

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

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.

Background

At the GE meeting of 11 February 2014 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	TA92 should be withdrawn.
Rationale for selecting this proposal	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.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	TA92 should be transferred to the 'static guidance list'.
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Respondent	Response to proposal	Details¹	Comment from Technology Appraisals
Public Health Wales	Disagree	Public Health Wales are not surprised that no evidence has emerged of effectiveness. There remains a concern that it is only a matter of time until someone else decides to market another vehicle for delivery of ozone into the mouth. Ideally therefore this guidance should be made static, this however is not what is proposed. Public Health Wales would suggest that it is important that any decision to withdraw the guidance should be accompanied by an explicit statement on the rationale for withdrawal, and that both the withdrawn guidance and the statement on the reasons for withdrawal should both remain available. For example "to date the treatment has no evidence for effectiveness and the reason for withdrawal of the guidance is in response to withdrawal of the product".	NICE acknowledges the lack of evidence for the effectiveness of the technology and the preference of Public Health Wales to transfer TA92 to the static list. NICE has reconsidered its proposal to withdraw TA92 and has decided to move this appraisal to the static list.

¹ Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Respondent	Response to proposal	Details ¹	Comment from Technology Appraisals
Faculty of General Dental Practice UK	Disagree	<p>The Faculty of General Dental Practice(UK) is of the opinion that the withdrawal of Nice Technology Appraisal Guidance No 92 could be interpreted as an indirect endorsement of the use of HealOzone.</p> <p>The FDGP(UK) believes that there is no compelling evidence for the efficacy of this technology, and no basis for NICE withdrawing this guidance.</p> <p>The NICE systematic review was independent from the Cochrane review, and we therefore have confidence that there is no evidence that HealOzone is effective at reducing or eliminating caries. Furthermore we would support the conclusions of the Cochrane review that further research is needed before any definitive statement can be made on the efficacy or otherwise of HealOzone.</p> <p>The FGDP(UK) believes that in the best interests of patients, NICE must continue to clearly state that there is no evidence to date that this technology works for the treatment of caries.</p> <p>The rationale for withdrawing NICE TA92 is that "...the manufacturer of HealOzone is no longer actively marketing the product. "</p>	<p>NICE notes that the website, www.HealOzone.de is currently selling the latest iteration of the HealOzone product (HealOzone X4) for delivery to the UK. It is also noted that the products are currently in use in UK dental practices and are being marketed to UK patients. NICE acknowledges the lack of evidence for the effectiveness of the technology and accepts there may be potential for patients and practitioners misinterpreting a withdrawal of TA92 as an endorsement. In light of the comments, NICE has reconsidered its proposal to withdraw TA92 and has decided to move this appraisal to the static list.</p>

Respondent	Response to proposal	Details ¹	Comment from Technology Appraisals
Faculty of General Dental Practice UK (continued)		<p>The FGDP(UK) would question NICE’s definition of “actively marketing”. While non-attendance at trade exhibitions, and a lack of paid adverts in UK dental media by the manufacturer may be taken to mean that HealOzone is not being marketed in the UK, www.healozone.de has an English language section to its website. This section can be found by clicking on a Union Jack, and you can purchase HealOzone for delivery to the UK. The Faculty considers these web pages to have been created and maintained, with the intention of facilitating sales to the UK market. Furthermore HealOzone and its latest iteration, HealOzone X4, are in use in UK dental practices and are being marketed to UK patients. The FGDP(UK) would therefore ask NICE to reconsider its definition of “actively marketing”.</p> <p>The technology remains indisputably ‘live’, and as there is no evidence to prove its efficacy the FGDP(UK) believes that if NICE withdraws TA92 patients and practitioners alike may misinterpret this as an endorsement.</p> <p>Therefore the FGDP(UK) would urge NICE to retain Technology Appraisal Guidance No 92.</p>	

No response received from:

<p><u>Manufacturers/sponsors</u></p> <ul style="list-style-type: none">• KaVo Dental UK (HealOzone) <p><u>Patient/carer groups</u></p> <ul style="list-style-type: none">• Action for Children• Action for Sick Children• Afiya Trust• Black Health Agency• British Dental Health Foundation• Children's Society• Equalities National Council• Muslim Council of Britain• Muslim Health Network• National Children's Bureau• National Parent Partnership Network• South Asian Health Foundation• Specialised Healthcare Alliance• WellChild <p><u>Professional groups</u></p> <ul style="list-style-type: none">• Association of Consultants and Specialists in Restorative Dentistry• British Association for Study of Community Dentistry• British Association of Dental Nurses• British Dental Association• British Fluoridation Society• British Geriatrics Society• British Homeopathic Dental Association	<p><u>General</u></p> <ul style="list-style-type: none">• Allied Health Professionals Federation• Association of British Healthcare Industries• Board of Community Health Councils in Wales• British Dental Trade Association• British National Formulary• Care Quality Commission• Commissioning Support Appraisals Service• Department of Health, Social Services and Public Safety for Northern Ireland• EUCOMED• Healthcare Improvement Scotland• Medicines and Healthcare Products Regulatory Agency• National Association of Primary Care• National Pharmacy Association• NHS Alliance• NHS Commercial Medicines Unit• NHS Confederation• Scottish Medicines Consortium <p><u>Comparator manufacturers</u></p> <ul style="list-style-type: none">• None <p><u>Relevant research groups</u></p> <ul style="list-style-type: none">• British Society for Dental Research• Centre for Evidence Based dentistry• Cochrane Oral Health Group• Health Research Authority
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<ul style="list-style-type: none"> • British Society for Disability and Oral Health • British Society for Oral Medicine • British Society of Dental Hygiene and Therapy • British Society of Paediatric Dentistry • British Society of Periodontology • National Oral Health Promotion Group • Royal College of General Practitioners • Royal College of Nursing • Royal College of Paediatrics and Child Health • Royal College of Pathologists • Royal College of Physicians • Royal Society of Medicine • United Kingdom Clinical Pharmacy Association <p><u>Others</u></p> <ul style="list-style-type: none"> • Department of Health • NHS East Surrey CCG • NHS England • NHS Vale Royal CCG • Welsh Government 	<ul style="list-style-type: none"> • MRC Clinical Trials Unit • National Institute for Health Research • Research Institute for the Care of Older People <p><u>Assessment Group</u></p> <ul style="list-style-type: none"> • Assessment Group tbc • National Institute for Health Research Health Technology Assessment Programme <p><u>Associated Guideline Groups</u></p> <ul style="list-style-type: none"> • National Collaborating Centre for Acute Care <p><u>Associated Public Health Groups</u></p> <ul style="list-style-type: none"> • Public Health England
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