



# **Clinical Commissioning Policy Proposition: The Use of Hyperbaric Oxygen Therapy**

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Draft for public consultation

# Clinical Commissioning Policy Proposition: The Use of Hyperbaric Oxygen Therapy

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**Prepared by NHS England Specialised Services Clinical Reference Group for  
Hyperbaric Oxygen Therapy**

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## **Equality Statement**

NHS England has a duty to have regard to the need to reduce health inequalities in access to health services and health outcomes achieved as enshrined in the Health and Social Care Act 2012. NHS England is committed to fulfilling this duty as to equality of access and to avoiding unlawful discrimination on the grounds of age, gender, disability (including learning disability), gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender or sexual orientation. In carrying out its functions, NHS England will have due regard to the different needs of protected equality groups, in line with the Equality Act 2010. This document is compliant with the NHS Constitution and the Human Rights Act 1998. This applies to all activities for which NHS England is responsible, including policy development, review and implementation.

## **Plain Language Summary**

Hyperbaric oxygen therapy (HBOT) is delivered by giving a patient oxygen to breathe while in a pressurised chamber so that a higher level of oxygen can be dissolved in the patient's blood plasma. HBOT is used for an increasing number of medical conditions worldwide. For some of these conditions, however, the theoretical basis for HBOT is unclear and in the majority of cases, the scientific evidence of clinical and cost effectiveness is not established. In UK the use of HBOT is already restricted to those areas where the evidence is least controversial. The use of HBOT is supported by this policy for two medical emergencies: for decompression illness (arising from dissolved gases coming out of solution into bubbles inside the body, or from gas escaping through ruptured lungs into the blood vessels, on depressurization) and gas embolism (gas bubbles in the blood vessels due to causes other than decompression illness).

## 1. Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to routinely commission hyperbaric oxygen therapy for the treatment of two emergency indications, gas embolism and decompression illness.

For the purpose of consultation NHS England invites views on the evidence and other information that has been taken into account as described in this policy proposition.

In 2016 NHS England plans to seek a recommendation from the Clinical Priorities Advisory Group and to make a final decision as to whether hyperbaric oxygen therapy will be routinely commissioned for the treatment of gas embolism and decompression illness.

## 2. The proposed intervention and clinical indication

HBOT has been used for an increasing number of medical conditions since its first introduction for the treatment of decompression illness over 50 years ago. For some of these conditions the theoretical basis for HBOT is unclear and, in the majority of cases, the evidence of clinical and cost effectiveness is not established although consensus expert opinion supports further research in several areas where supportive evidence is accumulating. The use of HBOT is most widely accepted as the primary treatment for divers who are suffering from decompression illness. Iatrogenic gas embolism may also occur after various medical or surgical procedures. There are no other treatments specific to these disorders and HBOT is the definitive treatment. In most other indications, hyperbaric oxygen therapy has been used in addition to standard methods of treatment.

This revised policy recommends routine commissioning for two emergency indications, gas embolism and decompression illness.

## 3. Definitions

HBOT is the delivery of oxygen inhaled at a partial pressure greater than 100 kPa. This takes place within a treatment chamber which may accommodate one or more

patients and attendant staff.

#### 4. Aim and objectives

This policy seeks to ensure equity of access to this treatment in England. It builds upon the 2007 systematic review by NHS Quality Improvement Scotland<sup>1</sup> by taking into account more recent information such as Rapid Evidence Reviews which were required to answer the questions below regarding the following indications selected by the CRG:

Indication	Research question
Carbon Monoxide poisoning	<p>Is there evidence to support the use of HBOT in enhancing recovery from acute carbon monoxide (CO) poisoning (either speed or completeness) compared to conventional treatments with normobaric oxygen?</p> <p>Is there evidence to support the addition of HBOT into the management pathway for acute CO poisoning resulting in a more rapid or complete resolution of neurological sequelae?</p> <p>Is there evidence to describe the patient group who are likely to derive benefit and the intervention that should be used?</p> <p>Is there evidence for the cost effectiveness of HBOT in the management of CO poisoning?</p>
Soft tissue radiation damage	<p>Is HBOT clinically effective in patients with soft tissue radiation damage whose symptoms have proved refractory to other modalities of treatment?</p> <p>Is there evidence to suggest that previous or ongoing treatment with Bleomycin might be a contraindication for HBOT for soft tissue radiation damage?</p>

Malignant otitis externa	<p>Is the addition of HBOT to standard best treatment (antibiotic treatment and surgical debridement) clinically effective in patients with malignant otitis externa whose symptoms are refractory to treatment with antibiotics and debridement alone?</p> <p>Is there sufficient evidence to identify the patients who are most likely to benefit and the treatment regimes that will produce best outcomes for translation into service provision?</p>
Necrotising soft tissue infections	<p>Is HBOT clinically effective in adult patients with necrotising infection compared to conventional treatment with antibiotics and surgical debridement?</p> <p>Is HBOT cost effective in adult patients with necrotizing soft tissue infection compared to conventional treatment with antibiotics and surgical debridement?</p>

Three promising indications were not selected for evidence reviews:

Prevention and treatment of osteoradionecrosis are the subjects of multi-centre RCTs currently active in the UK, HOPON and DAHANCA-21, respectively.

Clinical guidelines for the management of diabetic lower limb ulceration were due to be reviewed by NICE at the time that evidence reviews were being prioritised and so the CRG was advised that a further evidence review on this topic would not add any value.

Using this approach, this policy proposition identifies those conditions which, based on the current evidence available, will be funded routinely.

## 5. Epidemiology and needs assessment

Spending time at raised environmental pressure (e.g. SCUBA diving, compressed

air work such as tunnelling) causes additional inert gas from air or other breathing mixtures to dissolve in the tissues. A return to a lower pressure is known as decompression. If decompression is sufficiently controlled, the excess gases can be excreted in exhaled breath by the lungs. If decompression occurs too quickly to allow excretion by the lungs, these gases can form bubbles (gas emboli) within the tissues, most often in venous blood. Decompression to sub-atmospheric pressures, such as during altitude training for aircrew or an ascent to altitude after diving, can also generate or exacerbate gas emboli. Disease caused by evolved gas in this manner is known as decompression sickness.

If lung tissue is ruptured by expansion of gas during decompression, gas can escape into the systemic arterial circulation via the pulmonary veins and the left heart and usually causes brain injury. This escaped gas is termed arterial gas embolism.

Gas embolism can also occur when bubbles of gas enter the circulation during medical procedures such as renal dialysis, mechanical ventilation (life support machines) or certain types of surgery.

Regardless of mechanism of injury, the gas emboli can cause clinical manifestations ranging from lethargy and pain to severe neurological impairment, multi-organ failure and death.

The term decompression illness encompasses decompression sickness and gas embolism. In a diver, it is often not possible to determine whether a patient has evolved gas disease, escaped gas disease or both.

The application of high environmental pressure forces gas emboli to dissolve once more, allows the gas to be excreted through the lungs and discourages formation of new emboli. Administration of oxygen at high partial pressure ensures more complete removal of inert gas from the tissues, reduces the likelihood of further bubbling and is associated with more complete and rapid resolution of the clinical manifestations of bubble-related injury.

Data supplied to NHS England by providers show that an average of 293 divers and 2 cases of gas embolism were treated with hyperbaric oxygen annually in FYs

2011/12 to 2013/14.

## 6. Evidence base

Based on the findings in QIS<sup>1</sup> and the results of a review of the published evidence for the indications cited below, NHS England has concluded that there is sufficient evidence to support a proposal for the routine commissioning of this treatment for the indications of decompression illness and gas embolism.

AND

NHS England has concluded that there is not sufficient evidence to support a proposal for the routine commissioning of the treatment for the indications listed:

- Carbon Monoxide poisoning
- Soft Tissue radiation injury
- Malignant otitis externa
- Diabetic foot ulcer
- Necrotising soft tissue infections.

### **Evidence Base**

#### *Decompression illness and gas embolism*

Following on from the seminal publication in 1965<sup>2</sup>, a Cochrane review<sup>3</sup> and two Health Technology reports<sup>4,5</sup> have considered the effectiveness and safety of HBOT for decompression illness. All concluded that recompression therapy is standard treatment for these indications despite the absence of RCT evidence.

#### *All other indications listed above*

In May 2015, the NHS England Evidence Summary from the Specialised Commissioning Public Health Network<sup>6</sup> reported that:

- there was a paucity of reliable or robust evidence of the effectiveness of HBOT for all of the indications for which research studies were identified.

- in many cases reported benefits were confounded by small study numbers, the heterogeneity of the treatment protocols for both the administration of HBOT and in the clinical management that preceded the use of HBOT.
- few studies included adequate long term follow up.

There are a number of randomised controlled trials in progress and yet to report. These examine the use of HBOT in carbon monoxide poisoning (comparing the benefit of 3 hyperbaric treatments vs just one), prevention of osteoradionecrosis and the treatment of osteoradionecrosis.

In the UK the following studies are in progress or recently completed:

- HOPON which is investigating HBO's effectiveness as prophylaxis against osteoradionecrosis<sup>7</sup> and is due to close to recruitment in 2018.
- HOT II investigated the effect of HBOT on radiation proctitis, has very recently been published and calls for more research in this area.<sup>8</sup>
- DAHANCA-21 which will investigate the effect of HBOT on established osteoradionecrosis. It is planned to extend this study into the UK and it is already on the UKCRN portfolio (ID 13565). Ethical approval has been received for UK hyperbaric units to act as participating sites.<sup>9</sup>

In the US:

- One study examines the comparative outcomes of one versus three HBOT treatments for patients with severe carbon monoxide poisoning.<sup>10</sup> This trial is planned to complete in May 2018.

The evidence of cost effectiveness is scarce. There are no UK based studies. Those that exist are derived from other health systems.

For a number of indications, there is no agreed standard management preceding HBOT or where it does exist, for example surgical debridement and antibiotic administration, the detail varies, as does the duration. Similarly, where treatment is thought to be appropriate for refractory cases, there is no agreed definition of 'failure to respond' in the standard management protocol.

Whilst the expert clinical opinion of the CRG disputes the interpretation of the data

presented in the literature reviews (reference 6 gives some details) almost all of the primary source studies, together with the systematic reviews, conclude by calling for further evaluation. For the indications reviewed for this report, reliable estimates of the magnitude of any effect of HBOT and the place of HBOT in the management of the condition under study remain to be established.

Overall, the published evidence base is unclear in terms of standard pre HBOT management, optimal HBOT schedules, predictable outcome and degree of enhancement over standard interventions to support a decision for routine commissioning. A number of indications begin to show a trend towards a role for HBOT but further robust evaluation is required in order that the results can be considered reliable and generalisable.

### **7. Proposed criteria for commissioning**

Based on the findings of the evidence reviews, a summary of which is provided at Reference 6, HBOT will be commissioned for indications where the evidence base is commensurate with that usually considered sufficient to ensure a good use of NHS resources. Consequently the use of HBOT is supported for the following indications:

- Decompression illness
- Gas embolism

HBOT will not be routinely commissioned for other indications unless further published evidence becomes available.

### **8. Proposed patient pathway**

The use of HBOT for decompression illness and gas embolism is a medical emergency. Patients are referred directly from:

HM Coast Guard

Duty Diving Medical Officer (Institute of Naval Medicine)

British Hyperbaric Association National Diving Accident Advice Line

Another hyperbaric unit

An ambulance service

An emergency department

A secondary care clinician

A general practitioner

A patient, or an individual acting on behalf of the patient, directly accessing a provider

The patient pathway is described in detail in the service specification which can be found at <https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2014/04/d11-hyper-oxy-thera-0414.pdf>.

### **9. Proposed governance arrangements**

The detailed governance is covered in the service specification. In summary, all facilities are required to:

- be a member of the British Hyperbaric Association (BHA).
- work in accordance with the BHA publication 'Health and Safety for Therapeutic Hyperbaric Facilities. A Code of Practice.'
- be registered with the Care Quality Commission as a hyperbaric chamber service.
- satisfy the requirements of a Category 1, 2 or 4 hyperbaric facility as defined by the Cox Report.
- operate under the clinical responsibility of a suitably qualified and experienced fully registered medical practitioner; the Medical Director, as defined by the Cox Report.
- have robust clinical governance systems in place and conduct a rolling programme of clinical audits.
- ensure that all decisions regarding HBOT will be undertaken by a Hyperbaric Physician who has specialist knowledge and experience of the use of HBOT. This medical practitioner will be responsible for HBOT until it stops or until the case is handed over to another hyperbaric physician with the requisite knowledge and experience.

- declare to the BHA whether they are registered with the Care Quality Commission to provide treatment to children.
- ensure that children treated at the unit have their care overseen by a paediatric consultant.

In addition, Cox Category 1 facilities will be required to:

- declare to BHA whether they can accommodate ventilated patients on a continuous basis limited only by capacity of the host hospital critical care unit or if the capability is intermittent and to what extent that capability is predictable.
- ensure that sedated, ventilated patients are overseen by trained anaesthetic / intensive care staff in or next to the chamber, as appropriate.
- have a written agreement with their provider of medical cover that they will receive every reasonable level of support required, including the provision of trained professionals to assist with appropriate interventions if patients develop complications during treatment.

## **10. Proposed mechanism for funding**

NHS England will continue to routinely commission HBOT for the treatment of decompression illness and gas embolism from existing providers.

HBOT centres will need to provide a 24/7 access to the service whilst conforming to the standards as set out in the service specification.

## **11. Proposed audit requirements**

As outlined in the service specification:

Patients will be treated by the service within the timescales agreed with the commissioning authority, recognising that, in some instances, 'time to treatment' may be prolonged due to factors entirely outside of a facility's control.

Patients will receive a discharge letter on completion of treatment, onward referral if required and educational information at discharge.

Providers will have sufficient capacity to accept patients at the level agreed with the

commissioning authority. Feedback from patient experience outcome measures will be sought at least annually and will be acted upon as appropriate

Whenever circumstances reasonably permit, patients will be fully informed about why they should receive HBOT and why it may be beneficial to them. This should include clear written information.

Mortality rates for each condition being treated shall not exceed the standardised mortality rates that would be expected if HBOT was not being administered.

Each provider will complete the quality dashboard with the required frequency and within the required timeframe. Any measure that is below the accepted standard will be addressed by the provider and all reasonable measures taken to rectify the shortcoming in future.

## **12. Documents which have informed this policy proposition**

All references.

The clinical and cost effectiveness of hyperbaric oxygen therapy; HTA Programme: Systematic Review. NHS Quality Improvement Scotland 2008.<sup>1</sup>

## **13. Date of review**

This document will lapse upon publication by NHS England of a clinical commissioning policy for the proposed intervention that confirms whether it is routinely or non-routinely commissioned

## **References**

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3 Bennett MH, Lehm JP, Mitchell SJ, Wasiak J. Recompression and adjunctive therapy for decompression illness. Cochrane Database of Systematic Reviews 2012, Issue 5. Art. No.: CD005277. DOI: 10.1002/14651858.CD005277.pub3..

4 Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé. Hyperbaric oxygen therapy in Québec. Montréal: AETMIS; 2001.

5 Mitton C, Hailey D. Hyperbaric oxygen treatment in Alberta - technology assessment report, 1998 [Online]. Available from:  
<http://www.ihe.ca/hta/htapublications/reports/hbot.1.html>

6 NHS England Evidence Summary: Hyperbaric Oxygen Therapy. First published: May 2015. Prepared by: Specialised Commissioning Public Health Network

7 Details of the HOPON trial are available at  
<http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=4550>

8 Details of HOT II available at  
[http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045\(15\)00461-1/abstract](http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(15)00461-1/abstract)

9 Details of DAHANCA-21 available at  
<http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=13565>

10 Details of the carbon monoxide trial available at  
<http://clinicaltrials.gov/ct2/show/NCT00465855?term=hyperbaric+oxygen&rank=2>

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