NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of TA92; HealOzone for the treatment of tooth decay (occlusal pit and fissure caries and root caries)

This guidance was issued in July 2005.

In October 2008, the decision was made to defer the review of TA92 until 2013, when the results of an ongoing trial (NCT00495495) were expected to be available.

1. Recommendation

TA92 should be withdrawn. That we consult on this proposal.

2. Original remit(s)

To appraise the clinical and cost effectiveness of the HealOzone procedure, in comparison to conventional treatment, for the treatment and management of occlusal pit caries, fissure caries and root caries, and to provide guidance to the NHS in England and Wales.

3. Current guidance

1.1 HealOzone is not recommended for the treatment of tooth decay (occlusal pit and fissure caries and root caries), except in well-designed randomised controlled trials.

4. Rationale[1]

The results of 1 randomised controlled trial have become available since the guidance was published. However, this study does not suggest that HealOzone is effective. The manufacturer's web site indicates that the product is no longer actively marketed.

5. Implications for other guidance producing programmes

There is no proposed or ongoing guidance development that overlaps with this review proposal.

6. New evidence

The search strategy from the original assessment report was re-run on the Cochrane Library, Medline, Medline In-Process and Embase. References from May 2008

[1] A list of the options for consideration, and the consequences of each option is provided in Appendix 1 at the end of this paper

onwards were reviewed. Additional searches of clinical trials registries and other sources were also carried out. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

7. Summary of evidence and implications for review

There have been no relevant published clinical trials that have assessed the efficacy of HealOzone since the last review.

The previous review proposal (July 2008) identified an ongoing phase II/III study (NCT00495495) evaluating the efficacy of HealOzone. The study completed in December 2009 and, although unpublished, the results are accessible at clinicaltrials.gov. The trial found no statistically significant difference between the HealOzone and Placebo devices in the primary outcome, the proportion of teeth with lesion progression after 1 year (p=0.11). Secondary outcomes included change in caries lesion activity (p=0.98), progression of radiographic scores at 12 months (p=0.0416) and laser fluorescence progression at 12 months (increase from <20 to >30, p=0.66; increase at least 10, p=0.77).

The new evidence is unlikely to lead to a change in the recommendations of the original Guidance.

8. Implementation

No relevant Implementation data were found.

9. Equality issues

There are no relevant equality issues.

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Appendix 1 – explanation of options

When considering whether to review one of its Technology Appraisals NICE must select one of the options in the table below:

Options	**Consequence**	**Selected – 'Yes/No'**
A review of the guidance should be planned into the appraisal work programme.	A review of the appraisal will be planned into the NICE's work programme.	No
The decision to review the guidance should be deferred to [specify date or trial].	NICE will reconsider whether a review is necessary at the specified date.	No
A review of the guidance should be combined with a review of a related technology appraisal.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the specified related technology.	No
A review of the guidance should be combined with a new technology appraisal that has recently been referred to NICE.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the newly referred technology.	No
The guidance should be incorporated into an on-going clinical guideline.	The on-going guideline will include the recommendations of the technology appraisal. The technology appraisal will remain extant alongside the guideline. Normally it will also be recommended that the technology appraisal guidance is moved to the static list until such time as the clinical guideline is considered for review. This option has the effect of preserving the funding direction associated with a positive recommendation in a NICE technology appraisal.	No
The guidance should be updated in an on-going clinical guideline.	Responsibility for the updating the technology appraisal passes to the NICE Clinical Guidelines programme. Once the guideline is published the technology appraisal will be withdrawn. Note that this option does not preserve the funding direction associated with a positive recommendation in a NICE Technology Appraisal. However, if the recommendations are unchanged from the technology appraisal, the technology appraisal can be left in place (effectively the same as incorporation).	No

Options	Consequence	Selected – 'Yes/No'
The guidance should be transferred to the 'static guidance list'.	The guidance will remain in place, in its current form, unless NICE becomes aware of substantive information which would make it reconsider. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	No

NICE would typically consider updating a technology appraisal in an ongoing guideline if the following criteria were met:

i. The technology falls within the scope of a clinical guideline (or public health guidance)

ii. There is no proposed change to an existing Patient Access Scheme or Flexible Pricing arrangement for the technology, or no new proposal(s) for such a scheme or arrangement

iii. There is no new evidence that is likely to lead to a significant change in the clinical and cost effectiveness of a treatment

iv. The treatment is well established and embedded in the NHS. Evidence that a treatment is not well established or embedded may include;

- Spending on a treatment for the indication which was the subject of the appraisal continues to rise
- There is evidence of unjustified variation across the country in access to a treatment
- There is plausible and verifiable information to suggest that the availability of the treatment is likely to suffer if the funding direction were removed
- The treatment is excluded from the Payment by Results tariff

v. Stakeholder opinion, expressed in response to review consultation, is broadly supportive of the proposal.

Appendix 2 – supporting information

Relevant Institute work

Published

Clinical Guideline CG 19 Dental recall - Recall interval between routine dental examinations. Issued October 2004. Review decision August 2012: not to update at this time.

In progress

Public Health guidance 'Promoting oral health – the patient experience'. In progress, publication date TBC. *When checked 16 Dec 13 there was no remit or scope on the website to establish if there is any relevance to TA92*.

Details of changes to the indications of the technology

Indication considered in original appraisal	Proposed indication (for this appraisal)
HealOzone is a medical device that is manufactured by KaVo and CE marked for the treatment of pit and fissure caries and root caries.	No information was found to suggest there has been any change in the indication for this device.

Registered and unpublished trials

Trial name and registration number	Details
A Multi-Center Study to Evaluate the Safety and Efficacy of the Use of Ozone for the Management of Fissure Caries. NCT00495495 *In October 2008 the review decision was to defer a decision until 2013 'pending publication of the results of the ongoing trial', which is this one.*	Phase II / III, completed. Estimated enrolment: 394 patients. Primary outcome: ICDAS Severity Value [Time Frame: Baseline and One Year] Study completion date: December 2009. Results are available on the trial record. No publication found. The responsible party principle investigator was contacted in March and April 2013, but no response was received.