

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Low-level laser therapy for preventing or treating oral mucositis caused by radiotherapy or chemotherapy

Oral mucositis is inflammation of the lining of the mouth that can cause pain, dryness, ulcers and difficulty with swallowing. It is a common and serious side effect of chemotherapy and radiotherapy. This procedure uses low-energy lasers, inside or outside the mouth, to treat the affected tissue. The aim is to reduce inflammation and stimulate the healing process.

The National Institute for Health and Care Excellence (NICE) is looking at low-level laser therapy for prevention or treatment of oral mucositis secondary to radiotherapy or chemotherapy. NICE's interventional procedures advisory committee has considered the evidence and the views of specialist advisers, who are consultants with knowledge of the procedure.

The committee has made draft recommendations and we now want to hear your views. The committee particularly welcomes:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

This is not our final guidance on this procedure. The recommendations may change after this consultation.

After consultation ends:

- The committee will meet again to consider the original evidence and its draft recommendations in the light of the consultation comments.
- The committee will prepare a second draft, which will be the basis for NICE's guidance on using the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#).

Through our guidance, we are committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in developing our interventional procedures guidance. In particular, we encourage people and organisations from groups who might not normally comment on our guidance to do so.

To help us promote equality through our guidance, please consider the following question:

Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that we reserve the right to summarise and edit comments received during consultations or not to publish them at all if in the reasonable opinion of NICE, there are a lot of comments, or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 15/02/2018

Target date for publication of guidance: May 2018

1 Draft recommendations

- 1.1 Current evidence on the safety of low-level laser therapy for oral mucositis shows no major safety concerns. Evidence on efficacy is adequate in quality and quantity. Therefore, this procedure can be used provided that standard arrangements are in place for clinical governance, consent and audit.

2 The condition, current treatments and procedure

The condition

- 2.1 Oral mucositis (OM) is a common side effect of chemotherapy or radiotherapy used for treating head and neck cancer or before bone marrow transplantation. Symptoms usually start 5 to 10 days after chemotherapy or 14 days after radiotherapy and include dryness, halitosis, pain, inflammation and oral mucosa ulceration. Chemotherapy-associated OM can resolve within a few days after completion of chemotherapy, but radiotherapy-associated OM can last for weeks. OM can affect nutritional status (which may need enteral or parental nutrition) and quality of life, and can increase hospital stay. It can also require interruptions or dose reductions in chemotherapy or radiotherapy treatment.

Current treatments

- 2.2 Comprehensive oral hygiene, good hydration, a bland soft diet and avoiding alcohol and tobacco may increase the person's comfort. Ice, water-based moisturisers, painkillers and non-steroidal anti-inflammatory drugs can help reduce symptoms. Drugs such as palifermin are sometimes used to prevent or treat OM. Antibiotics may be needed to treat infectious complications.

The procedure

- 2.3 Low-level laser therapy aims to treat or prevent OM by promoting healing, reducing inflammation and increasing cell metabolism. A hand-held probe is used to deliver light in the red or near-infrared spectrum to the oral mucosa. It can be delivered intra-orally or

extra-orally, or as a combination of both approaches. During intraoral treatment the probe, which is about the size of a dental curing light, is introduced into the mouth. For extraoral treatment the probe is positioned close to the cheek. The procedure typically takes 20 to 30 minutes, delivered 2 to 5 times a week for the duration of the oncology treatment. The procedure may be started before treatment with chemotherapy or radiotherapy begins, with the intention of preventing OM.

3 Committee considerations

The evidence

- 3.1 To inform the committee, NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 8 sources, which was discussed by the committee. The evidence included 2 systematic reviews and meta-analysis and 6 randomised controlled trials (RCTs) one of which also reported outcomes from a prospective case series. These are presented in table 2 of the [interventional procedures overview](#) **[add URL]**. Other relevant literature is in additional relevant papers in the overview.
- 3.2 The specialist advisers and the committee considered the key efficacy outcomes to be: reduction in oral mucositis, improved quality of life, reduction in pain and the need for analgesia, improved nutrition, reduction in dysphagia and the need for feeding tubes, and reduction in chemotherapy treatment breaks.

- 3.3 The committee identified the following as possible theoretical safety events: pain and tissue damage.

Committee comments

- 3.4 The procedure can be used in children, but most of the evidence reviewed by the committee was from adults.

- 3.5 Most of the evidence reviewed by the committee was for intraoral treatment, and related to prophylactic use of this procedure.

- 3.6 The greatest benefit from the procedure appears to be in patients having radiotherapy for head and neck cancers, or having chemotherapy for haematological malignancies.

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Chairman, interventional procedures advisory committee

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