

SDCEP Phase-down of Dental Amalgam Use

Implementation Advice for Article 10(2) of the Regulation (EU) 2017/852 on Mercury

Consultation Feedback Form

Consultation is the opportunity for anyone with an interest in this implementation advice to provide feedback and influence its development. We welcome your views on the draft document as part of the formal consultation process.

Please return your form by **15 April 2018*** to:

Email: scottishdental.cep@nes.scot.nhs.uk

Tel: 01382 425751

*Feedback received after this date
may not be considered.

Freepost

Licence RSSH-ETXY-ZKBL

SDPBRN (Amalgam Phase-down Consultation)

Dundee Dental Education Centre,

Frankland Building

Small's Wynd,

Dundee, DD1 4HN

A collation of feedback received, with our responses, will be available on request. This may include the names of organisations who have provided feedback.

About you

Providing the information requested below allows us to understand respondents' interests in the topic.

Professional role:	
Sector, e.g. GDS, PDS/CDS, hospital: General Dental Practice	
Country: UK	
Responding: On behalf of an organisation	If an organisation, please give full name: Faculty of General Dental Practice (UK)
Specific interest/role in topic: Representative membership organisation for general practice dentists and general dental teams across the UK.	

Important Note:

Please ensure that feedback is relevant to the scope of the implementation advice, which is to facilitate compliance with Article 10(2) of the Regulation (EU) 2017/852 on Mercury. These restrictions in dental amalgam use are a predefined legal requirement in the UK, arising from global environmental concerns. The appropriateness of these restrictions, the patient groups specified and remuneration reforms are beyond the scope of the advice and therefore, we are not able to consider feedback on these issues.

1. Advice for Phase-down of Dental Amalgam Use

Please indicate the extent to which you agree with the following statements on the five-point scale. A brief comment (255 characters maximum) can also be included if required (see Important Note above).

Please note that 'adequately covers/describes' means that sufficient information is provided and the information is relevant and helpful.

Section 1 adequately covers the background to the implementation advice	Strongly disagree	1	2	3	4	5	Strongly agree
					x		
Comments:							
Section 2 adequately covers the approaches to phasing-down dental amalgam use	Strongly disagree	1	2	3	4	5	Strongly agree
				x			
<p>Comments:</p> <p>Section 2.1, page 5: lines 26-29 outline the factors contributing to the reduction in the use of dental amalgam seen to date. It could also be noted here that dental amalgam is becoming a less cost-effective option for patients and practitioners as the availability of mercury reduces and manufacturing costs rise.</p> <p>Section 2.1, page 6, lines 28-31, and elsewhere throughout the document (except for the Patient Information Leaflets): 'secondary teeth' would be a more appropriate term than 'permanent teeth' (they do not last forever), particularly when 'primary' is SDCEP's preferred term rather than 'deciduous'.</p> <p>Section 2.1, page 6, lines 36-37: new glass ionomer materials have wear resistance properties similar to resin composite and amalgam. (<i>Systematic review on highly viscous glass-ionomer cement/resin coating restorations (Part I): Do they merge Minamata Convention and minimum intervention dentistry? Andrej M. Kielbassa, Prof Dr med dent Dr h c/Georg Glockner, Dr med dent/Michael Wolgin, Dr med dent/Karl Glockner, Prof Dr med univ and med dent. Quintessence International 2016; 47(10):813-823.</i>) (<i>Clinical performance of a glass ionomer restorative system: a 6-year evaluation. Gurgan S., Kutuk ZB, Ergin E., Oztas SS, Cakir FY. Clin Oral Invest. 2017; 21(7): 2335-2343.</i>)</p>							
Section 3 adequately covers the advice for dental practitioners on the management of patients according to Article 10(2) of the Regulation (EU) 2017/852 on Mercury	Strongly disagree	1	2	3	4	5	Strongly agree
			x				

Comments:

Section 3, page 9, lines 6-7, offers the advice: “fluoride varnish and sealants are also recommended as preventive measures for children and young people”. As previously expressed, FGDP(UK) has concerns about the recommendation to apply sealants, which in the absence of any qualifier would appear to imply application to *all* children and young people, including both pre-molars and permanent molars.

In going beyond the recommendations of the UK Department of Health’s *Delivering Better Oral Health* (DBOH) - which only recommends fissure sealants for permanent molars in children aged seven and up, and only then for children whose teeth ‘give concern’ to the dentist – SDCEP is risking serious confusion among the profession as to appropriate practice on what is an everyday matter, with potential dento-legal implications for practitioners. It also risks undermining the widespread acceptance of the suitability of the recommendations in DBOH, which have been a positive development for both practitioners and patients. We are not convinced that default application of fissure sealants is a necessary intervention for low caries-risk children, and given SDCEP’s previous statement that the evidence for this recommendation is weak, would recommend its removal from this document.

Section 3, page 9, lines 21-23 suggest that an exception may be justified “when it is not possible to obtain adequate moisture control or patient cooperation and an alternative to dental amalgam cannot be used even as a medium-term restoration.” However Article 10(2) states that exceptions can only be made when “deemed strictly necessary...based on the specific medical needs of the patient” (page 8, lines 4-6). Inability to obtain adequate moisture control or patient cooperation are not specific medical needs of the patient, so it would not appear that this suggested exception would comply with the regulation.

Sections 3, page 9, line 29 states “When treating pregnant or breastfeeding patients, avoid using dental amalgam”. This would seem to be a simple re-statement of the regulation, though as such it could perhaps be more decisively worded. However it is within a section titled ‘advice points’, yet as advice, it fails to provide the practitioner with a recommended alternative to amalgam. The *Summary of Evidence and Information* does little to help, discussing concerns over the BPA present in some alternative restorative materials (page 10, lines 29-34), and citing on page 11, lines 2-5, that “as for dental amalgam, SCENIHR recommend that use of the alternative materials is discouraged in pregnant women. It should also be noted that some of the components found in alternative dental materials are associated with local allergic reactions, although the incidence of this is not clear”.

As practitioners become aware of the new regulations and turn to what is labelled as Implementation Advice, it is not unreasonable to expect to find there a recommendation on preferred alternatives to amalgam for each of the patient groups who can no longer have amalgam restorations placed. The document is definitive as to the recommended alternative approaches for treating primary teeth and for treating secondary teeth in patients under 15 years old (page 9, lines 10-23). However it provides no answer for the practitioner seeking advice on alternative materials for pregnant and breastfeeding patients other than to postpone non-urgent treatment for those who are pregnant, and indeed the exposition of the evidence on pages 10-11 will only leave the practitioner with even greater uncertainty. We strongly urge the addition of recommendations on:

- (i) which alternative materials and approaches are suitable for breastfeeding patients; and
- (ii) which alternative materials and approaches are suitable for the urgent treatment of pregnant patients.

Section 4 adequately summarises the evidence and information	Strongly disagree	1	2	3	4	5	Strongly agree
					x		

Comments:

Section 4.3, page 12, lines 34-39: following caries prevention approaches, it would be appropriate to include mention of methods for reversing the early caries lesion, involving the use of ACP- or CPC-containing products to produce remineralisation. (*Contemporary technologies for remineralization therapies- a review. Walsh L.J. International Dentistry South Africa; 2009, 11(6), 6-15*)

2. Patient Information

Please indicate how useful you think the included patient information leaflets are. Where possible, please provide explanations to support your answers (e.g. comment on the level of detail; whether the information is adequate; if not useful, why not).

(a) Information for Patients who are Pregnant or Breastfeeding	Not at all useful	1	2	3	4	5	Extremely useful
				x			
(b) Information for Parents or Carers of Patients Under 15 Years Old	Not at all useful	1	2	3	4	5	Extremely useful
			x				

Comments (please indicate which of the patient information leaflets these relate to):

Information for Patients who are Pregnant or Breastfeeding – p19, lines 15-18: reproducing the wording of the new regulation verbatim could unfortunately lead to confusion, as the regulation could be phrased better. After “deciduous teeth”, (line 16), we would suggest adding “[for the treatment of primary or permanent teeth]”. This clarification is made to practitioners in the draft advice (p3, line 36) and would also be very helpful for patients, and by extension to general dental teams who may have to explain the new regulations to them.

Information for Parents or Carers of Patients Under 15 Years Old – p17, lines 14-17: as above, reproducing the wording of the new regulation verbatim could unfortunately lead to confusion, as the regulation could be phrased better. After “deciduous teeth”, (line 15), we would suggest adding “[for the treatment of primary or permanent teeth]”.

Overall, these leaflets fail to address sufficiently the inconsistency between the stated environmental motive and the apparent safety issue suggested by the discrimination between patient groups. While it is stated that dental amalgam is safe, no explanation is given as to why it is no longer to be used for certain groups while it will continue to be used for others, other than that it is now the law. It may help to state that the use of amalgam is being phased out over time, starting with children and pregnant and breastfeeding women, though even that would be unsatisfactory as it still begs the question “why these groups?”. Fundamentally, the application of the precautionary principle to some but not all patients suggests that there is more to it than the purely environmental motive, and patients will not be blind to this.

This is likely to lead to some patients, for whom an amalgam filling remains the most appropriate option, becoming understandably concerned that the material their dentist is recommending is apparently unsafe for children and foetuses. Yet they may be unable or unwilling to pay for a more expensive alternative material. Conversely, there is a risk of damaging dentist-patient trust as patients advised to receive a filling of an alternative material may be unable or unwilling to pay the higher cost, yet at the same time are being told that amalgam is safe and is still used on other patients. They may think that the dental practice is persuading them to choose a more expensive option in its own interests.

While the root cause may be in the regulations themselves, the patient information leaflets do not appear to anticipate, let alone attempt to mitigate, such issues.

3. Implementation

Please answer these questions assuming the consultation draft of this implementation advice is published (255 characters maximum).

What might be the barriers to following this implementation advice?

While the price of dental amalgam is rising over time, it remains cheaper than alternative materials. A document labelled ‘implementation advice’ ought to consider the implications of the higher costs of the alternatives – at the very least identifying potential issues around costs to patients and providers, and for NHS contracts around the UK, and making recommendations for further consideration by the appropriate parties - yet this is not addressed.

What might help with following this implementation advice?

Communications support from government and public authorities, both nationally and through provision of appropriate patient-facing material, would be helpful in addressing potential patient concerns and misunderstandings.

4. Overall Impressions

Please indicate the extent to which you agree with the following statement on the five-point scale. A brief comment (255 characters maximum) can also be included if required (please see Important Note).

The advice will facilitate implementation of Article 10(2) of the Regulation (EU) 2017/852 on Mercury	Strongly disagree	1	2	3	4	5	Strongly agree
				x			
Comments:							

5. Equality

This question refers to potential discrimination, including by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, sexual orientation, geographical location or whether a person is a carer.

Do you think that any particular groups or individuals (patients or practitioners defined by the protected characteristics above) are likely to be disadvantaged or discriminated against by the advice?	Yes	No	Unsure
Please provide more details:			

6. Any Other Comments

Please comment on any other aspects of this implementation advice here.

Important Note:

Please ensure that feedback is relevant to the scope of the implementation advice, which is to facilitate compliance with Article 10(2) of the Regulation (EU) 2017/852 on Mercury. These restrictions in dental amalgam use are a predefined legal requirement in the UK, arising from global environmental concerns. The appropriateness of these restrictions, the patient groups specified and remuneration reforms are beyond the scope of the advice and therefore, we are not able to consider feedback on these issues.

--

Thank you for taking the time to contribute to this consultation.