

Consultation Report

Topic details

Title of Policy:	Hyperbaric Oxygen Therapy (HBOT) for Diabetic Lower Limb Ulceration (diabetic foot ulcer)
Programme of Care:	Trauma
Clinical Reference Group:	HBOT Clinical Advisory Group
URN:	1779

1. Summary

This report summarises the outcome of a public consultation that was undertaken to test the policy proposition.

2. Background

A diabetic foot ulcer is an open wound or sore on the skin that is slow to heal (NHS Choices, 2016). People with diabetes mellitus are at increased risk of foot ulceration. Usual treatment options include close monitoring of the ulcer, the use of antibiotic medicines, caring for the wound, and the removal of dead tissue (debriding).

Revascularisation (a treatment to help restore blood flow to the foot) can also be considered (National Institute for Health and Care Excellence 2015).

It has been suggested that treatment with Hyperbaric Oxygen Therapy (HBOT) can be a helpful addition to routine treatment in cases where the wounds have failed to heal.

Hyperbaric oxygen therapy (HBOT) involves the inhalation of pure oxygen at a pressure higher than normal atmospheric pressure, usually 2 to 3 atmospheres absolute (ATA). Treatment takes place in a pressure chamber, and when used for the treatment of diabetic foot ulcers, this usually lasts for 45 to 120 minutes a day for several weeks.

3. Publication of consultation

The policy was published and sign-posted on NHS England's website and was open to consultation feedback for a period of 30 days from 24 October 2018 to 23 November 2018. Comments were shared with the Policy Working Group (PWG) to ensure full

consideration was given to feedback and to support a decision as whether any changes to the service specification might be necessary.

Respondents to consultation were asked the following questions:

- Has all the relevant evidence been taken into account? If not, please provide details
- Does the impact assessment fairly reflect the likely activity, budget and service impact? If not, what is inaccurate?
- Does the policy proposition accurately describe the current patient pathway that patients experience? If not, what is different?
- Please provide any comments about the potential impact on equality and health inequalities which might arise as a result of the proposed changes that have been described
- Are there any changes or additions that need to be made to this document? If so, please describe.

4. Results of consultation

There were 24 responses to the public consultation in total.

- 17 from clinicians (3 of whom responded on behalf of their organisations, the remaining 14 responded as individuals);
- 5 from service providers (4 of whom responded on behalf of their organisation, the other responded as an individual);
- 1 from a patient;
- 1 from a medical journalist

Common themes in the responses related to:

- Concerns with the quality of the evidence review. In particular, the reference to one study being the most reliable. This claim and the quality of the study itself was strongly refuted by half of all respondents to this consultation, most notably by a clinician who identified themselves as having been a co-investigator on the study in question.
- Concerns about patient outcomes (including the number of amputations that might occur) as a result of this treatment not being routinely commissioned

5. How have consultation responses been considered?

Responses have been carefully considered and noted in line with the following categories:

- Level 1: Incorporated into draft document immediately to improve accuracy or clarity

- Level 2: Issue has already been considered by the CRG in its development and therefore draft document requires no further change
- Level 3: Could result in a more substantial change, requiring further consideration by the CRG in its work programme and as part of the next iteration of the document
- Level 4: Falls outside of the scope of the specification and NHS England's direct commissioning responsibility.

All of the issues raised fell into the category of level 2, in that no changes to the draft policy have been made as a result of consultation. However, because of the nature of the comments made in relation to one particular study cited in the evidence review, contact was made with the Journal in which the study was published in order to ascertain their response to the allegations made. The journal (Diabetes Care - journal of American Diabetes Association) confirmed that "neither the American Diabetes Association nor the editorial team of Diabetes Care has any plans to amend the publication status of this paper." On this basis, the Trauma PoC Board were satisfied that this policy and associated documents should progress to the Clinical Priorities Advisory Group (CPAG).

6. Has anything been changed in the policy as a result of the consultation?

There have been no changes made to the wording of the policy.

7. Are there any remaining concerns outstanding following the consultation that have not been resolved in the final policy proposition?

The PWG and the wider HBOT clinical community continue to voice concerns about the quality of the evidence review and, in particular, the references made to the Fedorko paper being 'the most reliable study' when so many comments refuting this have been received during the policy development process. However, it should be noted that the evidence review was completed by an independent company for and on behalf of NHS England in line with the policy development process and we believe that by approaching the journal for assurance about this particular study, that we have addressed the issues raised.