

**REPORT ON THE  
RCDSO/CDHSRU WORKSHOP  
ON  
DEVELOPING CLINICAL GUIDELINES/STANDARDS OF PRACTICE**

**J.L. Leake, P.A. Main, G.L. Woodward**

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Report  
on the  
RCDSO-CDHSRU Workshop  
on  
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Leake JL, Main PA, Woodward GL

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## **Executive Summary**

Under the auspices of Quality Assurance Committee of The Royal College of Dental Surgeons of Ontario (RCDSO) investigators from the Community Dental Health Services Research Unit (CDHSRU) held a workshop to test a model for developing clinical guidelines/standards of practice as required under the Regulated Health Professions Legislation. Forty two dentists and representatives of the public and professions from Ontario and Canada participated in a workshop held over three days. The participants were to learn, through direct experience, each of the steps as defined by the literature on clinical guideline development. Ultimately they were to recommend the steps for the RCDSO to follow in developing standards of practice.

The management of smooth surface enamel lesions in permanent teeth was selected as an example of a real topic where standards might be developed. In advance of the workshop, the participants were sent the literature on one of five aspects of the problem, papers on the methodology of critically appraising the literature and templates which outlined the basic steps to be followed in writing clinical guidelines.

During the first evening and the next morning, participants heard presentations on the development of clinical guidelines, the prevalence of smooth surface lesions, the role of economics in guideline development and the necessary considerations in writing clinical guidelines. Under the leadership of trained facilitators they worked in small groups to write the evidence-based recommendations and reported those back to all participants and facilitators where they received feedback. With that feedback they met again to revise their recommendations and to work on the overall recommendations for the RCDSO. That evening, the facilitators and the co-ordinators met to edit the recommendations into a consistent format for presentation to the large group. The second morning all participants met to review the evidence-based recommendations and the overall recommendations on the steps to be followed by the RCDSO.

The participants completed portions of the templates and developed preliminary evidence-based recommendations for the management of smooth surface enamel lesions.

Based on this experience, they recommended a seven-step process for the RCDSO to follow, namely:

- 1) Frame the question:
  - 1.1 Develop a protocol for choosing topics requiring guideline development based on distribution of care services, identified needs, and selected outcomes; and
  - 1.2 Clearly define the problem in consultation with key stakeholders.
- 2) Assemble and review the evidence.
- 3) Develop a preliminary evidence-based report.
- 4) Review and revise the evidence-based report:
  - 4.1 Circulate the preliminary evidence-based report for review;
  - 4.2 Revise the evidence-based report where necessary;
  - 4.3 Develop the clinical guideline based on the revised evidence-based report;
  - 4.4 Circulate the revised evidence-based report and the clinical guideline for comment;
  - 4.5 Revise the guideline based on comments and recirculate for further comment.
- 5) Adopt and publish the evidence-based guideline.
- 6) Disseminate the guideline through education and other means.
- 7) Schedule review according to Steps 1 through 6.

They also developed other comments for consideration by the RCDSO:

1. The RCDSO needs to clarify its definitions of standards of practice and clinical guidelines;
2. The RCDSO should review what others have done;
3. There should be a process that can be shared nationally;
4. The literature on practitioner behaviours should be consulted to learn the best ways to influence them;
5. Ethical values as well as data must inform the development of guidelines;
6. The guideline process should ideally maximize the oral health of the population, and participants felt that the profession would want to be involved in the entire process;
7. Future reviewers (at Steps 4.1 and 4.4) need training in critically appraising evidence; and

8. The issue of resource implications implicit within the seven step process of guideline development is as yet unresolved.

#### Conclusion

The workshop participants were able to test a process and define steps that the RCDSO should follow to develop clinical guidelines/standards of dental practice in Ontario. The workshop revealed many of the problems likely to be encountered and the participants developed additional comments for consideration.

## Background

In Ontario, there are at least four developments which challenge dental care providers to adapt their every day practices to meet the needs and expectations of their patients or clients.

First, evidence from the assessment of patients' attitudes towards their physicians indicates that people in Ontario expect a health care provider to be not only an expert clinical decision maker but also a communicator/educator/humanist/healer who is sensitive to individual needs, communicates well and collaborates with them in the decisions about their care (EFPO, 1993). Ethical considerations, require dental care providers to present clients with accurate probabilities of benefits, risks and costs for each care option, thereby allowing clients to make informed choices. Increasingly, clients are holding professionals accountable to provide care with predictable outcomes.

Second, caries and periodontal conditions have changed both in prevalence and in severity, such that formerly worthwhile practices may no longer produce the same degree of benefit. For example, the decline in prevalence (Johnston et al 1986) and severity of dental caries impacts on the effectiveness of clinical practices such that:

- universal application of additional preventive techniques will provide little or no benefit to most children in any one year;
- finding new caries is much more demanding; however
- given the slow progress of proximal enamel caries in permanent teeth (Woodward et al., 1993), the average early proximal carious lesion, not diagnosed at one examination, will not likely cause a problem over the next 12 month period when the child would normally be seen again.

Third, new technologies continue to be developed through research and promoted by the dental industry. For example in the area of childhood caries we have seen the development of caries risk assessment techniques (Vehkalahti et al. 1993), fluoride varnishes (Helfenstein and Steiner 1994), endodontic treatment of deciduous anteriors (Payne et al. 1993) and remineralization techniques



(Elderton and Osman, 1991 ). Old technologies - rightly or wrongly - are said to produce less benefit or more harm than originally believed e.g., tooth polishing before topical fluorides (Johnston and Lewis, 1995), dental amalgam (Virmy and Lorshieder, 1985) and fluoride supplements (Ismail, 1994).

Fourth, Ontario society, through new health legislation, is holding all health professions much more accountable for assuring the quality of care (Regulated Health Professions Act, 1994a). One of the specific objects of all colleges is to "...develop, establish and maintain programs and standards of practice of the profession...". The council of each college must establish a quality assurance program (Regulated Health Professions Act, 1991, 1994b) and have a Quality Assurance Committee. The duties of this Committee are to inspect the premises of the members of the profession and assess the records of care or otherwise assess the knowledge, skills and judgement of members (Regulated Health Professions Act, 1991, 1994c). The legislation assumes that the public interest will be better served where standards exist and become an aid in decision-making and the benchmark by which to assess current practices.

For dentistry, the Quality Assurance Committee of the Royal College of Dental Surgeons of Ontario (RCDSO) has announced it will continue its mandatory continuing education program (commenced in 1994) and implement a broad based screening assessment of dental practices. In addition it plans to develop standards of dental practice (RCDSO, 1995a) using an open, evidence-based approach. This approach has been endorsed by the Ontario Dental Association (Shosenberg, 1995).

The trend to evidence-based care is so profound a change that some have termed it a paradigm shift (Evidence-based Medicine Working Group, 1994). Evidence-based care replaces the apprentice learned, experiential consolidated, and expert driven basis for clinical decision making with careful reference to evidence contained in the medical/dental literature. Evidence from the literature is used to determine the best intervention for clinicians and patients to chose. However, not all literature is of equal quality for informing patients and practitioners; the design and the rigour of the study are two factors which may limit usefulness.

The Canadian Task Force on the Periodic Health Examination (CTFPHE) (1994) has developed a model which ranks the quality of the evidence available from the many, and sometimes conflicting, reports in the literature. The ranking is based on the strengths of the design of the scientific studies undertaken to demonstrate the benefits. The highest quality of evidence comes from the studies with the strongest design, randomised controlled trials (RCTs). The lowest quality of evidence is opinion, based on clinical experience or descriptive studies e.g. case reports. Between these two extremes lie non-randomised trials, observational studies, and comparisons between groups with and without the intervention at different times and places.

Figure 1 shows the CTFPHE's model. The bottom part of the figure shows the letter grade that the CTFPHE uses to classify any recommendation, i.e., to include or exclude a service. These range from A (good evidence to include) to E (good evidence to exclude). Using such an approach, all services can be rated by the strength of the science underlying their development and then classified according to whether practitioners should include them in their practice.

### ***Standards of practice and clinical practice guidelines***

The Oxford Dictionary of Current English (Thompson, 1995) defines 'standard' as "object or quality or measure serving as basis or example or principle to which others conform or should conform, or by which the accuracy or quality of others is judged". In dentistry, not all standards will relate to clinical care. Colleges may also need to issue standards in other areas, for training requirements for limited procedures (RCDSO, 1995b); or record keeping (RCDSO, 1995c); or infection control (RCDSO, 1995d). In many cases, these are based on other kinds of evidence, such as current legislation and legal precedent.

In an earlier publication (Leake and Woodward 1994), we defined 'standards of practice' as guidelines describing the process of care, which are issued by an authority (such as the RCDSO) for the purposes of providing a benchmark by which care is judged. This definition allows access to the methods of development of clinical practice guidelines, but leaves the ultimate decision to the legislated organisation as to what to issue as standards of care.

The Institute of Medicine (IOM) in the United States defined 'practice guidelines' as '...systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances' (Field and Lohr, 1990).

The Canadian Medical Association points out that practice guidelines can be used to help clarify which care is appropriate, form review criteria, promote utilisation of more beneficial care, and reduce liability. Their development and use is consistent with the increasing interest in quality assurance, accountability, and cost effectiveness (Harrigan, 1992). A systematic review has shown that clinical guidelines do improve medical practice (Grimshaw and Russell, 1993).

Others have described the process of developing medical practice guidelines (Agency for Health Care Policy and Research, 1993; Carter et al., 1995; Browman et al 1995). Investigators are achieving consensus on the requirement of both the development process and characteristics of clinical guidelines. Field and Lohr (1992) have provided a table of the desirable attributes of clinical practice guidelines and Hayward and Laupacis (1993) have described a format for abstracts of clinical practice guidelines. More recently, Hayward et al (1995) have presented a protocol to guide physicians on how to assess the validity of clinical practice guidelines.

Efforts to develop evidence-based practice guidelines or standards of care in dentistry lag behind those of medicine. Friedman (1972) developed treatment criteria to guide the assessment of the technical quality of dental care. Bailit et al. (1974) tested their standards in 47 patients but the standards were not widely disseminated. Some direct service programs have developed manuals outlining procedures for staff to follow to assure that only effective care is provided (Dental Branch, Indian Health Service, 1974; Dental Services Manitoba, 1981; NYPHD, 1982). Heflick (1991) has reported on the failure of early attempts to develop standards in the United States.

Bader and Shugars (1995) provide assessment criteria for guidelines in dental practice. They assessed dental guidelines issued by the American Heart Association, American Association of Oral and Maxillofacial Surgeons, the American Association of Endodontics, the American Academy of Pediatric Dentistry, the Food and Drug Administration (FDA), and the conference which issued criteria for placement and replacement of dental restorations. They found that '...few possess the

desirable attributes outlined by the IOM ... (and) as a result there are few valid and practical clinical guidelines available for use by practising dentists...’.

As an example, in October 1994, the House of Delegates of the American Dental Association adopted ‘Dental Practice Parameters for 12 oral health conditions (ADA 1995). They were developed through a consensus conference of 35 dentists and then by mailed review by a further 45 practitioners. Although the preamble states the parameters ‘... are intended, foremost, as an aid to clinical decision making ...’, they are very general. For example the parameter on restoring dental caries advises:

*The dentist should consider the characteristics and requirements of each case in selecting the material(s) and techniques to be utilized... (and)...The restorative material selected should restore form and function, and withstand the forces of occlusion...(pg. 15).*

No other advice is provided to guide the dentist on what basis to advise the patient which material to select. There is no reference to an evidence-based approach to their development, nor are any references cited in the document. As such, it represents the likely outcome, should the guidelines development process be left to an approach which doesn’t critically examine the evidence.

In England, the Advisory Board in General Dental Practice (1991) has issued a self assessment manual and standards for general dental practitioners. The purpose of the manual is to provide a framework for peer review of clinical topics ...by suggesting basic standards of clinical dentistry and by using case studies (to illustrate their application)...’ Unit 2 of the manual is divided into sections on a clinical area e.g. radiology, periodontology, endodontics. The focus of the ‘standards’ is on the achievement of clinical outcomes not the techniques to achieve them. Each section opens with a table of standards stating the desired clinical outcomes. The criteria are graded A to D; B and A indicate satisfactory or highly satisfactory outcomes of the procedure. These are not patient outcomes and probably we would call them process quality indicators. While there are references to scientific publications, there is no claim to the use of the level of evidence concept.

By 1993 only one dental regulatory and licensing agency for the dental profession in Canada, the College of Dental Surgeons of British Columbia, (CDSBC) had developed “Guidelines for

standards of practice". The preface to the documents states that the guidelines '...set down the criteria to be considered during the delivery of dental care in this province...(and)... may be considered in determining the appropriate standards of practice in professional review and courts of inquiry...'. However the guidelines are quite general. For example in the selection of material for the restoration of dental caries, the guidelines state '...the practitioner will adhere to sound scientific and clinical knowledge when making selection choices...' and list 10 factors which should be considered when selecting a restorative material.

Stephens et al.(1996) have issued a note of concern about the trend to guideline development in Canada. Briefly, they hold that the guidelines development process has failed (in the United States ?) because the process lacked sufficiently wide input from the '...teaching institutions, specialty societies, or the profession at large.' They suggest that the three elements of guidelines development are important:

- selecting areas where guidelines could be effective in improving care (appropriate topics);
- inclusion of all legitimate interests in the process, plus experts in biostatistics and health care economics; and
- definitive statement of the intention of the purpose of guideline development.

### ***Work to date***

#### **Community Dental Health Services Research Unit's (CDHSRU) program guidelines**

The CDHSRU is a partnership formed between the Department of Community Dentistry, Faculty of Dentistry, University of Toronto and the City of North York Public Health Department (NYPHD). Investigators and managers work together to research problems faced by the Community Dental Services division of the NYPHD. At the direction of the program manager, North York's existing guidelines for professionally applied topical fluoride, pit and fissure sealant, radiographs, space maintainers, restorative services, and infection control were selected for review. The review process involved several steps, starting with an assessment of the burden of illness and risk factors among North York children. This was followed by an assembly and written critical appraisal of the scientific literature on efficacy of the interventions and an assessment of the resources required to

provide them. When the review indicated that revisions to the existing guidelines were needed, recommendations for change were drafted keeping in mind the number of children to be treated and the likely change in health that would occur by revising the provision of the service. These potential gains in health were compared to the likely change in health that would occur if other procedures were affected by this change. The critical appraisals of the literature and the recommendations which followed from each were then reviewed by two panels.

To critically review the literature, computer aided searches were carried out using CD-ROM and Medline to locate relevant scientifically-based articles and studies. Existing guidelines from the University of Toronto, The University of Western Ontario and the American Academy of Paediatric Dentistry were also considered in some cases. Assessments of expected benefit versus harm were then written using the relevant literature. From these assessments, evidence-based recommendations and guidelines were drafted. If scientific evidence were lacking, expert opinion and existing guidelines from professional organisations or the Dental Faculties were used.

An internal (staff) panel, consisting of three dentists and one hygienist, all of whom work in North York's school-based dental program, initially reviewed each critical appraisal of the literature and the recommended changes to the then existing guidelines. The concerns and recommendations of the internal panel were discussed with the investigators from the CDHSRU and necessary changes were made to accommodate those providing the dental services. The documents were then reviewed by an external panel of experts, consisting of a representative of the Royal College of Dental Surgeons (the 1991-93 President), a representative of the Ontario Dental Association (the 1992-93 President), an epidemiologist, an ethicist, a paedodontist, a general practitioner, and a member of the internal panel. Concerns and recommendations of the external panel were discussed with members of the CDHSRU and any recommended changes were made. The literature reviews and their respective guidelines including any minority reports were then distributed after approval by both the internal and external panels. To April 1996, we have held six Internal Panel meetings and seven External Panel meetings

As next steps, the guidelines were issued to staff and training sessions were held on how to use the guidelines in their practice. The program managers of North York incorporated the guidelines into subsequent revisions of the program's Policy and Procedure Manual.

Compliance with the guidelines has been assessed in three ways. First, individual clinicians are assessed annually through individual patient and chart review. Second, the pattern of care for the program as a whole has been assessed through the program's computerised Management Information System - MIS (Bennett, 1993). Third assessment of compliance was made by collecting data on the dental services to compare the amount and type of care provided to children attending NYPHD with that provided by private dental practitioners (Leake et al., 1994a).

### **Survey of Dentist Opinions of Quality Assurance**

We also surveyed 771 dentists most of whom provide care on a fee-for service basis to children referred by the City of North York Public Health Department; about 20 of these provided care on a sessional or salaried basis in the health department's school clinics. Of the 282 who responded over 90% agreed that that the development of practice guidelines should be a part of a quality assurance program and 89% felt that provider compliance with these should be assessed. Nonetheless they felt that expert opinion was preferable to evidence from the literature as the basis of the guidelines (Woodward et al., 1996).

### **Work of the RCDSO**

Guidelines have been issued by the RCDSO for about 20 years. The RCSDO (1994a) issued notification that the information contained in issues of Dispatch and other publications is often referenced in Complaints and Disciplinary procedures. Since November of 1994, guidelines issued by the College (1994b) have contained the notice that:

*'College guidelines contain practice parameters and standards which should be considered by all Ontario dentists in the care of their patients. It is important to note that these Guidelines*

*may be used by the College or other bodies in determining whether appropriate standards of practice and professional responsibilities have been maintained.'*

The RCDSO has had considerable experience in developing guidelines in clinical areas such as training requirements for limited procedures (RCDSO 1995b), record keeping (RCDSO 1995c), or infection control (RCDSO 1995d). However the College has been slower to develop guidelines which might inform dentists and patients which procedure is best in a particular situation.

### **Purpose of workshop**

Accordingly we proposed a workshop to engage a group of dentists in a model process for developing dental practice guidelines which might be followed by the RCDSO. The guidelines could then be issued as standards of practice.. By testing such a process we felt the participants would 'learn by doing' the necessary steps and recognize how others need to be involved.

The specific purpose of the workshop was to follow and obtain participant feedback on a model process for the Board of the RCDSO to use to establish standards of dental practice as required by the RHLPA.

By the end of the workshop we expected to define:

- the required steps in the guideline development process;
- the documentation required at each step;
- who should be involved and their role at each step; and, if time permitted,
- the process for implementation and dissemination of (what would then be) standards; and
- the monitoring of practitioner compliance with standards.

At the end of the workshop we proposed that the RCDSO would have:

- an agreed upon process for the development of clinical standards/guidelines
  - draft guidelines for the management of a clinical condition
  - a draft protocol for future standard development, and perhaps implementation and monitoring;
- and



- a better understanding of the process upon which to determine how to proceed.

## **Methods of the workshop**

### ***Selecting and defining the topic***

In conjunction with the Quality Assurance (QA) Committee we selected early enamel caries on smooth surfaces of permanent teeth in order to have a real project. We divided the topic into five sub-topics for groups to work on:

- |         |  |
|---------|--|
| Group 1 | What are the accuracy and costs of diagnostic systems/technologies for the diagnosis of smooth surface enamel caries?              |
| Group 2 | What are the accuracy and costs of risk assessment systems for smooth surface enamel caries?                                       |
| Group 3 | What are the efficacy/effectiveness and costs of clinical (professionally applied) remineralization technologies?                  |
| Group 4 | What are the efficacy/effectiveness and costs of homecare/self care remineralization technologies?                                 |
| Group 5 | What are the comparative benefits, harms and costs of tooth coloured restorations versus amalgam in smooth surface coronal caries? |

### ***Assembling the evidence***

We conducted computer-aided searches on each topic area through Medline (from 1991-1995) using prior specified MeSH headings. The citations, including titles, authors and abstracts, resulting from the searches were copied onto word processing files according to topic. Each abstract was reviewed on computer screens by three people who indicated if the article appeared to warrant further examination. Any article requested by any one of the three reviewers was photocopied. Each photocopied article was again scanned by the same three raters against pre-established criteria (see Templates: Appendix 1) and scored for 'quality' using both the level of evidence and relevance to the problem. The references of the selected articles were searched for

apparently relevant publications and these were also copied and reviewed. No attempt was made to find the so called grey evidence i.e., presentations at conferences etc.

All three raters then met to decide which articles would be sent to the participants for their reading in preparation for the workshop. We planned to select three to four articles from those which best met the pre-established criteria and which demonstrated the range of possible tests/interventions in each topic area. In addition we included three or four articles on methodology of rating evidence in the participants package. These were selected from those published by the Evidence-based Working Group (1994) and others from our personal files of seminal articles.

### ***Developing templates***

We developed what we called templates for the work groups to complete. They were developed to ensure the results would have the desirable attributes of guidelines as identified by the IOM (Field and Lohr, 1992) and as used by Bader and Shugars (1995) in their review of present guidelines. The templates were designed to lead the workgroups through the necessary steps to achieve a complete examination of the question and a credible result. These were completed in advance by the co-ordinators up to and including step 4.2 and sent out to participants. With some variation for the requirements to answer the specific topic areas, they were as outlined in the generic template, Figure 2.

We also reviewed and provided a comparison of the steps involved in developing guidelines.

### ***Inviting participants***

The RCDSO invited members, including public members, of its Council, representatives of the Faculties of Dentistry, the Canadian Dental Association, the Ontario Dental Association, Specialist groups and interested general practitioners. The forty-two, who accepted the invitation to attend, were assigned to one of the clinical problems by the RCDSO and couriered the

curriculum, the selected literature and methodology articles for their assignment, the appropriate template and the levels of evidence criteria.

### ***Arranging the scientific program***

We arranged four presentations to further prepare the participants. These were:

1) Dr. George Browman, Chair, Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Ontario.

#### ***Can practice guidelines have teeth?***

2) Dr. David Banting, Faculty of Dentistry, University of Western Ontario, London, Ontario

#### ***The art and science of diagnosing dental caries.***

3) Dr. Amiram Gafni, Centre for Health Economics and Policy Analysis, McMaster University, Hamilton, Ontario.

#### ***The role of economic considerations as part of developing standards of care.***

4) Dr. James Leake and Mr. Graham Woodward, Community Dental Health Services Research Unit, Faculty of Dentistry and City of North York Public Health Department

#### ***Considerations in developing evidence-based practice guidelines for smooth surface enamel caries: building on the work of others.***

### ***Training facilitators***

Five individuals who were familiar with the levels of evidence concepts and had experience with the development of evidence-based guidelines were invited to facilitate the work groups. On the afternoon preceding the workshop we conducted a brief training session where we reviewed the rationale, methods and the likely areas of difficulty for the workgroups.

## ***Organising the work***

The workgroups heard the presentations Thursday evening and Friday morning. They began their work at 1:00 p.m. and made their preliminary evidence-based recommendation to all participants from 3:00 to 4:00. In light of the comments they received, the work groups met again to amend their reports. They were also free to work on their group's input for the suggestions to the RCDSO for the process to develop practice guidelines. At the end of the day they handed their completed templates, containing the evidence-based recommendations, and their suggestions for the RCDSO process to the facilitators. That evening, the co-ordinators and the facilitators worked to arrange the evidence-based reports and the process recommendations into presentation format. Saturday morning all participants met to receive and review the evidence-based recommendations (9:00 - 10:00) and to review and develop further suggestions for the RCDSO on the best process to follow when developing clinical practice guidelines for dentistry (10:00 - 1:00).

## **Results of the workshop**

### ***The evidence***

Appendix 1 contains the five templates and the MeSH headings for the search strategy, the pre-established selection criteria and the number of articles identified and copied. Table 1 shows the summary of the number of articles considered at each stage of the evidence gathering process. In all 2687 abstracts were considered and 244 articles were copied. An additional 20 articles were identified from the citations and copied. Depending on the group, each participant received 3 to 8 topic specific articles and 3 to 5 methodological articles. Copies of all articles were sent to the facilitators. For the group dealing with the professionally applied remineralization topic we conducted a second search to try to identify more articles of sufficiently high quality. Appendix 2 provides citations for all articles sent out by workgroup.

Appendix 3 shows the results of the review of methods of guidelines development found in the literature. Of interest is the similarity of the processes developed for the NYPHD (Leake, Main and Woodward submitted) and the OCTRF, (Browman et al.,1995) developed independently in Ontario.

Table 1  
 NUMBER OF ARTICLES CONSIDERED AND DISTRIBUTED  
 BY CO-ORDINATORS FOR WORKSHOP

GROUP	IDENTIFIED ON MEDLINE	COPIED FOR REVIEW	SENT TO PARTICIPANTS	ADDITIONAL 'METHODS' SENT
Diagnosis	101	44	3	4
Risk assessment	113	45	7	4
Professionally applied remineralization	178 + 303	30	5	5
Self applied Remineralization	539	62	8	4
Restorative materials	1453	83	5	3
Total	2687	264	28	20

### ***Attendees and participation***

Forty three people attended the workshop. Most were dentists but three public representatives on RCDSO's Council, one staff person to each of the Canadian Dental Association and the Ontario Dental Association and the registrar for the College of Dental Hygiene in Ontario attended.

Appendix 4 shows the participants and their affiliation. They were deliberately assigned to work groups where they had no special expertise in order to enable all to participate equally in the discussions and to encourage the recommendations to flow from the evidence available.

Participation was enthusiastic and continued at a high level until the workshop closed at 1:00 Saturday.

### ***Results achieved by the participants***

Appendix 5 shows the preliminary evidence-based recommendations from each of the groups arranged in a tabular format recommended by one of the groups and used by the Periodic Health Examination Task Force. The results point to some variation in the ratings; since in some instances, the co-ordinators would have rated the level of evidence and the recommendations differently. Only one of the groups was able to complete the comparison of outcomes and costs for the various options, and one group was able to provide the costs of the options they considered. Problems surfaced in evaluating the strength of the evidence for diagnostic tests. The methods of assessing these do not fit into the level of evidence concept (RCT's to expert opinion) and this group was not able to translate the strength of evidence into that format.

### **Agreed upon steps**

In plenary session the workshop agreed that the seven steps in writing the guidelines should be (see additional detail in Appendix 6):

- 1) Frame the question:
  - 1.1 Develop a protocol for choosing topics requiring guideline development based on distribution of care services, identified needs, and selected outcomes; and
  - 1.2 Clearly define the problem in consultation with key stakeholders.
- 2) Assemble and review the evidence.
- 3) Develop a preliminary evidence-based report.
- 4) Review and revise the evidence-based report:
  - 4.1 Circulate the preliminary evidence-based report for review;
  - 4.2 Revise the evidence-based report where necessary;
  - 4.3 Develop the clinical guideline based on the revised evidence-based report;
  - 4.4 Circulate the revised evidence-based report and the clinical guideline for comment;
  - 4.5 Revise the guideline based on comments and recirculate for further comment.
- 5) Adopt and publish the evidence-based guideline.
- 6) Disseminate the guideline through education and other means.
- 7) Schedule review according to Steps 1 through 6.

The issue of who should be involved at each step was not addressed as a specific topic. However as the above steps were being discussed, it was apparent the participants wanted an open process with opportunity for input from a wide array of expertise and interests. The authors provide their summary of the participants suggestions as follows. Step 1 should be the responsibility of the RCDSO, perhaps in conjunction with a national co-ordinating process. Steps 2 and 3 need not be done by the RCDSO, but could be contracted and completed by the contractor's reviewer who must be competent in clinical epidemiology and who works under the guidance of a dentist familiar with the issues and aware of where the grey evidence could be found. Step 4 would be the responsibility of the contractor under the authority of the contracting agency (e.g. RCDSO). Reviewers would include those expert in the Dental Faculty representatives, the Ontario Dental Association, other dental organisations, and the public. The workshop did not state explicitly who should actually write the draft guideline (Step 4.3) but it seems that it might be the contractor in consultation with the RCDSO. Step 5 would be the responsibility of the RCDSO. Again the workshop was silent on who should conduct Step 6, but there are opportunities for both Faculties and the Ontario Dental Association. Step 7 would need to be initiated by the RCDSO.

Appendices 6 and 7 show the detailed recommendations for each step plus additional details of the other recommendations outlined below.

### **Other comments**

Other comments were provided for consideration by the College. They are more generic and include:

1. The RCDSO needs to clarify its definitions of standards of practice and clinical guidelines;
2. The RCDSO should review what others have done;
3. There should be a process that can be shared nationally;
4. The literature on practitioner behaviours should be consulted to learn the best ways to influence them;
5. Ethical values as well as data must inform the development of guidelines;

6. The guideline process should ideally maximize the oral health of the population, and participants felt that the profession would want to be involved in the entire process;
7. Future reviewers (at Steps 4.1 and 4.4) need training in critically appraising evidence; and
8. The issue of resource implications implicit within the seven step process of guideline development is as yet unresolved.

## **Conclusions**

1. We developed search strategies, evidence-based templates and a workshop format to test and obtain feedback on a process to develop evidence-based clinical practice guidelines which could be used by the RCDSO to develop and issue standards of dental practice.
2. The workshop was able to test the process and define the steps the RCDSO should follow to develop standards of dental practice in Ontario. The process revealed many of the problems likely to be encountered and the participants developed additional recommendations to address them
3. Unlike in a previous workshop, (Leake et al.,1994b) the evidence-based recommendations for the various topic areas were not completed, likely due to the more rigorous expectations defined by the templates, the brief time, the incomplete evidence gathering process, the difficulty participants had critically appraising the evidence that was provided and the interest in forming recommendations on the overall process.
4. Support for an RCDSO led, open, evidence-based, approach was achieved and clarified in the development of the steps to be recommended to the RCDSO.
5. Participants called for national co-operation on the task of writing standards of care.



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## Figures

### *Figure 1*

#### Assessing the Evidence for Efficacy of Preventive or Treatment Technologies

##### Quality of Evidence

- I: Evidence obtained from at least one properly randomized controlled trial.
- II-1: Evidence obtained from well-designed controlled trials without randomization.
- II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.
- II-3: Evidence obtained from comparisons between times or places with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of treatment with penicillin in the 1940's) could also be included in this category.
- III: Opinions of respected authorities, based on clinical experience, descriptive studies or reports of expert committees

##### Classification of Recommendations

- A: There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination.
- B: There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination
- C: There is poor evidence regarding the inclusion or exclusion of the condition in a periodic health examination, but recommendations may be made on other grounds
- D: There is fair evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination
- E: There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination

Source: The Canadian Task Force on the Periodic Health Examination. (1994) The Canadian guide to clinical preventive health care. Ottawa, Canada, Health Canada

*Figure 2*

Generic template for Workgroups

- 1) Target population:
  - 1.1 Describe the patient populations to which this guideline applies.
  - 1.2 Describe patient populations excluded from this guideline.
- 2) Clinical problem:
  - 2.1 Describe the clinical problem including prevalence to which this guideline applies.
  - 2.2 Describe clinical problems to which this guideline does not apply.
- 3) Clinical flexibility:
  - 3.1 Describe any clinical situations in which this guideline need not apply.
  - 3.2 Discuss any patient factors, such as patient preferences, which may override this guideline.
- 4) Summary of the evidence:
  - 4.1 Describe the search strategy to collect evidence.
  - 4.2 Describe the criteria used to include/exclude evidence.
  - 4.3 Describe each reasonable or important option including:
    - i) devices and clinical procedure;
    - ii) ease of use in clinical settings;
    - iii) cost estimates of implementing the technique in clinical practice, e.g., training costs, capital costs of equipment or others;
    - iii) likely cost (estimated money or time) per patient assessed/treated;
    - iv) quality of the evidence supporting the use of the technique;
- 5) Comparison of costs:
  - 5.1 Compare relative outcomes and costs of the options.
- 6) Description of relative importance of the potential outcomes:
  - 6.1 Describe the relative importance (value) of the outcomes of the options, e.g., for restorative techniques - no treatment, vs. watchful waiting, vs. treatment over one or more years.
- 7) State evidence-based recommendation and any minority views.
- 8) Provide any comments or suggestions for further research.



**Appendix 1**  
**Completed Templates for Workgroups**

## Appendix 1 Completed Templates for Workgroups

### *Workgroup 1. Diagnostic Systems for Smooth Surface Carious Lesions*

#### 1) Patient Population

These guidelines apply to individuals with permanent teeth who are attending an Ontario dentist in 1996 for general dental care.

These guidelines do not apply to children with only deciduous dentition or individuals attending for specialized dental care (e.g. orthodontics, endodontics).

#### 2) Clinical Problem

These guidelines apply to carious smooth surface lesions, including buccal, lingual, and interproximal lesions.

These guidelines do not apply to pit and fissure lesions or root surface lesions.

#### 3) Clinical Flexibility

These guidelines need not apply to patients undergoing radiation therapy.

Individual may refuse the use of one or more specific diagnostic tests that these guidelines address.

#### 4) Review of the Evidence

A computer aided search (Medline) of the health care literature published from January 1991 to December 1995 was carried out. All searches were limited to English language articles involving human subjects. The search strategies and Medical Subject Headings used are listed below. Although the primary focus of this search was the diagnosis of smooth surface carious lesions, it may have been the source of articles for other workgroups.

- i. [**dental caries** (restricted to articles focusing on diagnosis, epidemiology, economics, radiography, classification) OR **dental caries activity tests**] AND **sensitivity and specificity** (tw)
- ii. **smooth surface caries** (tw)

Total Yield = 101 citations

Citations in the articles identified by the Medline search were sources of additional articles

The titles and abstracts of the identified articles were reviewed independently by J.L., P.M., and G.W., with each reviewer compiling a list of potential articles. From each reviewer's list, a master list of 44 potential articles was compiled and complete copies of these articles were distributed to the three reviewers. Each reviewer examined these articles to determine which articles might assist the workshop participants in carrying out their work.

Articles addressing caries diagnostic tests were considered as evidence if they were:

- i. review articles that reported data on sensitivity, specificity, likelihood ratios, odds ratios, or ROC analysis, from two or more studies; or,
- ii. studies that followed acceptable methods for assessing a diagnostic test and reported sensitivity, likelihood ratios, odds, ratios, or ROC analysis.

The reviewers then met to select five to eight articles which represented the best evidence. These articles, along with three methodology papers, were distributed to participants ahead of time (Appendix 2). The remaining articles were made available at the workshop.

### **Workgroup Proceedings**

Using the literature provided, the workgroup proceeded to:

- A. Describe each reasonable or important diagnostic system considered including:
  - i) devices and clinical procedures (see Table 1-G1);
  - ii) ease of use in clinical settings - NOT DONE;
  - iii) cost estimates of implementing the technique in clinical practice, e.g., training costs, capital costs of equipment or others (see Table 1-G1);
  - iv) likely cost (estimated price and time) per patient assessed - NOT DONE;
  - v) quality of the evidence supporting the use of the test (see Table 1-G1).
- B. Provide sensitivity/specificity, likelihood ratios, or ROC curves for each assessment technique (see Table 1-G1).

#### 5) Comparison of Outcomes and Costs

NOT DONE

#### 6) Relative Importance of False Negatives and False Positives

NOT DONE

#### 7) Evidence-based Recommendations

(see Table 2-G1)

8) Comments and Further Research

- The group defined dental caries as the presence of (a) enamel and (b) dentin caries.
- It was difficult to develop recommendations because of the unavailability of an extensive and complete review of the literature.
- There is a need for in vivo studies.
- Further research is needed to define the “gold standard” for caries diagnosis in vivo.
- Revised tables for the quality of the evidence and recommendations should developed for diagnostic systems.
- There are limitations associated with all the methods currently available for use in dental practice.
- It is imperative that dental students and practicing dentists are taught how to search, read and critique the published literature.
- A clinical examination should be carried out after carefully cleaning and drying a tooth surface.
- Because of the low prevalence of enamel and dentin caries in smooth surfaces, it is recommended that tests with very high specificity be developed and tested.

Table 1-G1. Comparison of Systems for Diagnosing Smooth Surface Carious Lesions

Diagnostic System	Devices & Procedures	Ease of Use	Cost to Implement	Cost per Patient	Quality of Evidence	Sensitivity, Specificity, LR, ROC	Comments
Clinical Exam, buccal/lingual enamel caries	should be carried out after carefully cleaning and drying the tooth surface		none		III		reliability may be low
Clinical Exam, buccal lingual dentin caries	should be carried out after carefully cleaning and drying the tooth surface		none		III		reliability may be low
Clinical Exam, mesial/distal enamel caries	should be carried out after carefully cleaning and drying the tooth surface		none		III		
Clinical Exam, mesial/distal dentin caries	should be carried out after carefully cleaning and drying the tooth surface		none		II-2	sensitivity=0.38 specificity=0.99	
Bitewing radiographs, mesial/distal enamel caries	proper radiographic techniques should be used		none, most dentists already have		II-2	sensitivity=0.29 specificity=0.95	
Bitewing radiographs, mesial/distal dentin caries	proper radiographic techniques should be used		none, most dentists already have		II-2	sensitivity=0.23 specificity=1.00	
FOTI mesial/distal enamel caries	fibre-optic cable of 0.5 mm		\$1500-2000		III		
FOTI mesial/distal dentin caries	fibre-optic cable of 0.5 mm		\$1500-2000		II-2	sensitivity=0.67 specificity=0.97	

Table 2-G1. Diagnosis of Smooth Surface Carious Lesions

Maneuver	Effectiveness	Level of Evidence	Recommendation*
<b>Clinical Exam</b>			
enamel lesion (b,l)	Sn=not available Sp=not available	expert opinion (III)	C
enamel lesion (m,d)	Sn=not available Sp=not available	expert opinion (III)	C
dentin lesion (b,l)	Sn=not available Sp=not available	expert opinion (III)	C
dentin lesion (m,d)	Sn=0.38 Sp=0.99	(II-2) (Peers et al. 1993)	B
<b>Bitewing X-ray</b>			
enamel lesion (m,d)	Sn=0.29 Sp=0.95	(II-2) (Angmar-Mansson & ten Bosch 1993)	C
dentin lesion (m,d)	Sn=0.23 Sp=1.00	(II-2) (Angmar-Mansson & ten Bosch 1993)	B (as a safety net)
<b>FOTI</b>			
enamel lesion (m,d)	Sn=not available Sp=not available	expert opinion (III)	C
dentin lesion (m,d)	Sn=0.67 Sp=0.97	(II-2) (Peers et al. 1993)	B (as a safety net)

b=buccal; l=lingual; m=mesial; d=distal

Sn=sensitivity; Sp=Specificity

FOTI=Fibre Optic Transillumination

\*contrary opinions may have been expressed in plenary but were not documented

## ***Workgroup 2. Risk Assessment Systems for Smooth Surface Carious Lesions***

### 1) Patient Population

These guidelines apply to individuals with permanent teeth who are attending an Ontario dentist in 1996 for general dental care.

These guidelines do not apply to children with only deciduous dentition or individuals attending for specialized dental care (e.g. orthodontics, endodontics).

### 2) Clinical Problem

These guidelines apply to carious smooth surface lesions, including buccal, lingual, and interproximal lesions.

These guidelines do not apply to pit and fissure lesions or root surface lesions.

### 3) Clinical Flexibility

These guidelines need not apply to patients undergoing radiation therapy.

Individual may refuse the use of one or more specific risk assessment systems that these guidelines address.

### 4) Review of the Evidence

A computer aided search (Medline) of the health care literature published from January 1991 to December 1995 was carried out. All searches were limited to English language articles involving human subjects. The search strategies and Medical Subject Headings used are listed below. Although the primary focus of this search was risk assessment systems, it may have been the source of articles for other workgroups.

- i. **caries prediction** (tw)
- ii. **risk factors AND dental caries risk factors** (tw)
- iii. **dental caries** (restricted to articles focusing on prevention and control)
- iv. **preventive dentistry** (restricted to articles on economics, methods, manpower, trends, and statistics and numerical)
- v. **dental caries risk factors** (tw) AND **odds ratio** (tw)
- vi. **dental caries AND predictive value** (tw)

Total Yield = 113 citations

Citations in the articles identified by the Medline search were sources of additional articles

The titles and abstracts of the identified articles were reviewed independently by J.L., P.M., and G.W., with each reviewer compiling a list of potential articles. From each reviewer's list, a master list of 45 potential articles was compiled and complete copies of these articles were distributed to the three reviewers. Each reviewer examined these articles to determine which articles might assist the workshop participants in carrying out their work.

Articles addressing caries diagnostic tests were considered as evidence if they were:

- i. review articles; or,
- ii. studies of permanent teeth in individuals greater than 10 years of age and that reported data for smooth tooth surfaces, such as sensitivity, specificity, likelihood ratios, odds ratios, or ROC analysis (for older adults, where data was found to be scarce, the smooth surface requirement was dropped).

Articles addressing caries risk assessment were not considered as evidence if they were:

- i. studies employing large numbers of dependent variables which were of no clinical use;
- ii. studies employing discriminant or linear correlation analysis;
- iii. studies of young children i.e. deciduous teeth; or,
- iv. studies of occlusal caries.

The reviewers then met to select five to eight articles which represented the best evidence. These articles, along with three methodology papers, were distributed to participants ahead of time (Appendix 2). The remaining articles were made available at the workshop.

### **Workgroup Proceedings**

Using the literature provided, the workgroup proceeded to:

- A. Describe each reasonable or important diagnostic system considered including:
  - i) devices and clinical procedures - NOT DONE;
  - ii) ease of use in clinical settings - NOT DONE;
  - iii) cost estimates of implementing the technique in clinical practice, e.g., training costs, capital costs of equipment or others - NOT DONE;
  - iv) likely cost (estimated price and time) per patient assessed - NOT DONE;
  - v) quality of the evidence supporting the use of the test (see Table 1-G2).
- B. Provide sensitivity/specificity, likelihood ratios, or ROC curves for each assessment technique (see Table 1-G2).

### 5) Comparison of Outcomes and Costs

NOT DONE



6) Relative Importance of False Negatives and False Positives

NOT DONE

7) Evidence-based Recommendations

(see Table 2-G2)

8) Comments and Further Research

The following standard is recommended.

When deciding what level of risk is appropriate for a given patient with respect to smooth surface dental caries, the dentist should examine the patient clinically and assess the following risk factors:

- a) previous caries experience
- b) exposure to water fluoridation

before deciding on the appropriate care.

Table 1-G2. Comparison of Systems for Caries Risk Assessment

RA Method	Devices & Procedures	Ease of Use	Cost to Implement	Cost per Patient	Quality of Evidence	Sensitivity, Specificity, LR, ROC	Comments
caries experience					II	moderate to good predictor sensitivity=0.50-0.60 specificity=0.72-0.90	use as a guideline
microbiologic testing					II	moderate predictor sensitivity=0.48 specificity=0.68	more evidence required
saliva testing							more evidence required
poor oral hygiene							
water fluoridation							
diet							
combination of methods					III	poor predictor	no better predictor than single risk factor

Table 2-G2. Caries Risk Assessment Systems

Maneuver	Effectiveness	Level of Evidence	Recommendation*
<b>Caries History</b>	Moderate to Good Predictor Sn=0.50-0.60 Sp=0.72-0.90	cohort study (II-1) (Russell et al. 1991) comparative study (II-1) (Lith & Grondahl 1992)	Use as a guideline (A)
<b>Microbiologic Testing</b>	Moderate Predictor Sn=0.48 Sp=0.68	cohort study (II-1) (Russell et al. 1991) literature review (van Houte 1993)	For S. Mutans > 10 <sup>8</sup> (C) More evidence needed
<b>Saliva Testing</b>	not assessed	unable to determine	More evidence needed
<b>Oral Hygiene</b>	not assessed		
<b>Water Fluoridation</b>	not assessed		
<b>Diet</b>	not assessed		
<b>Combination of tests</b>	not assessed		

\*contrary opinions may have been expressed in plenary but were not documented  
Sn=sensitivity, Sp=specificity

### ***Workgroup 3. Professionally Applied Remineralization Interventions for Smooth Surface Carious Lesions***

#### 1) Patient Population

These guidelines apply to individuals with permanent teeth who are attending an Ontario dentist in 1996 for general dental care.

These guidelines do not apply to children with only deciduous dentition or individuals attending for specialized dental care (e.g. orthodontics, endodontics).

#### 2) Clinical Problem

Are there professional interventions that work to reverse or arrest the caries process on smooth surface lesions?

These guidelines apply to carious smooth surface lesions, including buccal, lingual, and interproximal lesions.

We are restricting this to non-cavitated early lesions.

These guidelines do not apply to pit and fissure lesions, root surface lesions, or teeth which are caries-free.

By “professionally applied” we mean the application in office of the intended procedure.

#### 3) Clinical Flexibility

These guidelines may not apply to individuals who will be unable to return for follow-up care or who have medical contraindications.

Individual may refuse the use of one or more interventions that these guidelines address.

As with all other interventions, other factors may need to be taken into consideration from both the patient’s perspective and the clinician’s. Age, past caries experience, past oral hygiene experience, and others may be included.

#### 4) Review of the Evidence

A computer aided search (Medline) of the health care literature published from January 1991 to December 1995 was carried out. All searches were limited to English language articles involving human subjects. The search strategies and Medical Subject Headings used are listed below. Although the primary focus of this search was professionally applied remineralization interventions, it may have been the source of articles for other workgroups.

Search One

- i. **preventive dentistry** (tw)
- ii. **preventive dentistry** (restricted to articles on economics, manpower, methods, standards, trends, statistics and numerical)
- iii. **cariostatic agents AND treatment outcome**
- iv. **treatment outcome AND dental caries AND dental bonding**
- v. **treatment outcome AND dental amalgam**
- vi. **tooth demineralization AND fluorides**
- vii. **tooth demineralization AND dental caries**

Total Yield = 178 citations

Search Two

- i. **dental caries AND [progress\$ (tw) OR regress\$ (tw) OR revers\$ (tw)]**
- ii. **tooth remineralization**
- iii. **tooth demineralization** (restricted to articles focusing on diagnosis, epidemiology, radiography, therapy, and prevention and control)

(\$ = all possible suffixes, e.g. progress, progressing, progressed, progresses, progression)

Total Yield = 303 citations

Citations in the articles identified by the Medline search were sources of additional articles. A CDHSRU Report on caries progression (Woodward *et al.* 1991) was also examined for possible references.

The titles and abstracts of the identified articles were reviewed independently by J.L., P.M., and G.W., with each reviewer compiling a list of potential articles. From each reviewer's list, a master list of 30 potential articles was compiled and complete copies of these articles were distributed to the three reviewers. Each reviewer examined these articles to determine which articles might assist the workshop participants in carrying out their work.

Articles addressing professionally applied remineralization interventions were considered as evidence if they were:

- i. review articles or meta-analyses;
- ii. randomized clinical trials of interventions that reported lesions specific data (e.g. transitional matrices) for smooth surface lesions; or,
- iii. randomized clinical trials of caries preventive interventions that analyzed early lesions separately rather than simply an analysis of all lesions regardless of severity.

The reviewers then met to select five to eight articles which represented the best evidence. These articles, along with three methodology papers, were distributed to participants ahead of time (Appendix 2). The remaining articles were made available at the workshop.

## **Workgroup Proceedings**

Using the literature provided, the workgroup proceeded to:

- A. Describe each important remineralizing intervention including:
  - i) devices and clinical procedures - NOT DONE;
  - ii) ease of use in clinical settings (see Table 1-G3);
  - iii) cost of implementing in clinical practice, e.g., training costs, capital costs of equipment or other (see Table 1-G3);
  - iv) likely annual cost (price and time) per patient treated with this intervention - NOT DONE;
  - v) quality of the evidence supporting the intervention (see Table 1-G3).
- B. Provide estimates of efficacy (benefits and harms) of each intervention expressed as:
  - i) percent of lesions progressing, not progressing, and reversing; or
  - ii) numbers of lesions progressing, not progressing, and reversing per patient; or
  - iii) number of people needed to treat in order to reverse one lesion at expected prevalence - NOT DONE.

### 5) Comparison of Outcomes and Costs

NOT DONE

### 6) Consequences of Lesions Remineralized and Not Remineralized

NOT DONE

### 7) Evidence-based Recommendations

(see Table 2-G3)

### 8) Comments and Further Research.

The scientific evidence provided to this group was deemed insufficient for the group to recommend modalities for the treatment of the problem. We identified four treatments, three were non-classifiable, the fourth was II-C.

Table 1-G3. Comparison of Professionally Applied Remineralization Interventions

Intervention	Devices & Procedures	Ease of Use	Cost to Implement	Annual Cost/Patient	Quality of Evidence	Efficacy	Comments
topical fluoride, varnish		easy	negligible		II-3		
topical fluoride, gel		easy	negligible		not classified		
topical fluoride, solution		easy	negligible		not classified		
chlorhexadine		more technique sensitive	cost of incubator, caries screen test		not classified		

Table 2-G3. Professionally Applied Interventions for Remineralizing Early Carious Lesions

<b>Maneuver</b>	<b>Effectiveness</b>	<b>Level of Evidence</b>	<b>Recommendation*</b>
<b>fluoride varnish</b>	not estimated	comparative study (II-3) (Pettersson et al. 1991)	some indication that duraphat varnish works (C)
<b>fluoride gels</b>	not estimated	not provided	??
<b>fluoride solutions</b>	not estimated	not provided	??
<b>chlorhexidine</b>	not estimated	not provided	??

\*contrary opinions may have been expressed in plenary, but were not documented



## **Workgroup 4. Self-Applied Remineralization Interventions for Smooth Surface Carious Lesions**

### 1) Patient Population

These guidelines apply to individuals with permanent teeth who are attending an Ontario dentist in 1996 for general dental care.

These guidelines do not apply to children with only deciduous dentition or individuals attending for specialized dental care (e.g. orthodontics, endodontics).

### 2) Clinical Problem

These guidelines apply to carious smooth surface lesions, including buccal, lingual, and interproximal lesions.

These guidelines do not apply to pit and fissure lesions, root surface lesions, or teeth which are caries-free.

### 3) Clinical Flexibility

These guidelines may not apply to individuals who have medical contraindications.

Individual may refuse the use of one or more interventions that these guidelines address.

### 4) Review of the Evidence

A computer aided search (Medline) of the health care literature published from January 1991 to December 1995 was carried out. All searches were limited to English language articles involving human subjects. The search strategies and Medical Subject Headings used are listed below. Although the primary focus of this search was self-applied remineralization interventions, it may have been a source of articles for other workgroups.

- i. **dentifrices**
- ii. **tooth demineralization**
- iii. **tooth remineralization**
- iv. **toothpaste**
- v. **treatment outcome AND fluorides**

Total Yield = 539 citations

Citations in the articles identified by the Medline search were sources of additional articles. A CDHSRU Report on caries progression (Woodward *et al.* 1991) was also examined for possible references.

The titles and abstracts of the identified articles were reviewed independently by J.L., P.M., and G.W., with each reviewer compiling a list of potential articles. From each reviewer's list, a master list of 62 potential articles was compiled and complete copies of these articles were distributed to the three reviewers. Each reviewer examined these articles to determine which articles might assist the workshop participants in carrying out their work.

Articles addressing self-applied remineralization interventions were considered as evidence if they were:

- i. review articles or meta-analyses;
- ii. randomized clinical trials of interventions that reported lesions specific data (e.g. transitional matrices) for smooth surface lesions;
- iii. randomized clinical trials of caries preventive interventions that analyzed early lesions separately rather than simply an analysis of all lesions regardless of severity;
- iv. randomized clinical trials of interventions using an in-situ study design involving human enamel; or,
- v. articles on the methods and validity or in-situ remineralization studies.

Articles addressing self-applied remineralization interventions were not considered as evidence if outcome measure consisted of saliva flow or saliva constituents only and did not changes in lesion characteristics.

The reviewers then met to select five to eight articles which represented the best evidence. These articles, along with three methodology papers, were distributed to participants ahead of time (Appendix 2). The remaining articles were made available at the workshop.

### **Workgroup Proceedings**

Using the literature provided, the workgroup proceeded to:

- A. Describe each important remineralizing intervention including:
  - i) devices and clinical procedures (see Table 1-G4);
  - ii) ease of use in clinical settings (see Table 1-G4);
  - iii) cost of implementing in clinical practice, e.g., training costs, capital costs of equipment or other (see Table 1-G4);
  - iv) likely annual cost (price and time) per patient treated with this intervention (see Table 1-G4);
  - v) quality of the evidence supporting the intervention (see Table 1-G4).

- B. Provide estimates of efficacy (benefits and harms) of each intervention expressed as:
- i) percent of lesions progressing, not progressing, and reversing; or
  - ii) numbers of lesions progressing, not progressing, and reversing per patient; or
  - iii) number of people needed to treat in order to reverse one lesion at expected prevalence (Table 1-G4).

5) Comparison of Outcomes and Costs

NOT DONE

6) Consequences of Lesions Remineralized and Not Remineralized

NOT DONE

7) Evidence-based Recommendations

(see Table 2-G4)

8) Comments and Further Research.

In situ studies are difficult to classify using given levels of evidence.

Further in vivo research on the effects of the interventions on remineralization is required.

Studies should track individual lesions over time rather than mean caries scores (e.g. DMFT).

Table 1-G4. Comparison of Self-Applied Remineralization Interventions.

Intervention	Devices & Procedures	Ease of Use	Cost to Implement	Annual Cost/Patient	Quality of Evidence	Efficacy	Comments
xylitol chewing gum [ $\geq 1.5\%$ ]	chew one stick for 5 minutes 3 times per day	High	very low	\$200 / year	II-1	55% decrease in net progression of lesions over one year	children 8-9 years of age, high caries risk, low SES
NaF rinse 500 ppm	rinse with 10 ml for 1 minute once per day for 2 weeks	Medium	very low	\$200 / year	I in situ	positive remineralization effect	needs research
AmF (0.01%) & SnF <sub>2</sub> (0.01%) rinse	rinse with 10 ml for 1 minute	Medium	very low	not estimated	II-1 in situ	not assessed in study	needs research
Cheddar Cheese	chew 20g for 5 minutes	Medium	very low	not estimated	II-1 in situ	increased enamel microhardness	needs research
Fluoridated Toothpaste 1000 ppm	Brush	High	very low	\$10 / year	III	positive remineralization effect	needs research

Table 2-G4. Self-Applied Interventions for Remineralizing Early Carious Lesions.

Maneuver	Effectiveness	Level of Evidence	Recommendation*
<b>Xylitol Gum</b> [≥15%], 5 min., 3x/day	55% reduction in the net progression of carious lesions over 1 year	controlled trial without randomization (II-1) (Kandelman & Gagnon 1990)	Good evidence that chewing xylitol gum will reduce probability of lesion progression (A)
<b>NaF Rinse,</b> 500 ppm 10 ml for 1 min, 1x/day	positive effect on lesion remineralization	in situ RCT in situ (I) (Dodds & Edgar 1991)	Fair evidence that NaF rinse will promote lesion remineralization (B)
<b>AmF (0.01%) +</b> <b>SnF<sub>2</sub> (0.01%)</b> <b>Rinse,</b> 10 ml for 1 min	results for remineralization not presented in study	poorly designed, in situ controlled trial without randomization (II-1) (Gedalia et al. 1992)	Poor evidence that this intervention will or will not promote remineralization (C)
<b>Fluoridated</b> <b>Toothpaste</b> (250 or 1000 ppm)	positive effect on lesion remineralization	expert opinion (III)	Poor evidence that this intervention will or will not promote remineralization (C)
<b>Cheddar</b> <b>Cheese,</b> 20g chewed for 5 min.	increases the microhardness of demineralized enamel	poorly designed, in situ controlled trial without randomization (II-1) (Gedalia et al. 1992)	Poor evidence that this intervention will or will not promote remineralization (C)

\* contrary views may have been stated in plenary, but were not documented

## ***Workgroup 5. Restoration of Cavitated Smooth Surface Lesions***

### 1) Patient Population

These guidelines apply to a healthy young adult who is a regular dental attender with moderate caries activity, and who is attending an Ontario dentist in 1996 for general dental care.

These guidelines do not apply to children with only deciduous dentition or individuals attending for specialized dental care (e.g. orthodontics, endodontics).

### 2) Clinical Problem

These guidelines apply to the restoration of a Class II carious lesion on a molar tooth.

These guidelines do not apply to pit and fissure lesions, root surface lesions, or teeth which are caries-free.

### 3) Clinical Flexibility

These guidelines may not apply to individuals who have medical contraindications.

Individual may refuse the use of one or more interventions that these guidelines address.

### 4) Review of the Evidence

A computer aided search (Medline) of the health care literature published from January 1991 to December 1995 was carried out. All searches were limited to English language articles involving human subjects. The search strategies and Medical Subject Headings used are listed below. Although the primary focus of this search was restoration of smooth surface carious lesions, it may have been a source of articles for other work groups.

- i. **dental restoration, permanent** (restricted to articles focusing on adverse effects, classification, contraindications, economics, standards, and trends)
- ii. **dental amalgam** (restricted to articles focusing on adverse effects, economics, standards, and therapeutic use)
- iii. **composite resins**
- iv. **dental amalgam** (tw)
- v. **composite resins** (tw)
- vi. **smooth surface caries** (tw)

Total Yield = 1453 citations

Citations in the articles identified by the Medline search were sources of additional articles

The titles and abstracts of the identified articles were reviewed independently by J.L., P.M., and G.W., with each reviewer compiling a list of potential articles. From each reviewer's list, a master list of 83 potential articles was compiled and complete copies of these articles were distributed to the three reviewers. Each reviewer examined these articles to determine which articles might assist the workshop participants in carrying out their work.

Articles addressing restorative materials were considered as evidence if they were:

- i. meta-analyses comparing the survival of two or more materials;
- ii. cost studies (e.g. procedure times, prices);
- iii. long term survival studies of a single restorative material;
- iv. toxicity studies of materials other than amalgam; or,
- v. studies lasting longer than 3 years and comparing two or more of the following materials, amalgam, composite resin, glass ionomer, or gold foil.

Articles addressing material toxicity were not considered as evidence if they employed an in-vitro study design.

The reviewers then met to select five to eight articles which represented the best evidence. These articles, along with three methodology papers, were distributed to participants ahead of time (Appendix 2). The remaining articles were made available to the workgroup at the workshop.

### Workgroup Proceedings

Using the literature provided, the workgroup proceeded to:

- A. Describe each reasonable/important restorative intervention including:
  - i) devices (materials) and clinical procedures (see Table 1-G5);
  - ii) ease of use in clinical settings (see Table 1-G5);
  - iii) cost of implementing in clinical practices (see Table 1-G5);
  - iv) likely cost (price and time) per lesion restored (see Table 1-G5);
  - v) quality of the evidence supporting the use of the technology (see Table 1-G5).
- B. Provide estimates of the efficacy (benefits, harms) of each intervention (see Table 1-G5).

### 5) Comparison of Outcomes and Costs

Comparison of Outcomes and Costs of Composite Resin with Conventional Amalgam

Cost	Outcome		
	Worse	Same	Better
More	<b>X</b>		
Same			
Less			

6) Consequences of No Treatment, Watchful Waiting, and Treatment Over One Year, Ten Years, and a Lifetime, to Both the Individual and Society.

The consequences of treatment with composite resin instead of amalgam:

1. The initial restoration would be more expensive for the patient;
2. The initial restoration would not last as long. When replacement would be required it would be more expensive. Over the long term, the cost of maintaining a tooth initially restored by composite resin would be greater due to probable early endodontic treatment and the need for full coverage restoration. Mjor *et al.* (1992) estimated that the cost over the patient's lifetime of initially restoring a tooth using composite resin to be 33% greater than using amalgam.

7) Evidence-based Recommendation

(see Table 2-G5)

8) Comments and Further Research

- The group have proceeded with the assumption that all appropriate diagnostic tests have been done to establish the true need for the restoration.
- The group would like to stress that there are other treatment modalities that could be considered, but that we chose not to include them as it was not within the purview of the group. These materials would have to be considered at the time when more extensive restorative dentistry guidelines were being created.



Table I-G5. Comparison of Restorative Materials

Material	Devices & Procedures	Ease of Use	Cost to Implement	Cost per Lesion	Quality of Evidence	Efficacy	Comments
posterior composite resin	curing light, material, rubber dam, hand instruments	3 (most difficult)	highest	\$108	I	advantages=tooth coloured disadvantages=relatively poor longevity and higher cost risks=unknown	must consider patient preference and reduced cavity preparation
conventional amalgam	amalgamator, pluggers, carvers	1 (easiest)	middle	\$72	I	advantages=relatively good longevity disadvantages=sensitivity risks=mercury	must consider location and use of liners
glass ionomer cement	glass slab, spatula	2	lowest	\$99	II-2	advantages=fluoride release disadvantages=relatively poor longevity	
bonded amalgam	armamentaria for both composite resin and amalgam	3	mid-highest	\$90	II		

Table 2-G5. Restoration of Cavitated Carious Lesions

<b>Maneuver</b>	<b>Effectiveness</b>	<b>Level of Evidence</b>	<b>Recommendation*</b>
<b>posterior composite resin</b>	longevity 3-4 years, 16% need re-treatment after five years	Meta-analysis (I) (El Mowafy et al. 1994)	Should not be the restoration of choice (??)
<b>conventional amalgam</b>	longevity 12-13 years, <9% need re-treatment after 10 years	10 year prospective study (I) (Akerboom et al. 1993)	Should be the treatment of choice for the restoration of cavitated, smooth surface, carious lesions i.e. Class II (A)
<b>glass ionomer cement</b>	longevity 1-2 years	retrospective study (II-2) (Smales et al. 1991)	Should not be the restoration of choice (B)
<b>bonded amalgam</b>	not available	expert opinion (III)	not assessed

\* contrary opinions may have been stated in plenary but were not documented

**Appendix 2**  
**Citations of Articles Distributed in Advance to Workgroups**

## **Appendix 2 Citations of articles distributed to workgroups**

### **Group 1: *Diagnostic Systems for Smooth Surface Caries.***

#### Articles Sent to All Workgroups

1. Evidence-Based Care Resource Group. Evidence-based care. 2. Setting guidelines: How should we manage this problem? Canadian Medical Association Journal 1994;150(9):1417-1422.
2. Hayward RS, Wilson MC, Tunis SR, et al. Users' guides to the medical literature. JAMA 1995; 274(7) Aug 16:570-574.
3. Oxman AD, Guyatt GH. Guidelines for reading literature reviews. Canadian Medical Association Journal 1988;138:697-703.

#### Workgroup Specific Articles

4. Wenzel A, Verdonschot EH. Some considerations in the evaluation of diagnostic tests in dentistry. Dentomaxillofac Radiol 1994; 23(Nov):179-182.
5. Russell M, Pitts NB. Radiovisiographic diagnosis of dental caries: Initial comparison of basic mode videoprints with bitewing radiography. Caries Research 1993;27:65-70.
6. Angmar-Mansson B, ten Bosch JJ. Advances in methods for diagnosing coronal caries--a review. Advances in Dental Research 1993;7(2):70-79.
7. Peers A, Hill FJ, Mitropoulos CM, Holloway PJ. Validity and reproducibility of clinical examination, fibre-optic transillumination, and bite-wing radiology for the diagnosis of small approximal carious lesions: an in vitro study. Caries Research 1993;27:307-311.

**Group 2: Risk Assessment Systems for Smooth Surface Caries**

Articles Sent to All Workgroups

1. Evidence-Based Care Resource Group. Evidence-based care. 2. Setting guidelines: How should we manage this problem? Canadian Medical Association Journal 1994;150(9):1417-1422.
2. Hayward RS, Wilson MC, Tunis SR, et al. Users' guides to the medical literature. JAMA 1995; 274(7) Aug 16:570-574.
3. Oxman AD, Guyatt GH. Guidelines for reading literature reviews. Canadian Medical Association Journal 1988;138:697-703.

Workgroup Specific Articles

4. Wenzel A, Verdonshot EH. Some considerations in the evaluation of diagnostic tests in dentistry. Dentomaxillofac Radiol 1994; 23(Nov):179-182.
5. Vehkalahti M, Nikula-Sarakorpi E, Paunio I. Evaluation of salivary tests and dental status in the prediction of caries increment in caries-susceptible teenagers. Caries Research 1996;30:22-28.
6. Lith A, Grondahl HG. Predicting development of approximal dentin lesions by means of past caries experience. Community Dent Oral Epidemiol 1992; 20:25-9.
7. Van Houte J. Microbiological predictors of caries risk. Advances in Dental Research 1993;7(2):87-96.
8. Russell JI, MacFarlane TW, Aitchison TC, et al. Prediction of dental caries in Scottish adolescents. Community Dent Oral Epidemiol 1991; 19:74-7.
9. Alanen P, Hurskainen K, Isokangas P, et al. Clinician's ability to identify caries risk subjects. Community Dent Oral Epidemiol 1994; 22:86-89.
10. MacEntee MI, Clark DC, Glick N. Predictors of caries in old age. Gerodontology 1993; 10(2):90-97.
11. Disney JA, Abernathy JR, Graves RC, et al. Comparative effectiveness of visual/tactile and simplified screening examination in caries risk assessment. Community Dent Oral Epidemiol 1992; 20:326-32.

**Group 3: Professionally Applied Remineralization Interventions for Smooth Surface Caries**

Articles Sent to All Workgroups

1. Evidence-Based Care Resource Group. Evidence-based care. 2. Setting guidelines: How should we manage this problem? Canadian Medical Association Journal 1994;150(9):1417-1422.
2. Hayward RS, Wilson MC, Tunis SR, et al. Users' guides to the medical literature. JAMA 1995; 274(7) Aug 16:570-574.
3. Oxman AD, Guyatt GH. Guidelines for reading literature reviews. Canadian Medical Association Journal 1988;138:697-703.

Workgroup Specific Articles

4. Fejerskov O, Nyvad B, Joost Larsen M. Human experimental caries models: intra-oral environmental variability. Advances in Dental Research 1994; 8(2):134-143.
5. Helfernstein U, Steiner M. Prediction of costs in a selective caries prevention programme. Community Dental Health 1992;9:49-55.
6. Johansen E, Papas A, Fong W, Olsen TO. Remineralization of carious lesions in elderly patients. Gerodontology 1987;3:47-50.
7. Petersson LG, Arthursson L, Ostberg C, et al. Caries-inhibiting effects of different modes of duraphat varnish reapplication: a 3-year radiographic study. Caries Research 1991;25:70-73.
8. Vernon Pg, Raven SJ, Gilbert RJ, et al. The effect of study design on in situ treatment of carious enamel lesions. Journal of Dental Research 1992;71(Spec):814-818.
9. Arends J, ten Bosch JJ. Demineralization and remineralization evaluation techniques. Journal of Dental Research 1992; 71(Spec):924-928.
10. Stephen KW, Damato FA, Strang R. An in situ enamel section model for assessment of enamel re/demineralization potential. Journal of Dental Research 1992; 71(Spec):856-859.

**Group 4: Self-applied Remineralization Interventions for Smooth Surface Caries**

Articles Sent to All Workgroups

1. Evidence-Based Care Resource Group. Evidence-based care. 2. Setting guidelines: How should we manage this problem? Canadian Medical Association Journal 1994;150(9):1417-1422.
2. Hayward RS, Wilson MC, Tunis SR, et al. Users' guides to the medical literature. JAMA 1995; 274(7) Aug 16:570-574.
3. Oxman AD, Guyatt GH. Guidelines for reading literature reviews. Canadian Medical Association Journal 1988;138:697-703.

Workgroup Specific Articles

4. Kandelman D, Gagnon G. A 24-month clinical study of the incidence and progression of dental caries in relation to consumption of chewing gum containing xylitol in school preventive programs. Journal of Dental Research 1990; 69(11):1771-1775.
5. Dodds MWJ, Edgar WM. Interactions between fluoride and plaque in the remineralization of enamel caries-like lesions. American Journal of Dentistry 1991; 4:111-114.
6. Bjarnason S, Finnbogason SY. Effect of different fluoride levels in dentifrice on the development of approximal caries. Caries Research 1991;25:207-212.
7. Gedalia I, Davidov I, Lewinstein I, Shapira L. Effect of hard cheese exposure, with and without fluoride pre-rinse, on the rehardening of softened human enamel. Caries Research 1992; 26:290-292.
8. Vernon Pg, Raven SJ, Gilbert RJ, et al. The effect of study design on in situ treatment of carious enamel lesions. Journal of Dental Research 1992;71(Spec):814-818.
9. Arends J, ten Bosch JJ. Demineralization and remineralization evaluation techniques. Journal of Dental Research 1992; 71(Spec):924-928.
10. Stephen KW, Damato FA, Strang R. An in situ enamel section model for assessment of enamel re/demineralization potential. Journal of Dental Research 1992; 71(Spec):856-859.
11. Cain BE, Corpron RE, Fee CL, et al. Dose related remineralization using intraoral fluoride-releasing devices in situ. Caries Research 1994;28:284-290.

12. Mellberg JR, Petrou ID, Grote NE. A study of the ability of an in situ remineralization model to differentiate between the effects of two fluoride dentifrices that produced significantly different clinical caries results. *Journal of Dental Research* 1992; 71(5): 1169-1172.



**Group 5: Restoration of cavitated smooth surface carious lesions.**

Articles Sent to All Workgroups

1. \* Evidence-Based Care Resource Group. Evidence-based care. 2. Setting guidelines: How should we manage this problem? Canadian Medical Association Journal 1994;150(9):1417-1422.
2. Hayward RS, Wilson MC, Tunis SR, et al. Users' guides to the medical literature. JAMA 1995; 274(7) Aug 16:570-574.
3. Oxman AD, Guyatt GH. Guidelines for reading literature reviews. Canadian Medical Association Journal 1988;138:697-703.

Workgroup Specific Articles

4. Smales RJ, Webster DA, Leppard PI. Survival predictions of four types of dental restorative materials. Journal of Dentistry 1991; 19:278-282.
5. Akerboom HBM, et al. Long-term evaluation and reresoration of amalgam restorations. Community Dent Oral Epidemiol 1993; 21:45-48.
6. Mjor IA. Problems and benefits associated with restorative materials: side-effects and long-term cost. Advances in Dental Research 1992;6:7-16.
7. Jokstad A, Mjor IA, Kaping S. Clinical performance of three anterior restorative materials over 10 years. Quintessence International 1994;25:101-108.
8. El-Mowafy OM, Lewis DW, Benmergui C, Levinton C. Meta-analysis on long-term clinical performance of posterior composite restorations. Journal of Dentistry 1994; 22:33-43.

**Appendix 3**  
**Comparison of Guideline Development Processes:**  
**RCDSO WORKSHOP April 1996**

### Appendix 3 Comparison of Guideline Development Processes

STEPS	NYPHD/CDHSRU	IOM/AHCPR	OCTRF	RAND
1 Define the Problem	<ul style="list-style-type: none"> <li>→ deciding on the topic depending on                             <ul style="list-style-type: none"> <li>• burden of illness</li> <li>• identified need</li> <li>• distribution of care services</li> </ul> </li> <li>→ prioritization of order</li> </ul>	<ul style="list-style-type: none"> <li>→ define the question re clinical condition                             <ul style="list-style-type: none"> <li>• needs of Medicare/ Medicaid population</li> <li>• ↓ variations: MD patient adequacy of evidence</li> <li>• ↑ prevention/ treatment</li> <li>• cost of condition</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>→ prioritize topic</li> <li>→ select topic</li> <li>→ select outcomes</li> <li>→ frame the problem</li> </ul>	<ul style="list-style-type: none"> <li>→ frequency of procedures associated with greatest morbidity/ mortality</li> <li>→ procedures which consume a great deal of resources</li> </ul>
2 Assemble and Review	<ul style="list-style-type: none"> <li>→ training in critical appraisal</li> <li>→ using evidence</li> <li>→ how to read the literature</li> <li>→ economic considerations</li> <li>→ review existing guidelines</li> <li>→ full review of the literature</li> <li>→ grade strength of evidence</li> </ul>	<ul style="list-style-type: none"> <li>→ review and analyze the scientific research</li> <li>→ review estimates of patient outcomes influenced by intervention</li> <li>→ review of benefits and harms</li> <li>→ review current costs and estimate potential health care costs with guideline</li> <li>→ invite information and comments from researchers, professional and consumer organizations and publicly announce</li> <li>→ conduct public meeting</li> </ul>	<ul style="list-style-type: none"> <li>→ search existing guidelines</li> <li>→ gather, synthesize evidence</li> <li>→ grade strength of evidence</li> </ul>	<ul style="list-style-type: none"> <li>→ detailed literature review Medline + hand search and opinion of experts re literature</li> <li>→ categorized by level of evidence</li> <li>→ best information in literature on, use, cost, effectiveness, efficacy, and complications</li> </ul>
3 Develop Evidence Based Report (EBR)	<ul style="list-style-type: none"> <li>→ draft a report:                             <ul style="list-style-type: none"> <li>• current guideline</li> <li>• results of literature review</li> <li>• recommendations for implementation of new guideline</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>→ prepare guideline draft based on the available evidence and on professional judgment where evidence is insufficient</li> </ul>	<ul style="list-style-type: none"> <li>→ generate preliminary EBR</li> </ul>	<ul style="list-style-type: none"> <li>→ preliminary list of recommendations</li> </ul>
4a Review and Revise EBR	<ul style="list-style-type: none"> <li>→ send draft recommendations to internal panel</li> <li>→ incorporate program factor related changes to the draft recommendations</li> </ul>	<ul style="list-style-type: none"> <li>→ submit draft guideline to peer and pilot review by clinicians and experts</li> </ul>	<ul style="list-style-type: none"> <li>→ disseminate to 'disease site group'</li> <li>→ build consensus and ratify</li> <li>→ document minority opinions</li> <li>→ formulate practice guidelines                             <ul style="list-style-type: none"> <li>• disseminate ratified EBR</li> <li>• apply modulating factors</li> <li>• formulate clinical practice guidelines</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>→ review by experts for completeness, lack of bias</li> </ul>
4b Review and Revise EBR	<ul style="list-style-type: none"> <li>→ send draft recommendations for review by multidisciplinary external panel</li> <li>→ development of consensus</li> <li>→ revise EBR and practice guideline</li> <li>→ document minority opinions</li> </ul>	<ul style="list-style-type: none"> <li>→ revise draft guideline based on analysis of comments and information received</li> <li>→ prepare the guideline in approved AHCPR format</li> </ul>	<ul style="list-style-type: none"> <li>→ independent review                             <ul style="list-style-type: none"> <li>• submit EBR/policy for independent review</li> </ul> </li> <li>→ adjust guideline with consensus</li> <li>→ document modifications</li> <li>→ submit guideline for approval</li> </ul>	
				<ul style="list-style-type: none"> <li>→ assemble multispecialty panel</li> <li>→ conduct interviews by phone</li> <li>→ amend literature review and recommendations</li> <li>→ meet to assess appropriateness</li> <li>→ rate necessity of procedures                             <ul style="list-style-type: none"> <li>• appropriate</li> <li>• improper not to provide</li> <li>• reasonable chance to benefit patient</li> <li>• benefit to patient is not small</li> </ul> </li> </ul>

5 Implement New Guideline	→ include in Manual		→ negotiate practice policies • disseminate guidelines • apply non-clinical modulators • negotiate practice policies • monitor guideline/ policy discordance → adopt guidelines/ policies	
6 Disseminate Guideline	→ disseminate and diffuse the guideline	→ publish and disseminate		
7 Schedule Review	→ schedule review/update of guidelines	→ evaluate	→ schedule review	

**Appendix 4**  
**Listing of Workshop Participants and Their Affiliation**

## Appendix 4 Listing of Workshop Participants

### Co-ordinators

Dr. James Leake and Dr. Patricia Main

### List of Participants

Working Group 1 Diagnosis Dr. Amid Ismail (Facilitator)	Working Group 2 Risk Assessment Dr. David Banting (Facilitator)	Working Group 3 Prof. Remineralization Dr. Eric Meslin (Facilitator)	Working Group 4 Self Remineralization Mr. Graham Woodward (Facilitator)	Working Group 5 Restoration Dr. Pat Abbey (Facilitator)
1. Dr. Robin Begg (GP)	1. Dr. Stan Kogon (UWO)	1. Dr. Peter Fendrich (ODA)	1. Dr. Ewan Swan (ODA)	1. Dr. David Walker (OSOMS)
2. Dr. Sandra Bennett (OMH)	2. Ms. Fran Richardson (CDHO)	2. Dr. Neil Farrell (ODA)	2. Dr. Evelyn McNeel (CDA)	2. Dr. John Houston (OSPt)
3. Ms. Linda Samek (ODA)	3. Dr. David Kenny (HSC)	3. Dr. Peter Wiebe (OSPHD)	3. Dr. Don McFarlane (RCDS)	3. Dr. Bill Hettenhausen (RCDS)
4. Dr. Manfred Friedman (UWO)	4. Dr. Joseph Friedlich (OSOMS)	4. Dr. James Fargher (OSP)	4. Dr. George Citrome (RCDS)	4. RCDC Representative (RCDC)
5. Dr. Michael Casas (OSPD)	5. Dr. Michael Hornyak (GP)	5. Dr. Victor Kreuger (RCDS)	5. Dr. Wayne Pulver (ODA)	5. Mr. Brian Henderson (CDA)
6. Dr. Teresa Banky (OSP)	6. Dr. Richard Beyers (GP)	6. Dr. Dorothy McComb (RCDS)	6. Ms. Jodie Karpf (RCDS)	6. Dr. Gordon Organ (OAO)
7. Dr. Stephen Abrams (ODA)	7. Mrs. Solette Gelberg (RCDS)	7. Dr. Renee Kilmartin (UofT)	7. Dr. Paul Andrews (UofT)	7. Dr. Michael Taylor (OAO)
8. Dr. Hardy Limeback (UofT)	8. Dr. Omar El-Mowafy (UofT)	8. Dr. Ron Beveridge (GP)	8. Dr. Edward Mazak (Green Shield)	8. Ms. G. Lafond (RCDS)
9. Dr. Alan Milnes (UofT)				9. Dr. Jim Sandham (UofT)

**Appendix 5**  
**Preliminary Evidence-based Recommendations from Workgroups**

## Appendix 5 Preliminary evidence-based recommendations

### Workgroup 1. Diagnosis of Early Carious Lesions

Maneuver	Effectiveness	Level of Evidence	Recommendation*
<b>Clinical Exam</b>			
enamel lesion (b,l)	Sn=not available Sp=not available	expert opinion (III)	C
enamel lesion (m,d)	Sn=not available Sp=not available	expert opinion (III)	C
dentin lesion (b,l)	Sn=not available Sp=not available	expert opinion (III)	C
dentin lesion (m,d)	Sn=0.39 Sp=0.99	(II-2) (Peers et al. 1993)	B
<b>Bitewing X-ray</b>			
enamel lesion (m,d)	Sn=0.12 Sp=0.95	(II-2) (Angmar-Mansson & ten Bosch 1993)	C
dentin lesion (m,d)	Sn=0.40 Sp=0.99	(II-2) (Angmar-Mansson & ten Bosch 1993)	B (as a safety net)
<b>FOTI</b>			
enamel lesion (m,d)	Sn=not available Sp=not available	expert opinion (III)	C
dentin lesion (m,d)	Sn=0.40 Sp=0.99	(II-2) (Peers et al. 1993)	B (as a safety net)

b=buccal; l=lingual; m=mesial; d=distal

Sn=sensitivity; Sp=Specificity

FOTI=Fibre Optic Transillumination

\*contrary opinions may have been expressed in plenary but were not documented



**Workgroup 2. Risk Assessment Systems for Early Carious Lesions**

<b>Maneuver</b>	<b>Effectiveness</b>	<b>Level of Evidence</b>	<b>Recommendation*</b>
<b>Caries History</b>	Moderate to Good Predictor Sn=0.50-0.70 Sp=0.72-0.90	cohort study (II-1) (Russell et al. 1991) comparative study (II-1) (Lith & Grondahl 1992)	Use as a guideline (A)
<b>Microbiologic Testing</b>	Moderate Predictor Sn=0.48 Sp=0.68	cohort study (II-1) (Russell et al. 1991) literature review (van Houte 1993)	For S. Mutans > 10 <sup>6</sup> (C) More evidence needed
<b>Saliva Testing</b>	not assessed	unable to determine	More evidence needed
<b>Oral Hygiene</b>	not assessed		
<b>Water Fluoridation</b>	not assessed		
<b>Diet</b>	not assessed		
<b>Combination of tests</b>	not assessed		

\*contrary opinions may have been expressed in plenary but were not documented  
Sn=sensitivity, Sp=specificity

**Workgroup 3. Professionally Applied Interventions for Remineralizing Early Carious Lesions**

<b>Maneuver</b>	<b>Effectiveness</b>	<b>Level of Evidence</b>	<b>Recommendation*</b>
<b>fluoride varnish</b>	not estimated	comparative study (II-3) (Petersson et al. 1991)	some indication that duraphat varnish works (C)
<b>fluoride gels</b>	not estimated	not provided	??
<b>fluoride solutions</b>	not estimated	not provided	??
<b>chlorhexidine</b>	not estimated	not provided	??

\*contrary opinions may have been expressed in plenary but were not documented

**Workgroup 4. Self-Applied Interventions for Remineralizing Early Carious Lesions**

Maneuver	Effectiveness	Level of Evidence	Recommendation*
<b>Xylitol Gum</b> [≥15%], 5 min., 3x/day	55% reduction in the net progression of carious lesions over 1 year	controlled trial without randomization (II-1) (Kandelman & Gagnon 1990)	Good evidence that chewing xylitol gum will reduce probability of lesion progression (A)
<b>NaF Rinse,</b> 500 ppm 10 ml for 1 min, 1x/day	positive effect on lesion remineralization	in situ RCT in situ (I) (Dodds & Edgar 1991)	Fair evidence that NaF rinse will promote lesion remineralization (B)
<b>AmF (0.01%) + SnF<sub>2</sub> (0.01%) Rinse,</b> 10 ml for 1 min	results for remineralization not presented in study	poorly designed, in situ controlled trial without randomization (II-1) (Gedalia et al. 1992)	Poor evidence that this intervention will or will not promote remineralization (C)
<b>Fluoridated Toothpaste</b> (250 or 1000 ppm)	positive effect on lesion remineralization	expert opinion (III)	Poor evidence that this intervention will or will not promote remineralization (C)
<b>Cheddar Cheese,</b> 20g chewed for 5 min.	increases the microhardness of demineralized enamel	poorly designed, in situ controlled trial without randomization (II-1) (Gedalia et al. 1992)	Poor evidence that this intervention will or will not promote remineralization (C)

\*contrary opinions may have been expressed in plenary but were not documented

**Workgroup 5. Restoration of Cavitated Carious Lesions**

<b>Maneuver</b>	<b>Effectiveness</b>	<b>Level of Evidence</b>	<b>Recommendation*</b>
<b>posterior composite resin</b>	longevity 3-4 years, 16% need re-treatment after five years	Meta-analysis (I) (El Mowafy et al. 1994)	Should not be the restoration of choice (?)
<b>conventional amalgam</b>	longevity 12-13 years, <9% need re-treatment after 10 years	10 year prospective study (I) (Akerboom et al. 1993)	Should be the treatment of choice for the restoration of cavitated, smooth surface, carious lesions i.e. Class II (A)
<b>glass ionomer cement</b>	longevity 1-2 years	retrospective study (II-2) (Smales et al. 1991)	Should not be the restoration of choice (B)
<b>bonded amalgam</b>	not available	expert opinion (III)	not assessed

\*contrary opinions may have been expressed in plenary but were not documented

**Appendix 6**  
**Recommended Process for Developing Guidelines**  
**Steps and Components**

**As determined April 20th, 1996,**  
**RCDSO/CDHSRU Workshop**

## Appendix 6 Recommended process for developing guidelines

STEPS	Components
<p>1 Frame the question</p>	<p>Develop a protocol for ranking or choosing topics requiring guideline development, in consultation with other organizations.</p> <ul style="list-style-type: none"> <li>. distribution of care services</li> <li>. identified need</li> <li>. select outcomes</li> </ul> <p>Adopt clear definition of the clinical problem and outcome. Definition of the clinical problem should be carried out in consultation with the RCDS, the ODA, and other organizations.</p> <p>Once problem is identified, the solution should be evidence based.</p>
<p>2 Assemble and Review the Evidence</p>	<p>Develop/adopt a method for critiquing the literature that can be distributed to participants, e.g. articles by Sackett et al. on how to read a review article, how to critically assess a clinical trial.</p> <p>OR</p> <p>Offer workshops to address this area for individuals involved in the guideline development process.</p> <p>Look at existing guidelines</p> <p>Develop/adopt a format which includes experts to summarize and appraise the literature, so that it can be distributed to participants. For example, see "Summary Table Chapter 36" (Canadian Periodic Health Examination: Lewis and Ismail).</p>
<p>3 Develop Evidence Based Preliminary Report (EBR)</p>	<p>Carry out a review by someone trained in critical appraisal who has access to a dental expert to address dental questions.</p> <p>Write an EBR using a rigorous methodology, which uses levels of evidence.</p> <p>Generate a preliminary report with the supporting literature</p> <ul style="list-style-type: none"> <li>. chart</li> <li>. recommendations (preliminary)</li> <li>. record level of evidence</li> </ul>

<p>4 Review and revise EBR</p>	<p>Establish an appropriate committee including but not limited to experts and non-experts, members of the public, representatives of the Faculties of Dentistry, ODA, and other dental organizations, to review the document and prepare Evidence-Based Recommendations.</p> <p>Review and revise the preliminary report based on the committee's comments, and</p> <p>Develop draft guidelines.</p> <p>Disseminate the EBR and draft guideline widely for feedback and evaluation.</p> <p>Revise the draft in the Committee, after receiving the feedback, and prepare Clinical Practice Guidelines (CPGs).</p> <p>Document minority opinion</p>
<p>5 Publish new guideline</p>	<p>Send CPGs to the QA Committee and the RCDS for consideration, adoption and publication.</p>
<p>6 Disseminate guideline</p>	<p>Disseminate the CPGs to dentists. Organize a progressive program of undergraduate and continuing education to disseminate the guidelines. Methods were proposed: Continuing education Curriculum</p> <p>Facilitate training and education as required eg through the ODA.</p> <p>Generate feedback from the College based upon quality assurance evaluations.</p>
<p>7 Review the Guideline</p>	<p>Review and update each guideline in a stated periodicity, following the 7 steps.</p> <p>It is important to evaluate the guidelines using office review, evaluation of dental curricula and feedback from the dentists.</p>

**Appendix 7**  
**Details on General Recommendations**  
**RCDSO/CDHSRU WORKSHOP April 1996**



## Appendix 7 Details on General Recommendations

The participants reviewed the process in which they had participated as well as a table outlining steps used in other guideline initiatives. There was general discussion in relation to whether the guideline was a standard or otherwise. This issue will require consideration by the College and the QA Committee, to establish that they are approving a process to develop guidelines.

The concerns also addressed using well defined terminology so that everyone is using and meaning the same thing.

[There are two roles that the College fulfils, judge and advocate. In the first role the College uses standards, while in the second role a guideline?]

The College has already been involved in writing guidelines that are standards: record keeping, anaesthesia and sexual harassment.

There was a suggestion that Standards are easy to write, but the clarification was that they would be based on Evidence Based Guidelines, which are labour intensive.

There was a request that the report of the workshop be sent to all participants by the Workshop Organisers, Leake/Main as a courtesy and to maintain "openness"

### Detailed notes on general recommendations:

As part of the feedback of the participants there were some overarching or general recommendations to the College:

## **1 Terminology and Definitions**

Unambiguous definitions need to be included to avoid confusion.

### **1.1 Standards and/or Guidelines**

The CPGs should not be considered standards of care. After implementation, the RCDS may consider some of the CPGs as standards of care. Recommendations that are at the C level of evidence should remain as guidelines. It is also important to consider that even when standards are adopted, the dentists can deviate from the standard if a patient requests a procedure after being informed of the current standards at the time and after giving an informed consent. There is a need to clearly establish the role for the guidelines / are they standards?

## **2 Review Existing Guidelines**

An extensive review of guidelines developed by other dental organizations in Canada and other countries should be carried out first.

## **3 National Clinical Practice Guidelines:**

Clinical practice guidelines should be developed on a national level by a broadly represented group of experts representing disciplines applicable to the topic. The RCDS should take a leadership role in the development of clinical practice guidelines.

Develop and adopt a process that can be shared nationally so that areas can be divided up and the results can be shared.

## **4 Continuing Education Requirements**

The literature on influencing practitioner behaviours (e.g., Lomas, et al) should be consulted. This literature suggests that when clinicians are uncertain they can be influenced by a variety of factors, not all of which are appropriate.

## **5 Ethical Considerations**

We recognized that some of these judgements involve values for which there are no data, but involve considerations of ethical issues.

## **6 Guideline Process**

A process needs to be developed to establish which issues require guidelines. One suggestion was to establish links with other provinces and professional bodies to pin-point issues and establish a co-operative network for setting guidelines. The process should not be driven by a desire for the profession to decrease the risk of liability to its Members. The goal should be to maximize the oral health of the population.

The term "cost" should be replaced with the term "resources".

It is necessary to establish what the appropriate make-up of a panel to formulate guidelines is.

Members expressed the need to be involved in the entire process from the beginning. They felt that this would increase the 'buy-in' by members and facilitate the process, as the context could be established and maintained throughout.

Need process expertise and communication expertise within the working groups to facilitate the process. Members of the group felt however that there should not be a preponderance of experts in the group. Members who were not experts improved the validity of the process.

## **7 Funding the Guideline Process**

A permanent mechanism for funding needs to be established.

### Workshop Concerns

Concerns were raised that the process did not provide adequate literature to make a well-informed judgement regarding clinical practice guidelines or standards.

Some of the participants felt that the workshop should have addressed standards rather than clinical practice guidelines. The development of standards was the original intent of the Quality Assurance Committee for the workshop and this has been diverted to the development of clinical practice standards.