and protect teeth from future caries development.
- 9) Ascertaining why some individuals with very high disease levels (current disease) do not respond to traditional primary prevention interventions (e.g., fluoride).
- 10) How the ICCMSTM approach needs to be tailored to specifically manage children with VERY high rates of caries in the primary dentition.
- 11) Ascertaining whether ICCMSTM can work as a sensitive measure of changes in disease in high disease level individuals (primary dentition) where the vast majority of their teeth are at the most severe end of the caries continuum.

5.3 Integrated eLearning and Data Management Software

In order to facilitate the implementation of ICCMS™ in clinical practice and educational settings, the system should be supported by well-designed and tested clinical management software in dental schools and in the dental office. One of the challenges in producing such electronic systems is compatibility with other clinical software, since most practices and educational settings will have at least some form of data capture and management program which may be related to payment. Hence, the best approach identified at the 2013 launch of the Global Collaboratory was to design the ICCMS™ as a software package (or App) that can be utilized as either a stand-alone package or alternatively be accessible from within existing software systems via interoperable bridges.

ICCMS™ software cannot assume all of the roles that full-blown dental practice systems fulfill, but should provide a supportive and educational platform for the logical and comprehensive assessment and subsequent management of dental caries. The software will also have to be designed to have the capacity to allow outcome assessment and quality improvements to be recorded and reported in order that improvements in dental health can be supported. Embedded within the ICCMS™ software there could be e-learning elements to support users in understanding the steps involved in data gathering, synthesis and care planning.

Development work is underway - at the end of 2014 ICCMS™ codes have already been made available to a number of US Dental Schools through "Axium" software. On the dental practice side initial work to pilot these concepts is underway with the help of Dentrix software in the US and Software of Excellence EXACT software in Australia.

5.4 Implementation for ICCMS™ – GCCM

It is important to emphasize that the ICCMS™ is not static and it can and will be modified when new experiential or clinical research findings become available.

The ICCMS™ System will be supported by an increasing range of documents and tools which are currently under development. These include:

- 1. This ICCMS™ Guide to Practitioners and Educators.
- 2. The ICCMS™ Quick Reference Guide, which will correspond to a short "how to".
- 3. The ICCMS™ Resource Book which will cover the ICCMS™ and further supporting evidence and practical considerations in more detail.
- 4. ICDAS/ICCMS™ Updated E-learning tool (to be available by March 2015).
- 5. ICCMS™ iCaries Care practice support software APP.
- 6. ICCMS™ iCaries Care patient support software APP.
- 7. ICCMS™ Caries Care patient support paper-based tools.

Further implementation tools should be produced and evaluated in due course as part of the Global Collaboratory for Caries Management initiative – supported by Kings College London and the other participating Universities and Associations in collaboration with supporting Companies.

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Appendix B: Scottish Intercollegiate Guidelines Network's (SIGN) Grading of the Evidence

	SIGN Levels of Evidence	
1++	High quality meta-analyzes, Systematic reviews of RCT's or RCT's with very low risk of bias.	
1+	Well conducted meta-analyses, Systematic reviews of RCT's or RCT's with a low risk of bias.	
1	Meta-analyzes, systematic reviews of RCT's or RCT's with a high risk of bias	
2++	High quality systematic reviews of case control and cohort studies. High quality case control or cohort studies with a low risk of confounding and bias and a high probability that the relationship is causal.	
2+	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal.	
2	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal.	
3	Non analytic studies, e.g.: case reports, case series.	
4	Expert opinion.	

Grades of Recommendation

Note: The grade of recommendation relates to the strength of the supporting evidence on which the evidence is based. It does not reflect the clinical importance of the recommendation.

Grade A	Grade B	Grade C	Grade D	\square
At least one meta-analysis, systematic review, or RCT rated as 1++ and directly applicable to the target population	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results	A body of evidence including studies rated as 2+,directly applicable to the target population and demonstrating overall consistency of results	Evidence level 3 or 4	Recommended best practice based on the clinical experience of the guideline development group.
OR A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results	OR Extrapolated evidence from studies rated as 1++ or 1+	OR Extrapolated evidence from studies rated as 2++	OR Extrapolated evidence from studies rated as 2+	

Preventing Dental Caries in Children at High Caries Risk: Targeted prevention of dental caries in the permanent teeth of 6-16 year olds presenting for dental care. Scottish Intercollegiate Guidelines Network. July 2013. http://www.sign.ac.uk/pdf/Dental-caries-consultation-draft.pdf

Appendix C: Patients' risk factors. A consideration

The ICCMSTM recommends assessing the following risk factors using both interview data and clinical assessment:

Medical health

Current use of medications, recreational drugs, or systemic conditions that may cause hyposalivation⁷¹⁻⁷⁵.

Head and neck radiation

Patients undergoing radiotherapy for head and neck cancer are categorized as high risk for developing caries because of the side effects or sequelae of the treatment regimens^{100,101}. The symptoms include (but are not limited to) xerostomia or hyposalivation, mucositis (affecting eating and oral hygiene practices) and altered taste sensation (which may result in patients utilizing inappropriate or cariogenic means of addressing the issue).

Sugary drinks and snacks

Based on the evidence from systematic reviews and several well-conducted cohort studies 102-104 it can be concluded that there is a significant association, though weaker than in the past under modern dietary practices and fluoride exposure, between higher risk of dental caries and high exposure to sugared beverages and snacks. Therefore, consumption of sugared beverages and snacks needs to be included as a part of a patient's caries risk assessment.

Fluoride exposure

Patients under certain conditions can be considered to have inadequate fluoride exposure if they have the following profiles 52,55,66,88,105:

- No daily use of fluoridated toothpaste (less than 2x daily)
- For children: tooth brushing with non-fluoridated toothpaste

Concentration of fluoridated toothpaste less than 1000 ppm of fluoride.

Mothers or caregivers' caries experience

It is well accepted that development of early childhood caries is influenced by environmental factors beyond individual-level factors, including a mother or caregiver's dental health. Several mother-child dyad studies reported that there is a significant correlation between mothers and children's caries status¹⁰⁶⁻¹¹⁰, thus suggesting a mother's (or caregiver's) caries status can be a predictor for child's caries development.

Oral hygiene behaviors

Poor oral hygiene status as evidenced by accumulated plaque on the dentition can be predictive of caries development and, hence, is a useful risk indicator. However, the relationship between presence of plague and caries risk is complex because it depends on the presence of cariogenic bacterial species, which is the determinant factor, and, hence, its use in clinical risk assessment must be viewed with caution. A longitudinal study¹¹¹ demonstrated that visible plaque on the labial surface of incisors in young children (19 months) was good predictor of caries development at 36 months of followup, demonstrating a sensitivity of 83% and specificity of 92%. The research team was able to correctly classify 91% of children with regard to future caries risk using plague accumulation alone. Wendt et al. (1994) also demonstrated that oral hygiene (i.e., toothbrushing) status in infants and toddlers was associated with lower caries risk 112. In a 7-year follow up study, Tagliaferro et al. (2008) found that oral hygiene status was predictive of high caries at baseline but was not predictive of new caries incidence over the 7 year of the study¹¹³. Mascarenhas (1998) reported oral hygiene status to be an important risk indicator for both enamel and dentinal caries in 12-year olds 114 and Mathiesen et al. (1996) reported similar results for 14 year olds when brushing with a fluoride dentifrice¹¹⁵. Similarly in adults Domejean et al. (2011) found that visible heavy plaque increased risk for future caries development (OR 2.55; 2.35-2.76)¹¹⁶. In assessing oral hygiene practices, ICCMSTM recommends evaluating the frequency and time spent during tooth brushing and flossing, and timing (after meals, before bedtime).

Socioeconomic status (SES)

Even though definitions of SES may vary, an individual's SES is likely to be an important predictor of caries risk^{117,118}. However, the correlation between SES and dental caries has not always been negative. Data from several emerging economies or rich-developing countries show that caries is more prevalent in higher income groups. The same correlation existed in developed countries in the later part of the 19th and early part of the 20th centuries.

Current evidence from the literature indicating a reverse relationship between one's SES and caries level is mainly based on studies conducted in developed or industrialized countries. Therefore, the relationship might not be applicable to countries at different stages of development. In low-income developing countries, the SES-caries relationship might not be as clear, or can even be reversed (high SES individuals have a higher level of dental caries). Data from the Global Oral Health Data Bank, maintained by the World Health Organization (WHO), suggested that developing countries, where caries prevalence was low initially, experience a high level of caries prevalence as they are industrialized and exposed to refined 'cariogenic' foods¹¹⁹.

The ICCMSTM recommends assessing the following risk factors during the clinical examination of patients:

Active caries lesions as defined in a previous section.

Caries experience

Increased caries risk is associated with the presence of restorations (or extractions)¹²⁰⁻¹²². The level of evidence supporting the causal relationship between presence of restorations and increased caries risk is based on a small number of case-control or cohort studies. There is evidence that the presence of marginal ditching places teeth at increased caries risk^{123,124}. 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 it may be important to have a threshold at which the deficiency is recorded as present or absent. The ICCMS™ recommends that 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 full enter into the gap between tooth and restoration.

Thick and undisturbed biofilm

Dental caries is now considered an endogenous infection caused by a change in the oral microbial ecology (microbiome) resulting in the selection of bacterial species that have the potential to ferment sugars and starch 125,126. The individual differences and complexity of the microbiome are influenced by transmission of bacterial species between infants and their caregivers as well as other environmental sources including foods, drinks, and all human contacts 127. Recent evidence indicates dental caries and periodontal diseases occur because of a shift in the microbial ecology and the reduction in bacterial diversity of the microbiome in the oral cavity 128. The level of evidence supporting the causal relationship between accumulation of a thick layer of biofilm or in stagnation areas and increased caries risk is based on several case control and cross-sectional studies 42,49,129-134.

Dry mouth

There is an increased caries risk associated with xerostomia/hyposalivation. The level of evidence supporting the causal relationship between xerostomia/hyposalivation and increased caries risk is based a small number of case-control or cohort studies^{135,136}.

Exposed root surfaces

Increased risk of root caries is associated with the number of exposed root surfaces. The level of evidence supporting the causal relationship between root caries and exposed root surfaces is supported by one systematic review, and a small number of case-control or cohort studies¹³⁷⁻¹⁴¹.

Appliances that may increase development of the biofilm

Increased caries risk is associated with the use of an oral appliance including partial dentures. The level of evidence supporting the causal relationship between use of the oral appliances and increased caries risk is based on a small number of case-control or cohort studies, as well as expert opinions¹⁴²⁻¹⁴⁸.

PUFA

(Exposed Pulp, Ulceration associated with retained root fragments or sharp edges caused by carious destruction, Fistula, and Abscess)

Increased caries risk is associated with a higher PUFA score. The level of evidence supporting the causal relationship between an increasing PUFA score and increased caries risk is based on only one study¹⁴⁹.

Appendix D: Full Definition of ICDAS Caries categories (merged codes)²

	Definition of ICCMS™ Caries categories			ecific Tooth surfaces' Findings
I	Sound surfaces (ICDAS code 0)	Sound tooth surfaces show no evidence of visible caries (no or questionable change in enamel translucency) when viewed clean and after prolonged airdrying (5 seconds). Surfaces with developmental defects such as enamel hypomineralisation (including fluorosis); tooth wear (attrition, abrasion and erosion), and extrinsic or intrinsic stains will be recorded as sound.	Pits and Fissures	Multiple stained fissures if seen in other pits/ fissures, which are consistent with non-carious habits (e.g. frequent tea drinking or smoking).
	Initial stage caries	Carious opacity or brown carious discoloration with no sign of cavitation of the enamel surface. Some lesions on the smooth surfaces may only be revealed		Carious discoloration is apparent starting in the base of the fissure or pit and may extend up the wall of the pit/fissure but no distinct loss of enamel is apparent, i.e. the pit/fissure retains its original anatomical appearance. Appearance not consistent with stained pits/fissures (ICDAS TM code 0).
	(ICDAS codes 1 and 2)	after 5 seconds of air-drying.	Mesial / Distal	Usually seen from lingual/ buccal or from occlusal as a shadow confined to enamel.
ries			Buccal / Lingual	Near the gingival margin or adjacent to areas promoting plaque stagnation such as orthodontic/prosthetic attachments.
Caries categories	Moderate stage caries (ICDAS codes 3 and 4)	probe; use the probe <i>gently across the tooth area</i> (a limited discontinuity is detected if the ball drops into the enamel micro-cavity/discontinuity). Underlying dentine shadow (ICDAS TM code 4) appears as a shadow of grey, blue or brown discolored dentine visible through either an apparently intact enamel surface or an enamel surface with localized breakdown. It must clearly	Pits and Fissures	Localized enamel breakdown in the pits and fissures is typified by a widening of the fissure/fossa due to tooth structure carious loss at its entrance, or within it. Although the pit or fissure may appear substantially and unnaturally wider than normal, the dentine is not visible in the walls or base of the cavity or discontinuity. Underlying dentine shadows in the pits and fissures present as grey, blue or brown discolored dentine visible beneath the enamel surface or an opaque ring around the pit or fissure from undermined enamel.
		being scored then the surface should be coded "0". Dentinal shadowing is often seen easiest with the tooth surface wet as air-drying the enamel surface makes it more opaque and this may mask the underlying dentinal shadow.		Directly seen from lingual /buccal and when a discolored dentine is visible through the occlusal marginal ridge.
	Extensive stage caries (ICDAS [™] codes 5 and 6)	Cavitation due to caries exposing the dentin beneath. Exposure of dentine may not be immediately apparent without air-drying, initially the tooth viewed wet may appear only to have darkening of the dentin visible through the enamel. Once dried there is visual evidence of frank cavitation with dentin clearly visible on walls and base. The WHO/CPI/PSR probe can be used to assess depth of cavity to confirm dentine exposure where the base of the cavity cannot be visualized. Note: The deep pulpal dentine should not be probed.	Pits and Fissures	(In pits or fissures the enamel thickness is $0.5-1.0$ mm).

Appendix E: Root caries: Staging of lesions clinically, activity assessment and management options

Staging root caries lesions clinically²

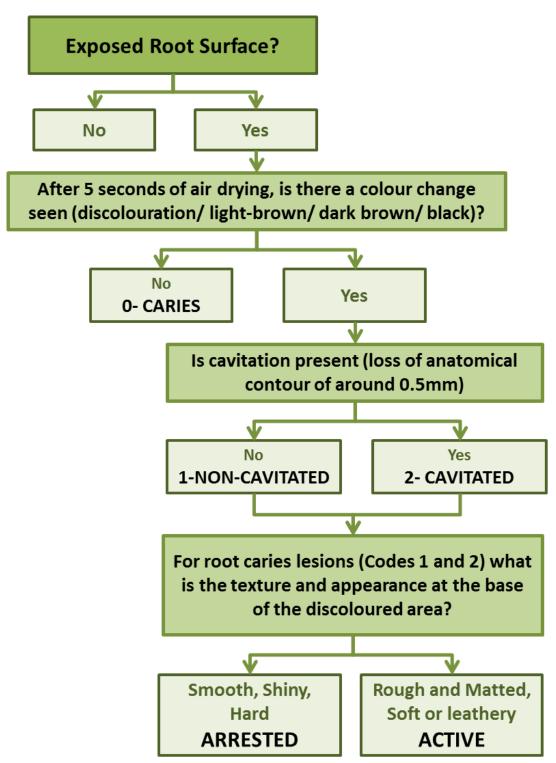
Staging of root caries is based on limited evidence in comparison to coronal caries. The ICCMSTM is looking forward to refining as more evidence comes along.

	Root Caries ICDAS Categorization and description
Code 0 (Sound)	The root surface does not exhibit any unusual discoloration that distinguishes it from the surrounding or adjacent root areas nor does it exhibit a surface defect either at the cement-enamel junction or wholly on the root surface. The root surface has a natural anatomical contour, or may exhibit a definite loss of surface continuity or anatomical contour that is not consistent with the dental caries process. This loss of surface integrity usually is associated with dietary influences or non-carious lesions such as abrasion or erosion. These conditions usually occur on the facial (labial) surface. These areas are typically smooth, shiny and hard. Abrasion is characterized by a clearly defined outline with a sharp border, whereas erosion has a more diffuse border. Neither condition shows discoloration.
Code 1 (Initial lesion)	There is a clearly demarcated area on the root surface or at the cement-enamel junction (CEJ) that is discolored (light/dark brown, black) but there is no cavitation present (loss of anatomical contour < 0.5 mm).
Code 2 (Moderate/ Extensive lesion)	There is a clearly demarcated area on the root surface or at the CEJ that is discolored (light/dark brown, black) and there is cavitation (loss of anatomical contour ≥ 0.5 mm ≤ -2 mm (Moderate), > 2mm (Extensive)) present.
Code E	If for any reason a root surface cannot be visualized directly, even with the assistance of gentle air drying, code E (excluded) can be recorded on the dental chart.

Root Caries lesion Activity^{2,49,150-163}

The characteristics of the base of the discolored area on the root surface can be used to determine whether the root caries lesion is active or not. These characteristics include appearance (shiny/glossy or matte/non-glossy), location in a plaque-stagnation area/not, and perception of texture on gentle probing (soft / leathery, or hard / rough / smooth). Active root caries lesions are usually located within 1 mm of the crest of the gingival margin [Ekstrand et al, 2008, 2013].

The following diagram of characteristics of lesion activity across the ICDAS root caries stages may be useful for reference when examining for root caries:



The management of root caries is most based on expert opinions. The evidence base for supporting any management strategy is either weak or does not exist. ICCMSTM recommends the following management strategies^{49,60,61,164-168}:

	Activity status		
ICDAS Root Categories	Active (leathery and/or soft)	Inactive (hard and shiny)	
Root Sound	Risk-based Prevention	n (Refer to Previous Table)	
Root Initial (Non-cavitated)	Oral hygiene, fluoride varnish, saliva stimulation, high fluoride toothpaste*; chlorhexidine varnish		
Root Moderate/Extensive (Cavitated)	TPOC (Glass ionomer cements, composite resin) Oral hygiene, fluoride varnish*, saliva stimulation, high fluoride toothpaste; chlorhexidine varnish	Refer to Primary Prevention Table and Emerging Evidence section TPOC if there is sensitivity or for esthetic reasons	

^{*} Best evidence is for the efficacy of 5% fluoride varnish rather than lower fluoride level varnishes.

Appendix F: Some considerations on Caries associated with restorations or sealants (CARS) and Non carious changes^{2,120-122,124,169-177}

(Caries-Associated with Restorations and Sealants (CARS) Detection Criteria			
	Caries Associated with Restorations and Sealants Codes			
Code 0	Sound tooth surface with restoration or sealant	A sound tooth surface adjacent to a restoration/sealant margin. There should be no evidence of caries (either no or questionable change in enamel translucency after prolonged air drying for 5 seconds). Surfaces with marginal defects less than 0.5mm in width (i.e. will not admit the ball end of the CPI Probe), developmental defects such as enamel hypoplasias; fluorosis; tooth wear (attrition, abrasion and erosion), and extrinsic or intrinsic stains will be recorded as sound. Stained margins consistent with non-carious habits (e.g. frequent tea drinking) and which do not exhibit signs consistent with demineralization should be scored as sound.		
Code 1	First visual change in enamel	When seen wet there is no evidence of any change in color attributable to carious activity, but after prolonged air drying (for approximately 5 seconds) an opacity or discoloration consistent with demineralization is visible that is not consistent with the clinical appearance of sound enamel.		
Code 2	Distinct visual change in enamel/dentin adjacent to a restoration/sealant margin	 If the restoration margin is placed on enamel the tooth must be viewed wet. When wet there is an opacity consistent with demineralization or discoloration that is not consistent with the clinical appearance of sound enamel (Note: the lesion is still visible when dry). If the restoration margin is placed on dentin: Code 2 applies to discoloration that is not consistent with the clinical appearance of sound dentin or cementum. 		
Code 3	Carious defects of <0.5 mm with the signs of code 2	Cavitation at the margin of the restoration/sealant less than 0.5mm, in addition to either an opacity or discoloration consistent with demineralization that is not consistent with the clinical appearance of sound enamel or with a shadow of discolored dentin.		
Code 4	Marginal caries in enamel/dentin /cementum adjacent to restoration/sealant with underlying dark shadow from dentin	The tooth surface may have characteristics of code 2 and has a shadow of discolored dentin which is visible through an apparently intact enamel surface or with localized breakdown in enamel but no visible dentin. This appearance is often seen more easily when the tooth is wet and is a derkening and intrinsic shadow which may be great blue, grange, or		
Code 5	Distinct cavity adjacent to restoration/sealant	Distinct cavity adjacent to restoration/sealant with visible dentin in the interfacial space with signs of caries as described in code 4, in addition to a gap > 0.5mm in width. OR In those instances where margins are not visible, there is evidence of discontinuity at the margin of the restoration/sealant and tooth substance of the dentin as detected by 0.5mm ball-ended probe run along the restoration/sealant margin.		
Code 6	Extensive distinct cavity with visible dentin	Obvious loss of tooth structure, the extensive cavity may be deep or wide and dentin is clearly visible on both the walls and at the base.		

Differential Diagnosis between Milder Forms of Dental Fluorosis (Questionable, Very Mild, And Mild) and Nonfluoride Opacities of Enamel^{2,78}

Characteristic	Milder Forms of Fluorosis	Nonfluoride Enamel Opacities
Area affected	Usually seen on or near tips of cusps or incisal edges.	Usually centered in smooth surface; may affect entire crown.
Shape of lesion	Resembles line shading in pencil sketch; lines follow incremental lines in enamel, form irregular caps on cusps.	Often round or oval.
Demarcation	Shades off imperceptibly into surrounding normal enamel.	Clearly differentiated from adjacent normal enamel.
Color	Slightly more opaque than normal enamel; paper-white. Incisal edges, tips of cusps may have frosted appearance. Does not show stain at time of eruption (in these milder degrees, rarely at any time).	Usually pigmented at time of eruption often creamy-yellow to dark reddish-orange.
Teeth Affected	Most frequent on teeth that calcify slowly (cuspids, bicuspids, second and third molard). Rare on lower incisors. Usually seen on six or eight homologous teeth. Extremely rare in deciduous teeth.	Any tooth may be affected. Frequent on labial surfaces of lower incisors. May occur singly. Usually one to three teeth affected. Common in deciduous teeth.
Gross hypoplasia	None. Pitting of enamel does not occur in the milder forms. Enamel surface has glazed appearance, is smooth to point of explorer.	Absent to severe. Enamel surface may seem etched, be rough to explorer.
Detection	Often invisible under strong light; most easily detected by line of sight tangential to tooth crown.	Seen most easily under strong light on line of sight perpendicular to tooth surface.

Appendix G: Evidence considerations for managing patients' risk factors

Home care	Clinical interventions	Evidence Level based on Grade	Comments
	/approaches	Statement	
Tooth brushing twice a day with at least 1,000 ppm F dentifrice		(Level of Evidence 1++; GRADE A)	Reviews confirm the benefits of using fluoride toothpaste in preventing caries in children and adolescents when compared to placebo, but only significantly for higher efficacy toothpastes with fluoride concentrations of 1000 ppm and above. The relative caries preventive effects of fluoride toothpastes of different concentrations increase with higher fluoride concentration. There was strong evidence that daily use of fluoride toothpaste has a significant caries-preventive effect in children compared with placebo (prevented fraction 24%). The effect was boosted by supervized tooth brushing, increased brushing frequency to twice daily, and use of a toothpaste concentration of 1,500 ppm fluoride. Studies are mostly limited to the permanent dentition decision of what fluoride levels to use for children under 6 years should be balanced with the risk of fluorosis and for some with higher levels of risk for fluorosis and low levels of risk for caries, lower levels of fluoride in toothpaste could be considered fluoride.
	Motivational reinforcement	(Level of Evidence 3, Grade D)	Although there is strong evidence that brushing twice per day with a tooth paste containing at least 1000 ppm F has significant benefits in the prevention and control of dental caries, there is limited evidence supporting motivational reinforcement of tooth brushing to change behavior 62-64.
Rx F- Mouthrinse		(Level of Evidence 1++, GRADE A)	Both daily (226 ppm F) and weekly (900 ppm F) rinses are efficacious in reducing caries with a prevention fraction of 26% ⁵⁸ .
	Sealants	Level of Evidence 1++, GRADE A)	The application of sealants is a recommended procedure to prevent or control caries. Sealing the occlusal surfaces of permanent molars in children and adolescents reduces caries up to 48 months when compared to no sealant, after longer follow-up the quantity and quality of the evidence is reduced ⁶⁵ .
	F- Varnish 2x /yr.	(Level of Evidence 1-, GRADE B)	This updated review confirms a substantial caries-inhibiting effect of 5% fluoride varnish in both permanent (43%) and primary teeth (37%), however the quality of the evidence was assessed as moderate, as it included studies with a high risk of bias studies, with considerable heterogeneity ⁶⁷ .
	Fluoride gels or solution (2% NaF)	(Level of Evidence 1+, GRADE A)	Reviews confirm the efficacy of fluoride gels and solution with similar levels of efficacy to other fluoride interventions ^{54,55} .
	High Conc. F- Toothpaste	(Level of Evidence 1-, GRADE B)	High fluoride toothpastes (>1450 ppm F) and higher efficacy F toothpastes have been shown to be of added benefit to children and adults at risk of caries. Studies using 5000 ppm F have demonstrated benefits on adolescents ⁵⁹ and also on the treatment of root caries ^{49,60,61}
General Behavior Modification in Oral Health	(Motivational Engagement)	(Level of Evidence 1++, GRADE A)	Motivational interviewing has been found to be one of the most effective approaches to altering behaviors in the dental office ⁵⁷ .

Home care	Clinical interventions /approaches	Evidence Level based on Grade Statement	Comments
Risk Modification plan	Dietary intake	(Level of Evidence 1-, GRADE B)	There is some evidence that one-to-one dietary interventions in the dental setting can change behavior, although the evidence is greater for interventions aiming to change fruit/vegetable and alcohol consumption than for those aiming to change dietary sugar consumption ⁶⁹ .
	Use of recreational drugs	(Level of Evidence 3, Grade D)	There is limited evidence on the role of dental personnel other than referral to specialists. Necessary behavioral change has some unique characteristics, probably requiring specialized training.
	Medication induced hyposalivation	(Level of Evidence 3, Grade D)	Although there is strong evidence on the role of certain drugs in reducing salivary flow, there is limited evidence on the effectiveness and practicality of changing such regimes to benefit oral health. Any such changes must clearly be undertaken in consultation with medical practitioner to ensure effective control of underlying medical conditions.
Increase frequency of fluoride varnish to 4 x /yr.		(Level of Evidence 1-, Grade B)	The benefit of more frequent applications is not clear, but may be beneficial for children at high risk of caries ⁶⁷ .
Combinations of Fluoride therapies		(Level of Evidence 1-, Grade B)	Topical fluorides (mouthrinses, gels, or varnishes) used in addition to fluoride toothpaste achieve a modest reduction in caries compared to toothpaste used alone ⁵⁷ . Combined use of Fluoride therapies for example F varnish and high fluoride toothpaste and mouthrinses may be appropriate for those at high risk (Expert opinion).
Using fluoride dentifrice (1,100 ppm F as NaF), 0.12% chlorhexidine gluconate rinse and 0.05% NaF rinse	Topical NaF gel application (1.1% NaF), counseling on reducing frequency of carbohydrate ingestion	Level of Evidence 1++; GRADE A	There is evidence ¹⁷⁹ that daily use of fluoride toothpaste, 0.12% chlorhexidine rinse 1 minutes 1 week each month, and daily 0.05% F-rinse the other 3 weeks per month results in a statistically significant 24% reduction of mean DMFS between intervention and control (conventional dental care) group in a two year RCT.

Appendix H: Level of evidence for individual lesions' interventions

The level of evidence for each intervention on permanent teeth is as follows:

M _{Initial} Active	No or weak evidence that mechanical removal of biofilm alone, without fluoride prevents lesion progression – however moderate evidence when fluoride dentifrice used. Dental caries is a microbial disease and oral hygiene is an integral part of caries management. Level of evidence for topical clinically applied fluoride - Moderate – 1 Level of evidence for oral hygiene with fluoridated dentifrice - Moderate – 1 for concentrations of Fluoride >1000 ppm b caries preventive effect may be less on occlusal surfaces Level of evidence for resin sealant for initial lesions substantial – 1*	
M _{Moderate} Active	Level of evidence for Fissure sealing Moderate lesions 2 ⁺ . Level of evidence for proximal infiltration1-, 2 ⁺ Level of evidence TPOC 1 ⁻	
M _{Extensive} Active	Level of evidence TPOC 1 ⁻	

The level of evidence for each intervention level is as follows – some data relating to permanent teeth has been extrapolated to primary teeth:

M _{Initial} Active	No or weak evidence that mechanical removal of biofilm alone, without fluoride prevents lesion progression – however moderate evidence when fluoride dentifrice used. Dental caries is a microbial disease and oral hygiene is an integral part of caries management. Level of evidence for topical clinically applied fluoride - Moderate – 1 ⁻ Level of evidence for oral hygiene with fluoridated dentifrice - Moderate – 1 ⁻ for concentrations of Fluoride >1000 ppm b caries preventive effect may be less on occlusal surfaces *Level of evidence for resin-based sealant for initial lesions is substantial for permanent teeth - very limited evidence relates to primary teeth – 1 ⁺ Level of evidence for supervision of oral hygiene with fluoridated toothpaste - 1 ⁻	
M _{Moderate} Active	Level of evidence for fissure sealing Moderate lesions is 2 ⁺ for permanent teeth – very little evidence relates to primary teeth Level of evidence for separation of teeth to detect cavitation is 2+ Level of evidence TPOC 1 ⁻	
M _{Extensive} Active	Level of evidence TPOC 1 ⁻	

Appendix I: New Evidence on Current or Emerging Technology

Fluoride supplements	Fluoride supplements (tablets, drops, lozenges or chewing gums) for preventing dental caries in children – no benefit over topical fluoride in permanent teeth. Weak evidence found.	This review suggests that the use of fluoride supplements is associated with a reduction in caries increment when compared with no fluoride supplement in permanent teeth. The effect of fluoride supplements was unclear on primary teeth. When compared with the administration of topical fluorides, no differential effect was observed. We rated 10 trials as being at unclear risk of bias and one at high risk of bias, and therefore the trials provide weak evidence about the efficacy of fluoride supplements.
Review xylitol chewing gums (10-20 min. chewing after meals)	Weak evidence for reducing coronal caries in children 5 and older (Level of Evidence 1). Extrapolated for adults (no direct evidence) (Level of evidence = 4, Expert opinion).	On the basis of results from three studies, a majority of the panel recommended the use of xylitol lozenges or hard xylitol candy after meals for children older than 5 years. The majority of the panel also suggested a dose of 5 to 8 grams per day divided into two or three doses to maximize clinical benefits. As discussed previously, hard candy also should be used under supervized conditions in neurologically healthy children to reduce the risk of choking. The panel did not find sufficient evidence to support recommendations for use of xylitol by children younger than 5 years. Some members of the panel thought that the existing weak evidence was not sufficient to support a recommendation for the use of xylitol delivered through lozenges.
Antimicrobials Chlorhexidine	(Level of Evidence 1+) ¹⁸²	Within the limitations of this review, it may be concluded that in the absence of regular professional tooth cleaning and oral hygiene instructions, CHX-V may provide a beneficial effect in patients in need of special care. The strength of this recommendation is graded as 'weak'.
	Chlorhexidine ¹⁸¹	Although chlorhexidine has been shown to reduce <i>Stretococcus mutans</i> in the oral cavity temporarily, most of the clinical studies that evaluated coronal caries as the outcome did not show a statistically significant reduction in caries with the use of chlorhexidine in any vehicle.

Appendix J: Glossary for key words

Note- This glossary will be developed further and made available on the ICDAS website² (www.icdas.org)

Diagnosis: disease –This should be read in conjunction with the glossary of key terms¹.

Diagnosis: lesion – the human professional summation of all the signs and symptoms of the lesion to arrive at an identification of the status of a lesion in terms of its depth, extent and current activity.

Prognosis – lesion / disease. The likely future outcome for a specific lesion in terms of disease stasis (arrest), regression or progression / The likely future outcome for a patient in terms of the initiation, arrest or progress of the disease in the mouth.

Risk assessment: a process using (non-clinical and clinical) data collection and synthesis aimed at determining the likelihood of disease/lesions being initiated or progressing in a specific time period.

Risk categories: descriptors which specify the level/extent of the likelihood of the initiation or progress of the disease in terms of the number of lesions which will occur within a future specified time period. (Although the level of disease in a population appears to be a continuous scale, in terms of tooth-site numbers affected by caries, there is a general consensus of among dental professionals of using a limited number of discrete categories, such as Low, Medium, High, Extremely High, with or without specifying the number of lesions defining these categories).

Risk indicators: factors which are associated with the initiation or progress of the disease.

Risk factors: determinants which contribute to the initiation or progress of the disease. **Caries experience**: the sum total of a patient's past caries history, including decayed missing (due to caries) and filled teeth.

Primary prevention (Patient level; site/surface level): the use of techniques (by the patient/carer or Dental professional) aimed at avoiding the onset/initiation of clinical signs of a disease.

Secondary prevention: the use of techniques (by the patient/carer or Dental professional) aimed at: (i) arresting the disease process at any stage of that process and /or (ii) reversing the disease process in its initial stages.

Tertiary prevention: the use of techniques (by the Dental professional) aimed at removing irreversibly diseased tissue and restoring function and/or aesthetics in such a way that further disease progression is avoided.

Healthy tooth tissue: the absence of signs of currently active disease, not absence of signs of past disease.

Disease severity (mouth): the overall level of caries in a mouth in terms of the total number of lesions, combined with the severity of those lesions.

Lesion extent (tooth): the degree to which a lesion has produced demineralization and tissue destruction in a tooth or tooth-site in terms of pulpal direction and/or surface area of a tooth.

Intervention Plan: the sum total of the intended procedures (by patient/carer and/or dental professional aimed at preventing and treating the disease (caries) process and the specific caries lesions present.

Prevention Plan: the sum total of the intended procedures (by patient/carer and/or dental professional aimed at preventing the disease (caries) process and the specific caries lesions present.

Recall: (for this document the convention of including) both *regular* and *intervening* appointments – both for the examination of the overall patient disease (caries) activity and specific lesion behavior, i.e. both review and monitor

Review (or Re-assessment): (for this document) appointment for patient with a view to the Dental professional reassessing the caries (disease) process, including in relation to patient behavior.

Monitoring of lesion(s): (for this document) Dental professional assessment of specific lesion behavior over a time period, which may vary between patients – i.e. lesion reassessment.

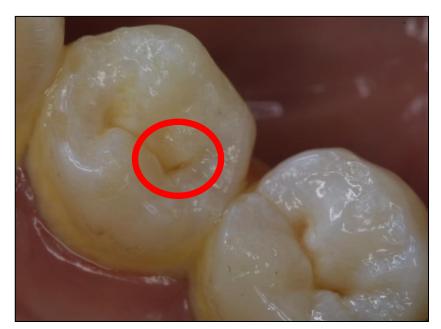
The lesion severity (collapsed) ICDAS codes: Lesion severity code A: The combination of ICDAS codes 1 and 2; Lesion severity code B: The combination of ICDAS codes 3 and 4; Lesion severity code C: The combination of ICDAS codes 5 and 6.

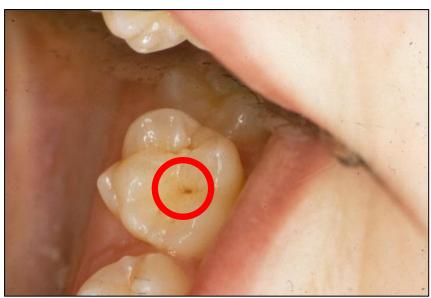
Appendix K: ICCMS™ Caries Staging Photographs and Radiographs

We hope to add future examples over time to the ICDAS webpage (www.icdas.org)

Pits and fissures

Clinically initial caries lesions





Clinically moderate caries lesions (after examining the radiographs some of the lesions may be classified as extensive)









Clinically extensive caries lesions









Smooth tooth surfaces

Clinically initial caries lesions







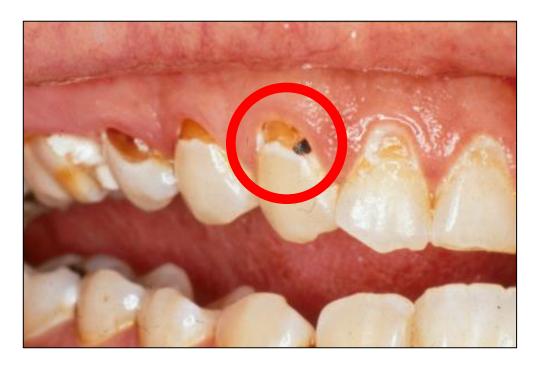
Clinically moderate caries lesions





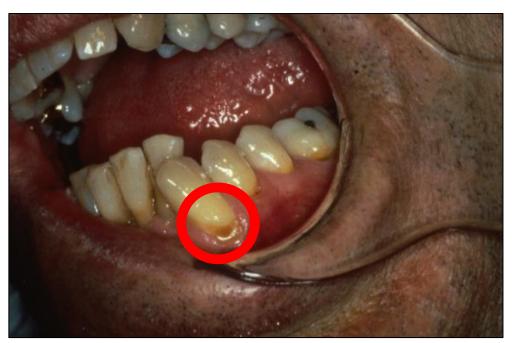
Extensive caries lesions

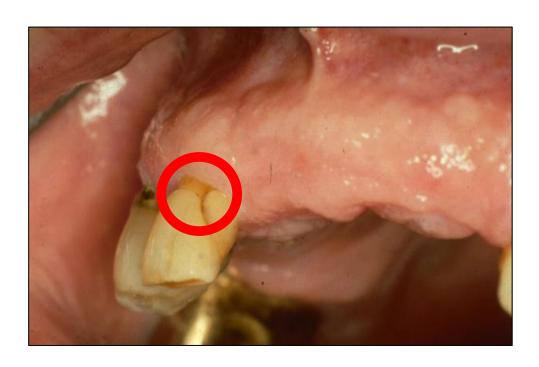




Root Caries

Clinically non-cavitated lesions





Clinically cavitated lesions



Courtesy of <u>bigdiastema.com</u>



Courtesy of $\underline{\text{lifecaredental.com.au}}$

Radiographic caries lesions

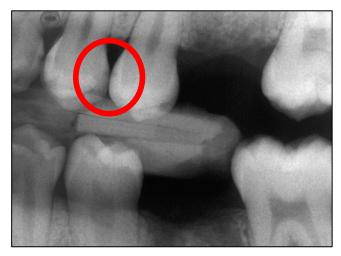
RA: Initial stages

1= radiolucency in the outer ½ of the enamel



RA: Initial stages

2= radiolucency in the inner $\frac{1}{2}$ of the enamel \pm EDJ

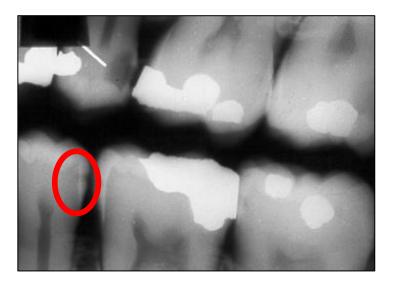




RA: Initial stages

3= radiolucency limited to the outer 1/3 of dentin





RB: Moderate stages

4= radiolucency reaching the middle 1/3 of dentin

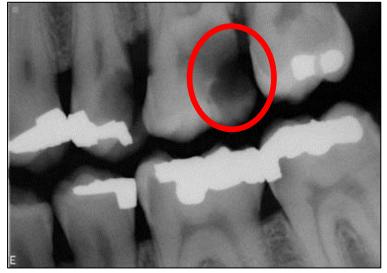




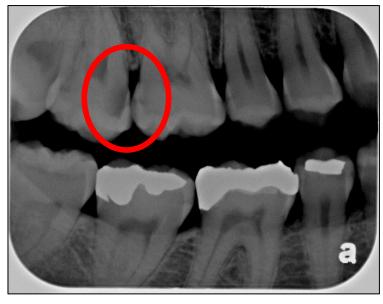
Courtsey of http://dc681.4shared.com/doc/Q-C5tOw2/preview.html

RC: Extensive stages

5= radiolucency in the inner 1/3 of dentin







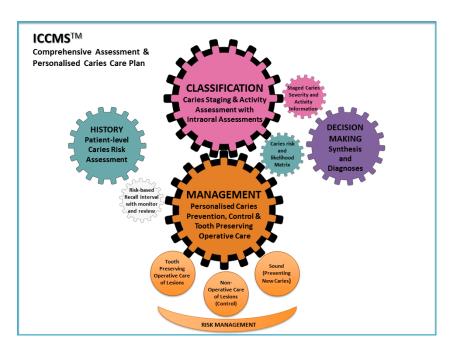
Appendix L: ICCMS™ Clinical Case Example

Note- This case uses the FDI tooth numbering systems.

Patient attending a Dental Clinic in Copenhagen

Patient information:

Male, 25 years old, he lives in Elsinnore, Denmark (ppm F in the water supply = 0.3ppm)



Element 1- Risk Assessment: Assessment of Patient Risk Factors

Chief medical and dental complaints: "I have problems with food impaction and have not been to the dentist in the last 3 years"

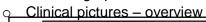
Assessment of Patient level caries risk factors

Patient level caries risk factors	At risk	Information
Head and Neck Radiation		No radiotherapy
Dry mouth (conditions, medications/recreational drugs/self-report)		No medicines, no diseases, no self-reported dry mouth
Inadequate oral hygiene practices	\checkmark	Patient refers that some days he only brushes once a day his teeth (with 1100ppm F toothpaste)
Deficient exposure to topical fluoride	\checkmark	Some days he only brushes his teeth one time
High frequency/ amount of sugary drinks/ snacks	\checkmark	Patient refers drinking coffee all day long with sugar (>5 in between meals per day)
Symptomatic-driven dental attendance		No
Social-economic status/Health access barriers		He studies to become a school teacher

Element 2- Classification: Caries Staging and Lesion Activity Assessment plus Intraoral Caries Risk Factors

- Plaque assessment: presence of thick plaque and gingivitis

- Visual and radiographic assessment



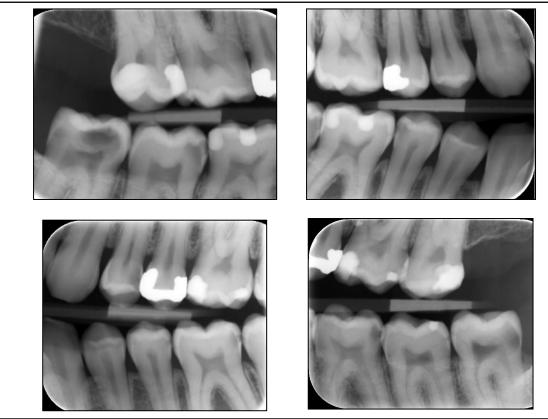






- Several coronal caries lesions were detected and staged as Initial, Moderate or Extensive in a number of surfaces by means of the ICCMS[™] visual scoring system. Lesions were further assessed as Active or Inactive was further assessed in each lesion.

o Bite-wing radiographs - overview



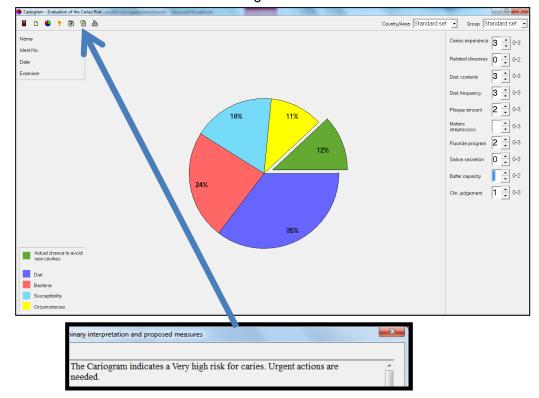
Several radiolucency zones could be detected and staged in a number of surfaces by means of the ICDAS/ICCMS™ radiographic scoring system as: RA (Initial stages), RB (Moderate stages), RC (Extensive stages).

The combination of clinical (C) and radiographic (R) information (for posterior teeth) of the lesion severity ends up classifying the lesion into the categories of $Initial_{CR}$, $Moderate_{CR}$ or $Extensive_{CR}$.

Assessment of Intraoral level caries risk factors

Intraoral level caries risk factors	At risk	Information	
Hypo-salivation/Gross indicators of dry mouth		Saliva secretion: Normal	
PUFA (Exposed pulp, Ulceration, Fistula, Absess) – Dental sepsis		No PUFA	
Caries experience	✓	High for the country figures at same age group. D ₃ MFT=15 (D ₃ =6; D1,2=3)	
Thick plaque: Evidence of sticky biofilm in plaque stagnation areas	\checkmark	Plaque index; Approximal sites: 45%. Gingivitis index: Approximal sites: 55%. No pathological pockets Calculus lingually on the lower incisors. No changes in color from normal at the oral mucosa etc.	
Appliances, restorations and other causes of increased biofilm retention		No presence of biofilm retention	
Exposed root surfaces		No exposed root surfaces	

Caries risk status of the patient
 In this case the Cariogram software was used.



The patient's risk status was assessed as High Risk Status.

Element 3- Decision Making: Synthesis and Diagnosis

1. ICCMS™ caries diagnosis:

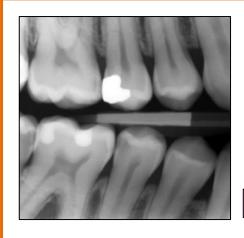




48 occlusal: Extensive active 48 buccaly: Extensive active



47 occlusally, mesially: Moderate active

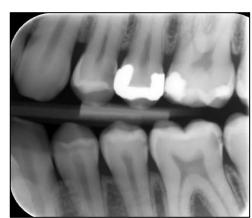




16 mesial: Initial active



46 mesial: Initial active 45 distal: Moderate active





24 distal: Moderate active





35 distal: Initial active 36 distal: Moderate active

37 mesial & buccal: Initial active

38 distal: Extensive active

2. ICCMS™ caries risk analysis to assess likelihood of new lesions or caries progression

In this patient the ICCMSTM caries risk analysis, assessed by means of the likelihood of new lesions or caries progression, depicted:

- 1) The stratification of this individual as a High Risk Status, and
- 2) The current caries activity status at the patient level as Extensive-stage active caries lesions.

		Current Caries Activity Status at the Patient Level			
		No active caries lesions	Initial-stage active caries lesions	Moderate- or extensive-stage active caries lesions	
Risk status	Low risk	Low likelihood	Moderate likelihood	Moderate likelihood*	
	Moderate risk	Low likelihood	Moderate likelihood	High likelihood	
	High risk	Moderate likelihood	High likelihood	High likelihood	

So, it is **highly likely** that the patient will develop new lesions within a short period if the caries promoting factors are not changed.

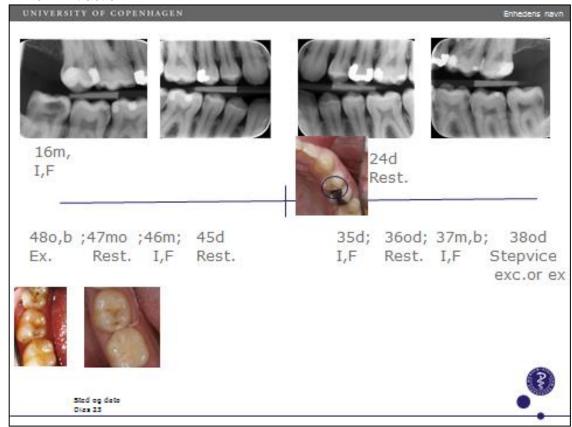
Element 4- Management: Comprehensive Caries Care Plan

- 4.1 Managing a patient's risk factors (Prevent New Caries)
- Home care
 - Instruction in tooth brushing and flossing
 - o Tooth brushing 2/day ≥ 1,450 ppm F- dentifrice
 - o General Behavior Modification in Oral Health:
 - Diet counseling: stop /reduce the use of sugar in the coffee
 - Diet counseling: reduce the number of in-between meals
- Clinical Interventions/ approaches
 - o Motivational reinforcement and One-to-one dietary intake interventions
 - o F Varnish four times per year
 - Recalls every 3 months where professional cleaning and local treatment with fluoride is done on active lesions

4.2 Managing Individual Lesions

Following the recommended levels of clinical management for active (Minitial: NOC; MModerate: TPOC in general; MExtensive: TPOC in general), in this patient the management of individual lesions will be:

- 16 Mesial: NOC
 - Oral hygiene instructions
 - Fluoride varnish
- 24 Distal: TPOC
 - Restoration
- 38 Occlusal-Distal: NOC / TPOC
 - o Stepwise excavation / Extraction
- 37 Mesial, Buccal: NOC
 - Oral hygiene instructions
 - Fluoride varnish
- 36 Occlusal-Distal: TOPT
 - Restoration
- 35 Distal: NOC
 - o Oral hygiene instructions
 - Fluoride varnish
- 45 Distal: TPOC
 - o Restoration
- 46 Mesial: NOC
 - o Oral hygiene instructions
 - Fluoride varnish
- 47 Mesial-Occlusal: TPOC
 - Restoration
- 48 Occlusal, Buccal
 - Extraction



Appendix M: Supporters of ICCMS™ and the Global Collaboratory for Caries Management



ICDAS Foundation



Kings College London

Kings Policy Institute KCL Dental Institute



Dental Protection



Calcivis



Henry Schein



Smile-on



Temple University



GSK



Colgate/ GABA



Premier





SS White