PIT AND FISSURE SEALANTS

Evidence-based guidance on the use of sealants for the prevention and management of pit and fissure caries

Supplementary documentation on guideline development methodology

2010

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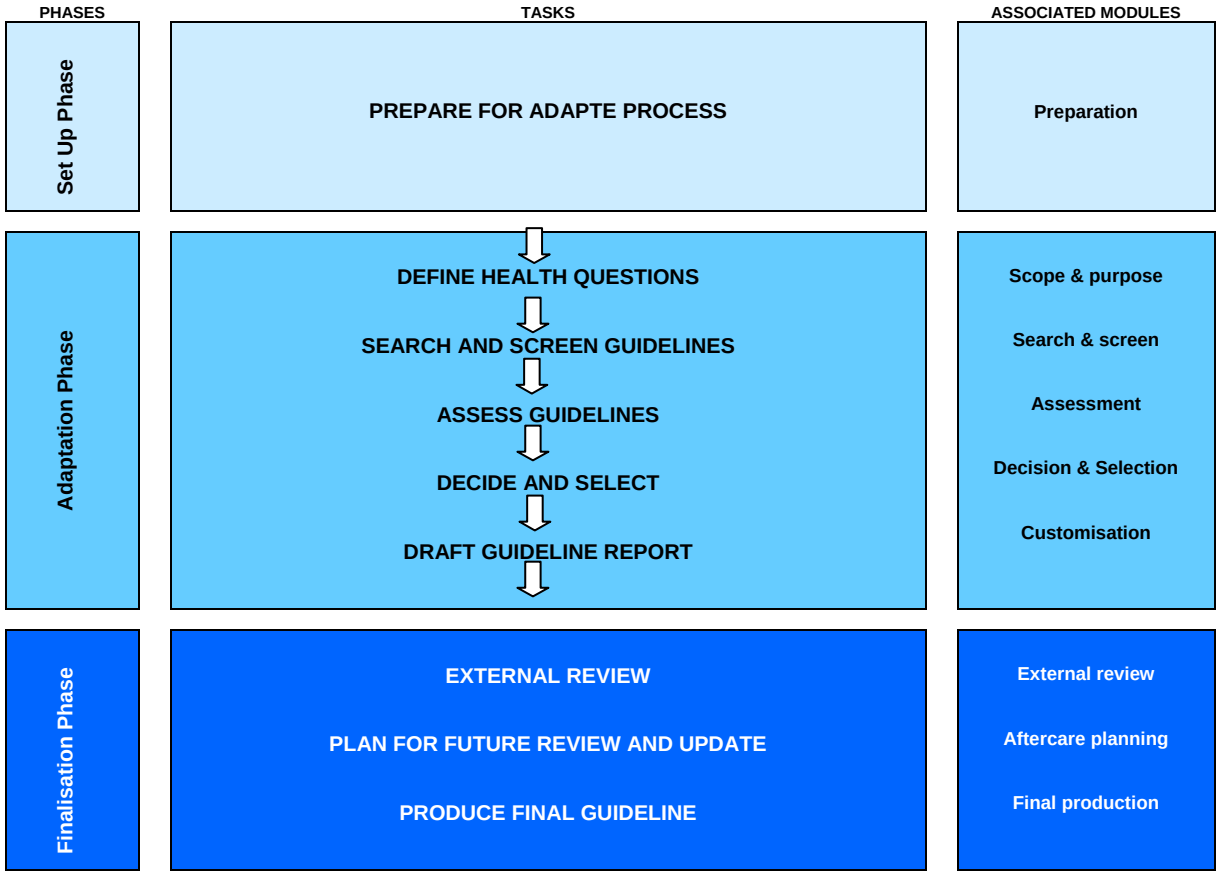
Guideline available at: http://ohsrc.ucc.ie/html/guidelines.html

1. Introduction

Evidence-based clinical guidelines are an important element in the continuous process of improving the quality and effectiveness of healthcare. The development and updating of high-quality guidelines requires substantial resources, and the volume of guidelines on similar topics is increasing. In order to take advantage of existing guidelines and reduce the duplication of effort, guideline adaptation has been proposed as an option for guideline development. The ADAPTE Collaboration is an international collaboration of guideline developers, researchers and clinicians which has developed and validated a generic adaptation process, called ADAPTE, which provides a framework for adapting existing clinical practice guidelines as an alternative to *de novo* guideline development.

It is recognised that that cultural and organisational differences between and within countries can lead to legitimate variations in recommendations, even when the evidence base is the same. The ADAPTE process has been designed to ensure that the adapted guideline not only addresses specific health questions relevant to the context of use, but also is suited to the needs, priorities, legislation, policies and resources in the targeted setting. ADAPTE respects the evidence-based principles of guideline development, including systematic search methods, explicit inclusion/exclusion criteria, and involvement of a multi-disciplinary Guideline Group and provides a systematic process for identifying, appraising and selecting guidelines and their recommendations for inclusion in the adapted guideline. The adaptation process consists of three main phases – Set-up, Adaptation and Finalisation – each with a set of modules (Figure 1).

Figure 1: Summary of the ADAPTE process (reproduced with permission from *The ADAPTE Process: Resource Toolkit for Guideline Adaptation, Version 2.0. Available from: http://ww.g-i-n.net*)



Further detail on the ADAPTE process is available at www.adapte.org and in the ADAPTE Manual and Resource Toolkit.[1]

2. Development of this guideline

2.1 Set up Phase

The Irish Oral Health Services Guideline Initiative is a project funded by the Health Research Board, to develop evidence-based guidelines for the public dental service in the Republic of Ireland. The project is headed by a team representing the Oral Health Services Research Centre, Cork, the Health Service Executive public dental service and the UK Cochrane Centre. A small team of researchers based at the Oral Health Services Research Centre, Cork is responsible for all stages of the guideline development process (Appendix 1).

The Initiative has developed guidelines *de novo* on topical fluorides[2] and strategies to prevent dental caries in children and adolescents.[3] The topic of pit and fissure sealants was selected to complete the suite of guidelines on caries prevention for the public dental service. Work on the *Strategies* guideline had identified several high-quality guidelines on pit and fissure sealants, and therefore the research team decided to use the ADAPTE process for developing the guideline on pit and fissure sealants.

The research team drafted the scope and key questions for the guideline. Key stakeholders were identified (Table 1) and invited to comment on the draft scope and key questions, which were amended accordingly.

Table 1: List of Stakeholders

- Cork School of Dental Hygiene
- Cork University Dental School and Hospital – Department of Oral Health and Development
- Dental Health Foundation
- Dublin Dental School and Hospital – Department of Public and Child Dental Health
- Dublin School of Dental Hygiene
- Irish Dental Association – Public Dental Surgeons' Committee
- Irish Dental Hygienists Association
- Irish Society of Dentistry for Children
- Irish Society for Disability and Oral Health
- Oral Health Promotion Research Group – Irish Link
- Society of Chief and Principal Dental Surgeons

A Guideline Group (Appendix 1) representing key stakeholders was established, and met on three occasions, with further discussion and consultation conducted by conference call. At the first meeting, an introduction to guideline development and the ADAPTE process was presented, and the Group fully supported using ADAPTE for developing this guideline. The final scope and the key questions were also agreed at the first meeting. The Guideline Group also decided at the first meeting that, although the remit of the project was to develop guidelines for the public dental service, the guideline

on the use of pit and fissure sealants would be relevant to clinicians in private practice, and the guideline should reflect this wider target audience. None of the Guideline Group reported any conflict of interests. The scope of the guideline can be found in Appendix 2, and the key questions are presented in Table 2.

Table 2: Key questions

Background questions relating to caries diagnosis

1. What is the best method for identifying occlusal caries?
2. How accurate are current caries detection methods at identifying whether caries extends into dentine?

Key Questions

1. How effective are fissure sealants at preventing dental caries in:
    a) Primary teeth?
    b) Permanent teeth?
2. Are fissure sealants effective in preventing the progression of non-cavitated enamel or dentine carious lesions in children and adults?
3. Are teeth that have lost sealants or have partially retained sealants at higher risk of caries than teeth that were never sealed?
4. Which patients should be selected for sealant application?
5. Which teeth should be fissure sealed?
6. Is there a difference in sealant retention or caries (at 6 months, 1, 2, 3, and 4 years) between resin-based sealant and glass ionomer cement sealants?
7. What is the best way to apply sealants to maximise retention with regard to:
    a) Tooth cleaning prior to application?
    b) Isolation?
    c) Preparation of enamel, including the use of bonding agent?
    d) Rinsing and drying the tooth?
    e) Application of sealant?
    f) Polymerisation?
    g) Four-handed versus two-handed application technique?
8. When should teeth be fissure sealed?
9. What interim preventive measures can be used for permanent teeth that require sealant but for which adequate isolation cannot be achieved e.g. partial eruption, poor patient co-operation?
10. Is there an optimum time for reviewing sealants after application?
11. Are there any side-effects or adverse reactions associated with use of fissure sealants?
12. Is there a difference in the retention/effectiveness of sealants applied by a dentist compared to those applied by a dental hygienist?
13. Is there a difference in the cost per sealant applied by a dentist/dental nurse team to the cost per sealant applied by a dental hygienist/dental nurse team?
14. What is more cost effective - to provide fissure sealants to all patients or to adopt a high risk strategy - in the context of a dental service with intervals of at least two years between dental visits and variable levels of staff?

2.2. Adaptation phase: Search and screen guidelines

The research team conducted a search for relevant guidelines in guideline repository websites, the websites of various guideline development organisations and in PubMed and Google (Table 3).

Table 3: Websites searched for guidelines

Websites	Web address
NHS Evidence Health Information Resources (formerly National Library for Health)	http://www.library.nhs.uk/
National Institute for Health and Clinical Excellence (NICE)	http://www.nice.org.uk/
Scottish Intercollegiate Guidelines Network (SIGN)	http://www.sign.ac.uk/
NZ Guideline Group	http://www.nzgg.org.nz/
Australian National Health and Medical Research Council	http://www.nhmrc.gov.au/publications/
National Guideline Clearinghouse	http://www.guideline.gov/
Centers for Disease Control and Prevention (CDC)	http://www.cdc.gov/OralHealth/guidelines.htm
Guidelines International Network (G-I-N)	http://www.g-i-n.net/
TRIP database	http://www.tripdatabase.com/
FDI World Dental Federation	http://www.fdiworldental.org/home/home.html
CMA Infobase (Canadian Medical Association)	http://www.cma.ca/index.cfm/ci_id/54316/la_id/1.htm
PubMed	www.PubMed.com
Google	www.google.com

Sixteen non-duplicate guidelines or policy statements were identified in the search (Table 4). No language restrictions were applied at this point. The retrieved guidelines were screened according to the following list of a-priori inclusion/exclusion criteria:

- Fissure sealants are the main topic of the guideline
- Publication date from 2000 onwards
- Indication that a literature search has been done (ideally using a systematic method)
- References are included
- Explicit link between the recommendations and the supporting evidence

Following application of inclusion/exclusion criteria, 7 guidelines were retained (Table 4).

Table 4: Full set of guidelines identified in search, and reasons for exclusion following initial screening

Organisation/Author	Year	Country	Language	Title	Screen
Centers for Disease Control and Prevention (CDC) [4]	2009	USA	English	Preventing dental caries through school-based sealant programs: updated recommendations and reviews of evidence.	
Finnish Medical Society Duodecim & Finnish Dental Society Appollonia Association [5]	2009	Finland	Finnish	Karieksen hallinta (Management of dental caries)	Reject – not FS guide & can't translate
American Dental Association: Council on Scientific Affairs[6]	2008	USA	English	Evidence-based clinical recommendations for the use of pit-and-fissure sealants: a report of the American Dental Association Council on Scientific Affairs.	
American Academy of Pediatric Dentistry[7]	2009	USA	English	Guideline on management of dental patients with special health care needs.	Reject – not FS guide
American Academy of Pediatric Dentistry[8]	2009	USA	English	Guideline on pediatric restorative dentistry.	Reject – not FS guide
HealthPartners Dental Group and Clinics[9]	2008	USA	English	HealthPartners Dental Group and Clinics caries guideline	Reject – not FS guide No references
American Academy of Pediatric Dentistry[10]	2009	USA	English	Guideline on periodicity of Examination, preventive dental services, anticipatory	Reject – not FS guide

				guidance/counselling and oral treatment for infants, children and adolescents.	
Haute Autorité De Santé (HAS)[11]	2005	France	French & English	Assessment of caries risk and indications for pit and fissure sealants (first and second permanent molars) in children and in adolescents under 18	
Zahnarztliche Zentralstelle Qualitatssicherung (ZZQ)[12]	2005	Germany	German	Leitlinie Fissurenversiegelung.	
American Academy of Pediatric Dentistry[13]	2005	USA	English	Adolescent oral health care.	Reject – not FS guide
European Academy of Paediatric Dentistry[14]	2004	Europe	English	EAPD guidelines for use of pit and fissure sealants.	
Task Force on Community Preventive Services[15]	2002	USA	English	Recommendations on selected interventions to prevent dental caries, oral and pharyngeal cancers, and sports-related craniofacial injuries	Reject – is a systematic review
Jokovic and Locker[16]	2000	Canada	English	Evidence-based recommendations for the use of pit and fissure sealants in Ontario's public health programs. (Update of 1993 and 1999 guidelines)	
British Society of Paediatric Dentistry[17]	2000	UK	English	British Society of Paediatric Dentistry: a policy document on fissure sealants in paediatric dentistry.	
Scottish Intercollegiate Guideline Network (SIGN)[18]	2000 ^	Scotland	English	Preventing Dental Caries in Children at High Caries Risk. Targeted prevention of dental caries in the permanent teeth of 6-16 year olds presenting for dental care.	Reject – not FS guide
Royal College of Surgeons Faculty of Dental Surgery (UK) [19]	2000	UK	English	UK National Clinical Guidelines in Paediatric Dentistry. Management of the stained fissure in the first permanent molar.	Reject – not FS guide

^ Was reviewed in 2005, but no substantial changes required.

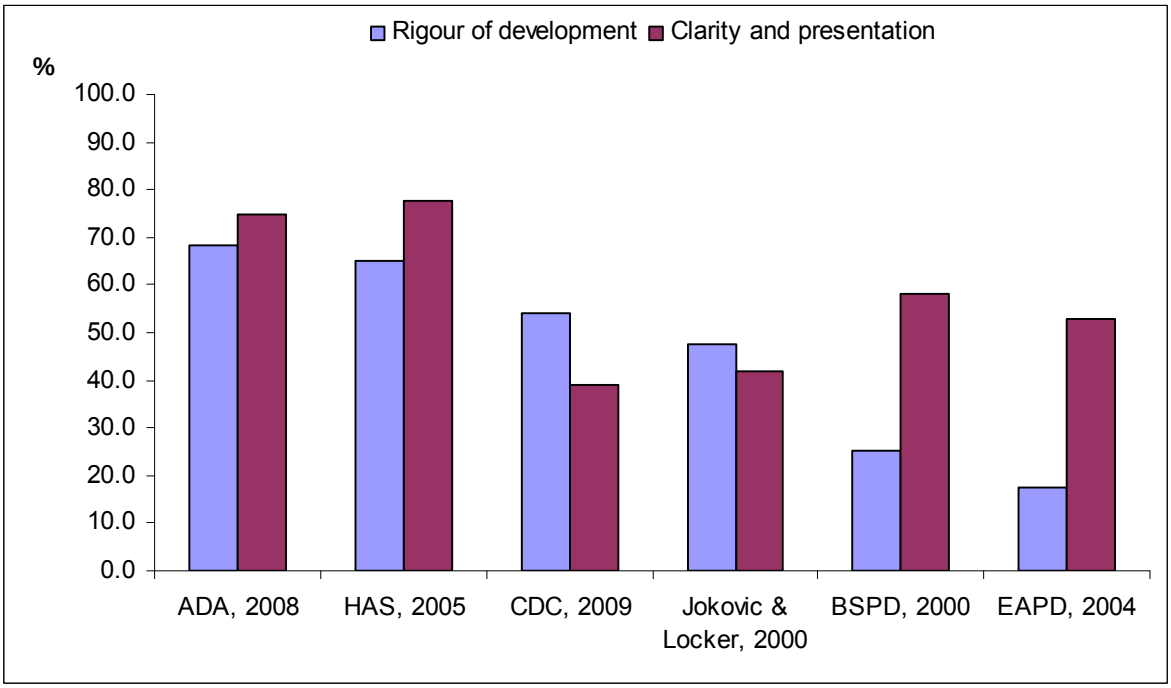
Five of the guidelines were in English, one was in French, with a summary version in English, and one was in German. The research team had the summary version of the German guideline translated.

2.3. Adaptation phase: Assess guidelines

The AGREE instrument[20] was used to appraise the quality of the 7 guidelines. The five English language guidelines were independently appraised by three researchers and the full versions of the two non-English language guidelines were each appraised by a single researcher. At this stage, the German guideline[12] was eliminated, as it did not appear to contribute anything additional to the others, and translation of the full guideline would have been costly and time consuming.

Pooled scores for each of the six AGREE domains were calculated for the remaining six guidelines. Figure 2 shows the pooled domain scores for rigour of development and clarity and presentation. The rigour of development score is particularly helpful in the ADAPTE process for deciding which guidelines should be kept as "source" guidelines for adaptation.

Figure 2: Pooled AGREE scores for Rigour of Development and Clarity and Presentation



In addition to the AGREE scores for the potential source guidelines, the Guideline Group also considered the currency of the guidelines (i.e. how up-to-date they were) and the extent to which the key questions for their guideline were addressed by each of the potential source guidelines. Based on this assessment, three guidelines were selected as the source guidelines:

- *Evidence-based clinical recommendations for the use of pit-and-fissure sealant* (American Dental Association, 2008)[6],
- *Preventing dental caries through school-based sealant programs: updated recommendations and reviews of evidence* (Centers for Disease Control and Prevention, 2009)[4] and
- *Assessment of caries risk and indications for pit and fissure sealants (first and second molars) in children and in adolescents under 18* (Short version in English and long version in French) Haute Autorité de Santé, 2005.[11]

Each of the three source guidelines offered a different perspective on fissure sealants: both the ADA and the HAS guidelines covered sealant application for individual patients, with the HAS guideline providing greater detail on application technique, whereas the CDC guideline was specifically for school-based sealant programmes (i.e. programmes targeted at schools with a high proportion of disadvantaged children, in which the sealants are applied in the school). The HAS guideline also had a comprehensive literature review, up to 2004, of economic evaluations of fissure sealant. The Guideline Group agreed to keep the guideline of the European Academy of Paediatric Dentistry[14] as a "satellite" guideline, due to the clarity of presentation of the recommendations and its relative currency, although its score for rigour of development was low.

The characteristics of the three source guidelines are presented in Table 5. An Irish guideline on strategies to prevent caries in children and adolescents[3], which had been developed by this research team, was also kept as a "satellite".

Table 5: Guideline Evaluation Sheet – Search and Selection of Evidence

Overall was the search for evidence comprehensive?	**ADA, 2008**	**CDC, 2009**	**HAS, 2005**
Clearly focussed question	Yes	Yes	Yes
Databases searched	Medline	Medline, Embase, Cochrane Library, Web of Science (specifically for review of surface preparation)	Medline, Embase, Pascal, Cochrane Library
Internet sites searched for source guidelines	No	No	National Guideline Clearinghouse, HTA database, NHS Health Economic Evaluation Database, CODECS^ , BDSP† , Internet search engines, Grey literature
Years covered in search	Up to: Sept 2006 for new studies, Oct 2006 for systematic reviews, Jun 2005 for FS & caries Jan 2007 for enamel prep	Through Aug 2008 for systematic reviews of sealant effectiveness. *Note: A number of reviews were undertaken for the CDC guideline. The search periods for these reviews are given below:* 1. 1966-June 2005 for a) systematic review of evidence on the effectiveness of sealants in managing caries lesions[21] b) the effect of dental sealants on bacteria levels in caries lesions[22] 2. 1966 through 2006 for the comparison of the effects of toothbrushing and handpiece prophylaxis on sealant retention[23] 3. 1990-2005 for exploring four-handed delivery on the retention of resin-based sealants.[24] 4. 1990-through 2005 for the risk of caries development in teeth with partially or fully lost sealant relative to the risk in teeth that were never sealed.[25]	1993 - Oct 2004
Languages covered	English	English	French & English
Search strategy provided	Yes	No	Yes
Snowballing* methods used	No	No	No
Hand search of reference lists	Yes	Not reported	Yes
Local experts and/or societies asked for guideline recommendations	Yes	Yes	Yes
Overall was bias in the selection of articles avoided?	**ADA, 2008**	**CDC, 2009**	**HAS, 2005**
Inclusion and exclusion criteria reported	Yes	No	No
Number of persons who selected and analysed data is documented	ADA division of Science staff members (number not specified)	No	One
Procedure to resolve disagreement is described	No	No	No
Number of excluded references documented	Yes	No	No
Reasons for exclusion given and appropriate	Yes	No	No
Process for selection of evidence described	Unclear	No	Unclear

*"Snowball" methods such as pursuing references of references and electronic citation tracking are especially powerful for identifying high quality sources in obscure locations
^Connaissances et Décision en Economie de Santé †Banque de données en santé publique, Renne

The recommendations from the three source guidelines were compiled in a recommendation matrix and compared. Only one guideline[6] provided a consistent grading of evidence and recommendations, which made it difficult to apply the ADAPTE process exactly at this stage. Instead, the original evidence supporting the recommendations in the source guidelines was obtained and critically appraised by the research team using the Scottish Intercollegiate Guideline Network (SIGN) methodology checklists[26] and the level of evidence was graded according to SIGN criteria (Table 6).

Table 6: Grading of evidence and recommendations

LEVELS OF EVIDENCE	
1++	High quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1+	Well conducted meta-analyses, systematic reviews or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews or RCTs with a high risk of bias
2++	High quality systematic reviews of case-control or cohort studies High quality case-control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2-	Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series
4	Expert opinion
GRADES OF RECOMMENDATIONS	
A	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population OR A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results
B	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results OR Extrapolated evidence from studies rated as 1++ or 1+
C	A body of evidence including studies rated as 2+, directly applicable to the target population, and demonstrating overall consistency of results OR Extrapolated evidence from studies rated as 2++
D	Evidence level 3 or 4 OR Extrapolated evidence from studies rated as 2+
GPP **Good Practice Point**	Recommended best practice based on the clinical experience of the Guideline Development Group

Reproduced with permission from SIGN guideline development handbook, SIGN 50 (http://www.sign.ac.uk/guidelines/fulltext/50/index.html)

A search was conducted for systematic reviews and randomised clinical trials published since the source guidelines (described in detail below) and relevant publications were also critically appraised and graded.

2.4 Updating the source guidelines

2.4.1 Search for systematic reviews

A total of 20 systematic reviews were identified from the reference lists of the three source guidelines [15 21-25 27-40] A search was run in PubMed, filtered by systematic reviews in clinical queries and limited to 2004 (end date of the search in the oldest source guideline (HAS)[11] to February 2010, to identify new systematic reviews not included in the three source guidelines. Searches were also run in Embase and the Cochrane Library and limited to 2004-February 2010. The search strategies are detailed below.

PubMed search strategy:

("Pit and Fissure Sealants" [Mesh]) OR ("fissure sealants") OR ("dental sealants") OR ("resin sealants") OR (fissure seal$) OR (dental seal$) OR (resin seal$) OR (("Glass Ionomer Cements" [Mesh] OR "Resin Cements" [Mesh]) OR glass ionomer OR glassionomer) AND (sealant$))

EMBASE search strategy:

('fissure sealant'/exp) OR ('dental sealant') OR ('resin sealant') OR ('glass ionomer sealant') OR ('resin-modified sealant')

Cochrane Library search strategy:

'Pit and Fissure Sealants' [MeSH] OR (fissure* NEAR/6 seal*):ti,ab,kw OR (dental* NEAR/3 sealant)ti,ab.kw OR (resin NEAR/4 sealant*):ti,ab,kw OR delton OR helioseal OR fissurit OR conseal OR ionoseal OR clinpro OR 'guardian seal' OR 'seal rite' OR (('Glass Ionomer Cements' [MeSH] OR 'Resin Cements' [MeSH] OR 'glass ionomer':ti,ab,kw OR glassionomer: ti,ab.kw) AND sealant *)

The searches identified six relevant additional systematic reviews[41-46-], of which one was an update of a Cochrane systematic reviews that was included in a source guideline, and one was a review with both systematic and narrative elements. The six additional reviews are listed in Table 7. Reference lists of identified systematic reviews were searched but no additional relevant systematic reviews were identified.

Table 7: Systematic reviews published subsequent to the three source guidelines

Authors and year of publication	Title	Reference	Search period:
Azarpazhooh and Main, 2008a[41]	Pit and fissure sealants in the prevention of dental caries in children and adolescents: a systematic review	Journal of the Canadian Dental Association 2008;74(2):171-177	2000 - 2007
Azarpazhooh and Main, 2008b[42]	Is there a risk of harm or toxicity in the placement of pit and fissure sealant materials? A systematic review	Journal of the Canadian Dental Association 2008;74(2):179-183	To March 2007
Bader & Shugars, 2006[43]	The evidence supporting alternative management strategies for early occlusal caries and suspected occlusal dentinal caries	*The Journal of Evidence-based Dental Practice* 2006;6(1):91-100	Not reported (This review is a summary of systematic reviews, with a search of Medline for evidence where reviews are not available. The strength of evidence is graded, but the criteria used are not described.

Hiiri et al. 2010[44]	Pit and fissure sealants versus fluoride varnishes for preventing dental decay in children and adolescents (update of 2006 review)	Cochrane Database of Systematic Reviews 2010(3):CD003067	To Nov 2009
Yengopal et al., 2009[45]	Caries-preventive effect of glass ionomer and resin-based fissure sealants on permanent teeth: a meta analysis	Journal of Oral Science 2009;51(3):373-382	To 15th Jan 2008
Yengopal & Mickenautsch, 2010[46]	Resin-modified glass-ionomer cements versus resin-based materials as fissure sealants: a meta-analysis of clinical trials	European Archives of Paediatric Dentistry 2010;11(1):18-25	To 15th April 2009

2.4.2 Search for clinical trials

The PubMed search detailed above was filtered by RCT in clinical queries and limited to 2004-February 2010 to identify randomised or quasi-randomised trials relevant to the key questions published since the three source guidelines. Embase and the Cochrane Library were also searched from 2004-February 2010 using the search strategies detailed above. For questions relating to the effectiveness of pit and fissure sealants, parallel and split mouth trials were included only if the allocation of the test and control group (or teeth) to the intervention was randomised or quasi-randomised. In vitro studies were excluded. Reference lists of relevant systematic reviews were searched but no additional relevant clinical trials were identified. The searches identified 19 clinical trials, relevant to the key questions, published since the three source guidelines and which were not already included in the updated Cochrane systematic review[28] of the effectiveness of pit and fissure sealants for preventing decay (Table 8).

Table 8: Clinical trials published since the source guidelines

Author	Included	Excluded	Reason for exclusion
Amin et al., 2008[47]	√		
Barja-Fidalgo et al., 2009[48]	√		
Burbridge et al., 2007[49]	√		
Corona et al., 2005[50]	√		
Fuks et al., 2007[51]	√		
Heifetz et al., 2007[52]		√	Not randomised
Hoszek et al., 2005[53]		√	One glass ionomer vs. another glass ionomer
Kamala & Hegde, 2008[54]		√	Split mouth design not appropriate due to potential carry over effect
Kargul et al., 2009[55]	√		
Kim et al., 2008[56]		√	Longitudinal (no comparison group)
Lygidakis et al., 2009[57]	√		
Oba et al., 2009[58]	√		
Oliveira et al., 2008[59]		√	Not randomised
Peng et al.,2006[60]		√	In Chinese
Skrinjaric et al., 2008[61]		√	Not randomised
Subramaniam et al., 2008[62]		√	Not randomised
Vierira et al., 2006[63]		√	One glass ionomer vs. another glass ionomer
Yazici et al., 2009[64]	√		
Yildiz et al., 2004[65]		√	Not randomised

2.4.3 Search for evidence relating to caries detection

To address the background questions relating to caries detection, a mixture of systematic and non-systematic methods were used. A simple search for systematic reviews on the accuracy of different

caries detection methods was undertaken in PubMed, filtered by Clinical Queries for systematic reviews, and limited to 2000 - February 2010. The search terms used were:

Dental Caries"[MeSH]) OR (("Dental Caries Activity Tests"[MeSH]) OR ("caries diagnosis") OR (diagnosis AND caries)) AND (("Predictive Value of Tests"[MeSH]) OR ("Sensitivity and Specificity")

Eleven publications were identified, of which 6 were relevant.[30 31 66-69] In addition, text books and narrative reviews were also consulted.

2.4.4 Search for economic evaluations

A search was conducted in PubMed from 2004 to February 2010 to identify relevant articles on the economic aspects of fissure sealants, published since the HAS guideline (the only fissure sealant guideline that evaluated the literature on the economic aspects of fissure sealing). The Cochrane Library was also searched for economic evaluations. Of the 37 non-duplicate records retrieved, 5 potentially relevant articles [70-74] and one systematic review[41] were identified. The systematic review by Azarphazooh and Main[41], which searched from 2000 to 2007, yielded 2 studies[75 76] which fell outside the time range of our search and had not been identified by HAS. Another review, which had been undertaken by the US Task Force on Community Preventive Services,[15] and which included an economic evaluation of school-based sealant programmes, had not been included in the HAS guideline but was brought to the attention of the research team by an external reviewer. Following assessment of the full text articles, only 4[15,70,72,77] of the 8 studies addressed our key question, which related to the cost-effectiveness of a universal sealant strategy vs targeted sealing. One study[78] which was included in the HAS guideline was also pertinent.

PubMed search strategy for the identification of economic evaluations:

("Pit and Fissure Sealants" [MeSH]) OR ("fissure sealants") OR ("dental sealants") OR ("resin sealants") OR (fissure seal$) OR (dental seal$) OR (resin seal$) OR (("Glass Ionomer Cements" [MeSH] OR "Resin Cements" [MeSH] OR "glass ionomer" OR glassionomer) AND (sealant$))

AND

("economics" [MeSH]) OR ("cost allocation" [MeSH]) OR ("cost allocation") OR ("cost-allocation") OR ("cost benefit") OR ("cost-benefit") OR ("cost benefit analysis") OR ("cost effectiveness") OR ("cost saving") OR ("health care cost") OR ("cost utility analysis") OR ("QALY") OR ("economic evaluation") OR ("economic analysis")

2.4.5 Search for reports of adverse effects

A search was run in PubMed to identify reports of adverse effects associated with the use of pit and fissure sealants. The search was limited to 2007-February 2010 in order to identify reports published since the end of the literature search for the systematic review on the risk of harm or toxicity with the use of fissure sealants by Azarpazhooh and Main.[42] In vitro studies and animals studies were excluded. A 2008 report from the National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction[79] was considered relevant to the key questions was used as the major source of evidence by the Guideline Group.

PubMed search strategy for identification of reports of adverse effects

(“Pit and Fissure Sealants” [MeSH]) OR (“fissure sealants”) OR (“dental sealants”) OR (“resin sealants”) OR (fissure seal$) OR (dental seal$) OR (resin seal$) OR ((“Glass Ionomer Cements” [MeSH] OR “Resin Cements” [MeSH] OR “glass ionomer” OR glassionomer) AND (sealant$))

AND

((allergy) OR ("Hypersensitivity"[Mesh]) OR ("bisphenol-A") OR (acceptability) OR ("Patient Acceptance of Health Care"[Mesh]) OR ("adverse effect" OR "adverse reaction" OR "toxicity" OR "toxic") OR ("Stomatitis"[Mesh]) OR ("Nausea"[Mesh]) OR ("Vomiting"[Mesh]) OR (stomatitis OR nausea OR vomiting OR harm* OR bisphenol))

2.4.6 Search for polymerisation

None of the source guidelines included recommendations on the polymerisation of sealant materials. The Guideline Group considered that the topic of polymerisation was far broader than just sealant materials, and following the presentation of a narrative overview of light-curing units and the factors influencing polymerisation of composite materials, the Guideline Group agreed to focus recommendations on testing and maintaining light-curing units. Therefore a PubMed search using the search terms “light curing unit$”, “protocol$”, and “guideline$” was conducted to identify reports relevant to this key question. The search was limited to reports published within the last 10 years (2000-2010) because it was considered that reports older than this were likely to be outdated due to advancements in technology.

2.5. Adaptation phase: Decision and selection

Summaries of the evidence were presented to the Guideline Group at two meetings, and further discussions were held by conference call. For each of the guideline recommendations, the Guideline Group assessed the consistency between the evidence presented in the guideline, its interpretation and the recommendations, and also the effect of any new evidence on the recommendation. The group also considered the acceptability and the applicability of the recommendations taking into account the culture, organisation and availability of dental care services in Ireland.

The Guideline Group then used informal consensus to adapt or adopt recommendations, and to develop new recommendations, when necessary. Table 9 presents the recommendations from the 3 source guidelines, and indicates which recommendations were adopted, adapted, updated or rejected.

Table 9: Matrix of recommendations showing which recommendations from the three source guidelines were adapted or adopted in formulating recommendations for this guideline

	ADA, 2008	CDC (School-based), 2009	HAS, 2005
Patient assessment	***Not recommendations, but part of preamble in recommendations section.*** *Dentists are encouraged to employ caries risk assessment strategies to determine whether placement of pit and fissure sealants is indicated as a primary preventive measure. The risk of experiencing dental caries exists on a continuum and changes across time as risk factors change. Therefore, caries risk should be re-evaluated periodically.*	***Not recommendations, but part of text (summarised)*** *In school-based programs, clinicians also must consider risk at the level of the school and community. Local and state health departments commonly use the percentage of children participating in the free or reduced-cost federal meal program as a proxy for income to prioritize schools for sealant programs… Caries risk among children from low-income families is sufficiently high to justify sealing all eligible permanent molars and is the most cost effective prevention strategy…Thus, children participating in SBSPs usually receive sealants as a primary preventive measure without undergoing a routine assessment of their caries risk.*	Individual caries risk should be assessed during the first visit, particularly when there may be an indication for sealing of permanent molars. *Table of risk factors for caries provided, divided into individual and collective risk factors.* A single individual risk factor is sufficient to classify an individual in the at-risk category and to indicate fissure sealing.
ADAPTED RECOMMENDATION	Recommendation from an existing Irish Guideline[3] was used: Children and adolescents who are assessed as being at high caries risk should have resin-based fissure sealant applied and maintained in pits and fissures of permanent teeth *Similar recommendation for adults*	In the public dental service, a targeted population sealant programme should be considered for all individuals in specific high-caries risk groups, such as children attending special schools or designated disadvantaged schools	
Tooth surface Assessment	***Not recommendations, but part of text of full guideline (summarised).*** *–Visual examination after cleaning and drying the tooth is sufficient to detect early non-cavitated lesions in pits and fissures.* ***ADAPTED*** *–The use of explorers is not necessary for the detection of early lesions, and forceful use of a sharp explorer can damage tooth surfaces.* ***ADAPTED*** *–The clinician should use recent radiographs, if available, in the decision-making process, but should not obtain radiographs for the sole purpose of placing sealants.* ***ADAPTED*** *–Other diagnostic technologies should only be used as adjuncts to assist in caries diagnosis*	Differentiate cavitated and non-cavitated lesions. – Unaided visual assessment is appropriate – Dry teeth before assessment with cotton rolls, gauze or, when available, compressed air – An explorer may be used to gently confirm cavitations (that is, breaks in the continuity of the surface); do not use a sharp explorer under force. – Radiographs are unnecessary solely for sealant placement – Other diagnostic technologies are not required **ADAPTED**	Not covered specifically, but is incorporated into the caries risk assessment
ADAPTED RECOMMENDATION	– Teeth should be clean, dry and well illuminated for visual assessment – A probe should not be used to explore pits or fissures. *Forceful use of a probe can damage tooth surfaces* – Radiographs should not be taken for the sole purpose of placing sealants	– Other diagnostic technologies are not necessary for the sole purpose of placing sealants	

	ADA, 2008	CDC (School-based), 2009	HAS, 2005
Indications for sealant– Primary teeth	Sealants should be placed in pits and fissures of children's **primary teeth** when it is determined that the tooth, or the patient, is at risk of developing caries **ADAPTED**	Not covered	Not covered
ADAPTED RECOMMENDATION	Routine application of sealants on primary molar teeth is not recommended, but may be considered for selected^ high caries risk children		
Indications for sealant– Permanent teeth	Sealants should be placed in pits and fissures of children's and adolescents' permanent teeth when it is determined that the tooth, or the patient, is at risk of developing caries. **ADAPTED** Sealants should be placed in pits and fissures of adult's permanent teeth when it is determined that the tooth, or the patient, is at risk of developing caries **ADAPTED**	Seal sound and noncavitated pit and fissure surfaces of posterior teeth, with first and second permanent molars receiving highest priority. **ADAPTED**	Pits and fissures in the first and second permanent molars should be sealed as early as possible in patients aged <20 with high ICR (individual caries risk), to prevent the risk of occlusal caries **ADAPTED**
ADAPTED RECOMMENDATION	Children and adolescents who are assessed as being at high caries risk should have resin-based fissure sealant applied and maintained in pits and fissures of permanent teeth *Similar recommendation for adults*	In children and adolescents, priority should be given to sealing first and second permanent molar teeth	When indicated, sealants should be applied as soon as the permanent molars are sufficiently erupted to be isolated
Sealants for Caries management	Pit and fissure sealants should be placed on early (noncavitated) carious lesions, as defined in this document, in children, adolescents and young adults and adults to reduce the percentage of lesions that progress. (*In the guideline, the recommendation for adults is separate, as different level of evidence applies.)* **ADAPTED**	Seal sound and noncavitated pit and fissure surfaces of posterior teeth, with first and second permanent molars receiving highest priority. **Not recommendation but part of preamble:** *For students with cavitated carious lesions who are unlikely to receive treatment promptly, dental practitioners in sealant programs may use interim management strategies. Strategies could include placement of sealants for small cavitations with no visual signs of dentinal caries and atraumatic restorative procedures.*	If there is any suspicion of dentinal caries, open fissure to confirm or eliminate the diagnosis. Use a bur or air abrasion. Once fissures have been opened, restoration material must be used instead of sealant. If caries are limited to enamel, do not open fissures. **ADAPTED**
ADAPTED RECOMMENDATION	When indicated, sealant should be applied to pit and fissure surfaces that are sound or that have demineralisation that appears confined to enamel*		Not a recommendation, but explanatory note in algorithm: *A non-operative approach to the management of suspicious lesions is advocated. Provided they remain intact, sealants can slow or arrest the progression of suspicious lesions. Fluoride varnish can prevent caries, but specific evidence for its effect on suspicious lesions is lacking. Follow-up is essential for both approaches.*

^Fissure sealing of primary molar teeth may be considered as part of a comprehensive caries-preventive programme for children with medical or other conditions where the development of caries, or its treatment, could put the child's general health at risk

* The term "non-cavitated lesions" is not widely used by clinicians in Ireland, and while the Guideline Group approved of the definition of "early non-cavitated lesions" used in the ADA guideline, it was decided to change the terminology to "demineralisation that appears confined to enamel". Pits and fissures in fully erupted teeth that may display discoloration not due to extrinsic staining, developmental opacities or fluorosis. The discoloration may be confined to the size of a pit or fissure or may extend to the cusp inclines surrounding a pit or fissure. The tooth surface should have no evidence of a shadow indicating dentinal caries. If radiographs are available, they should be evaluated to determine that neither the occlusal nor proximal surfaces have signs of dentinal caries.[30] There should be no localised enamel breakdown due to caries.

	ADA, 2008	CDC (School-based), 2009	HAS, 2005
APPLICATION TECHNIQUE			
Material choice	Resin-based sealants are the first choice of material for dental sealants. **ADOPTED**	Not specified, but use of resin-based sealant can be assumed based on the nature of the studies included in systematic reviews conducted for the CDC guideline	If isolation is satisfactory, use a resin-based sealant.
Personnel	When possible a four-handed technique should be used for placement of resin-based sealants When possible a four-handed technique should be used for placement of glass ionomer cement sealants **ADAPTED**	Use a 4-handed technique, when resources allow.	Not covered
ADAPTED RECOMMENDATION	When possible a four-handed technique should be used for placement of pit and fissure sealants		
Placement technique–cleaning	Routine mechanical preparation of enamel before acid etching is not recommended **ADAPTED**	Clean the tooth surface. Toothbrush prophylaxis is acceptable. Additional surface preparation methods, such as air abrasion or enameloplasty are not recommended	Clean the teeth using a dry brush (without pumice powder or prophylaxis paste) on a slow rotary instrument or air polishing. If a dry brush is used, the teeth may be cleaned before isolation. **ADAPTED** (from the French guideline: The best method of cleaning cannot be defined from the literature. Based on professional agreement, mechanical cleaning performed dry, and air polishing are suggested because they do not leave debris that can impair bonding of the resin.
ADAPTED RECOMMENDATION	Mechanical preparation of enamel before placing a fissure sealant is not recommended		Clean the tooth with a dry bristle brush in a slow handpiece or with a dry toothbrush Use of prophylaxis paste or pumice is not required
Isolation	*Not a recommendation: Maintain a dry isolated field during placement*	Not covered	Isolate the tooth to be sealed ideally with a dental dam or use cotton wool rolls combined with suitable aspiration **ADAPTED**
ADAPTED RECOMMENDATION			Isolate the tooth to be sealed with either a dental dam or cotton wool rolls/isolation shields combined with effective aspiration

	ADA, 2008	CDC (School-based), 2009	HAS, 2005
Etching	Use of available self-etching bonding agents, which do not involve a separate etching step, may provide less retention than the standard acid-etching technique and is not recommended. **ADAPTED**	Not covered	Not covered
ADAPTED RECOMMENDATION	**NEW** Condition the enamel by etching with 35–37% phosphoric acid then wash and dry carefully to obtain a chalky white enamel surface Manufacturer's instructions should be consulted for recommended etch and rinse times **ADAPTED** Use of no-rinse, self-etching bonding agents instead of acid etching prior to sealant application is not recommended *No-rinse, self-etching bonding agents may provide less retention than the acid-etching technique*		
Inadequate isolation	GIC may be used as an interim preventive agent when there are indications for placement of a resin-based sealant but concerns about moisture control may compromise such placement **ADAPTED** A compatible one-bottle bonding agent, which contains both an adhesive and a primer may be used between the previously acid-etched enamel surface and the sealant material when, in the opinion of the dental professional, the bonding agent would enhance sealant retention in the clinical situation. **UPDATED**	Not covered	If isolation is not ideal, choose one of the following options: – Glass ionomer sealant – Fluoride varnish (effective, but not as effective as sealant) **ADAPTED** – Postpone sealing and insist on other preventive measures **Not recommendation but included in French version of guideline**: *"The available literature does not demonstrate that the use of an adhesive system improves resin-based sealant retention."* **UPDATED**
ADAPTED RECOMMENDATION	**NEW** Where resin-based sealant is indicated and moisture control is difficult to achieve but patient co-operation allows, resin-based sealant should be attempted and reviewed within 6 months **ADAPTED** Glass ionomer cement may be considered on a case by case basis as an interim preventive measure when there are indications for placement of a resin-based sealant but concerns about moisture control may compromise such placement **UPDATED** Clinical evidence on the use of bonding agent following acid-etching to enhance sealant retention is inconclusive and no recommendation on its use can be made at this time.	Not covered	**ADAPTED** Where resin-based sealant is indicated but adequate moisture control cannot be achieved, fluoride varnish containing at least 22,600 ppm F should be applied to pits and fissures at intervals of 3–6 months until isolation can be achieved

	ADA, 2008	CDC (School-based), 2009	HAS, 2005
Polymerisation	Not covered	Not covered	Not covered
NEW RECOMMENDATIONs	Position the light-curing tip as close as possible to the surface being sealed and cure for at least the recommended curing time If more than one surface on a tooth is being sealed, e.g. occlusal and buccal/palatal, cure each surface separately Protocols for testing the light output and curing performance of light curing units should be implemented in accordance with the manufacturer's instructions Manufacturer's instructions for sealant materials and for curing lights should be available in all dental surgeries		
Monitoring	The oral health care professional should monitor and reapply sealants as needed to maximise effectiveness **ADAPTED**	Seal teeth of children, even if follow-up cannot be ensured. Evaluate sealant retention within one year **ADAPTED**	Fissure sealing should be part of overall prevention. Check-up should occur at regular intervals which depend on initial caries risk. – If initial caries risk is high, the patient should be seen 3–6 months later. – If initial caries risk is low, the patient should be seen once a year However, check-up frequency will change with changes in caries risk During checkups, reassess caries risk and check sealant: - if sealant has been partially lost, repair to prevent plaque retention - if sealant has been totally lost, repeat sealing process depending on caries risk. **ADAPTED**
ADAPTED RECOMMENDATION	Sealants should be checked when the patient is recalled, and repaired or replaced if necessary. The recall interval for high caries risk children should not exceed 12 months*		

* based on Irish guideline recommendation[3]

2.6. Review and finalisation of the adapted guideline

A draft guideline was circulated to the Guideline Group for comment, and was revised before circulation to the wider stakeholder group and external reviewers. The developers of the source guidelines were contacted and reviewers from the American Dental Association (ADA) and the Centers for Disease Control and Prevention (CDC) commented on the adapted guideline. A list of external reviewers can be found in Appendix 1.

The key stakeholder groups who were not represented on the Guideline Group were invited to contribute comments on the consultation draft of this guideline. The consultation draft of the guideline was also reviewed by 6 external reviewers (Appendix 1). Following revision of the guideline to incorporate feedback from stakeholders and external reviewers, the Guideline Group held their final meeting in August 2010 to sign-off on the final content of the guideline.

3. Funding

The development of this guideline was funded through a Strategic Health Research and Development Research Award from the Health Research Board (HRB) (S/A013). The content of this guideline was not influenced by the funding body.

Updating the guideline

The guideline will be updated in 2012.

Appendix 1: Project personnel, Guideline Group members and external reviewers

Guideline Project Team

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Appendix 2: Guideline Scope

1. Guideline title

Pit and Fissure sealants – evidence-based guidance on the use of sealants for the prevention and management of pit and fissure caries

1.1 Short title

Fissure sealants

1.2 This document is the scope. It defines exactly what this guideline will (and will not) examine, and what the guideline developers will consider.

2. Background

a) The Guideline Development Project is a collaboration between the Public Dental Service, the Oral Health Services Research Centre and the UK Cochrane Centre and is funded by the Health Research Board. The guideline development process will follow the standards for quality clinical practice guidelines as specified by the AGREE Collaboration and described in the AGREE* Instrument. The guideline will provide recommendations for good practice that are based on the best available evidence of clinical and cost effectiveness.

b) The selection of the topic for this guideline was influenced by the results of the *North South Survey of Children's Oral Health in Ireland, 2002*[80] and by the *Lot 3 Final Report–Fissure sealants and targeted approach to service delivery*.[81] These reports were commissioned by the Department of Health and Children as part of the Contracts for epidemiology, Oral Health Services research and specified consultancy services for Dental Services.

c) This guideline will be developed in accordance with the priorities of the National Health Strategy *Quality and Fairness.*[82] The need to provide better health for all, fair access, responsive and appropriate care delivery and high-performance, evidence-based health care will be considered during the guideline development process. The clinical guidelines developed during this Guideline Development Project are intended to support the role of healthcare professionals in the effective use of fissure sealants for caries prevention, in partnership with patients, taking account of their individual needs and preferences, and ensuring that patients (and their parents and carers) can make informed decisions about their care and treatment.

3. Clinical need for the guideline

a) The pit and fissure surfaces of molar teeth are the most susceptible tooth surfaces to decay and account for most of the decay experience in permanent teeth of children and adolescents. Fissure sealants are materials that are applied in a thin layer into the pits and fissures of back teeth to create an impervious barrier between the tooth surface and the oral environment, thereby preventing decay. A Cochrane systematic review of 16 trials found that fissure sealants reduced caries on occlusal (chewing) surfaces of first permanent molars by 78% after 2 years and 60% after 4 years compared to unsealed teeth[28].

b) The incorporation of fissure sealants as part of the school dental service has been strongly advocated in a number of reports.[83-86] Fissure sealant application has consequently become the key caries-preventive strategy of the school dental service, accounting for the greatest input of staff and resources. The prevalence of fissure sealants in 8-,12- and 15-year-olds is

higher in the Republic of Ireland compared to Northern Ireland (47%, 70% and 69% vs 33%, 55% and 57% for each age group respectively)[80], which reflects the strong focus placed on fissure sealants in the public dental service.

c) Yet, in spite of actively targeting the most vulnerable teeth, particularly the first permanent molar, approximately 54% of all 12-year-olds and 72% of 15-year-olds have experienced decay on pit and fissure surfaces[87]. Among those with decay, pit and fissure caries accounts for over 80% of caries experience in 8-year-olds, and over 75% of caries experience in 12-year-olds.[80] An evaluation of the fissure sealant programme in Meath found that approximately 2 years after sealant placement, 56% of sealants on first permanent molars were completely retained, 27% were partly retained and 13% were missing.[88] Although these figures compared favourably with similar international studies, there is clearly room for improvement in sealant retention rates within the public dental service.

d) A report on fissure sealants and the targeting of dental services concluded that the current system of targeting specific classes was not in line with evidence.[81] Mulcahy[89] found that policies on sealant use varied between dental areas, and both Mulcahy and a situation analysis conducted for this guideline project found that only 13% of dental areas used formal or evidence-based guidelines on sealant use. The development of evidence-based clinical practice guidelines on the use of fissure sealants should improve the effectiveness and efficiency of existing sealant programmes.

4. The guideline

a) The guideline development process will follow international best practice, as specified by the AGREE Collaboration, details of which are available at www.agreecollaboration.org.

b) The areas that will be addressed by the guideline are described in the following sections.

4.1 Population

4.1.1 Groups that will be covered

Children, adolescents and dentate adults, including those with special care needs.

4.1.2 Groups that will not be covered

Edentulous adults

4.2 Healthcare setting

Dental practice (public or private) in the Republic of Ireland

4.3 Clinical management

4.3.1 What the guideline will cover:

a) Methods for detecting occlusal caries

b) Indications for use of fissure sealant (type of patient, type of dentition, type of tooth)

c) Effectiveness of different types of sealant: (resin-based sealants and glass ionomer cement) at preventing caries on pit and fissure surfaces – measured in terms of caries prevention or sealant retention.

d) Application technique, including:

- tooth cleaning prior to application
- isolation,
- preparation of enamel, including the use of bonding agent
- rinsing and drying the tooth
- application of sealant
- polymerisation

- evaluating sealant retention
- four-handed versus two-handed application technique

e) Use of fissure sealant for the management of occlusal caries

f) Follow-up and review of fissure sealants

g) Side-effects or adverse reactions associated with fissure sealant use

h) Cost-effectiveness of different sealant strategies e.g. high risk v seal all

i) Cost-effectiveness of sealants applied by different dental health care professionals

4.3.2 What the guideline will not cover:

a) Any other caries preventive measure.

b) Use of pit and fissure sealants on smooth surfaces

c) Preventive resin restorations (PRRs)/sealant restorations (restorations using an adhesive restorative material which involves the use of sealant as part of the restoration)

4.4 Audit support within guideline

The guideline will include key review criteria for audit, which will enable objective measurements to be made of the extent and nature of local implementation of this guidance, particularly its impact upon practice

4.5 Status

This is the final scope.

4.5.1 Guideline development

The guideline development process will begin in 2009 and will be completed by Sept 2010.

5. Further information

Information on the standards for guideline development is available on the AGREE Collaboration website: www.agreecollaboration.org. The structure and format adopted for this scope is based on the scope documents used by the National Institute for Health and Clinical Excellence (NICE). Further information on the guideline development process is available on the website of the National Institute for Health and Clinical Excellence (NICE): www.nice.org.uk/guidelinesprocess.

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