

**Clinical
Commissioning
Policy Proposition:
Hyperbaric Oxygen
Therapy for
Decompression
Illness/Gas Embolism**

Reference: NHS England



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

Published by NHS England, in electronic format only.

Draft for consultation

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Draft for consultation

1 Executive Summary

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Plain Language Summary

About decompression illness/gas embolism

- An air or gas embolism is a bubble that becomes trapped in a blood vessel and blocks it. This can lead to many different symptoms depending on where the blockage occurs. It's one of the leading causes of death among divers (NHS Choices, 2015).
- Air embolisms can also occur during surgery or other medical procedures, but this is rare (NHS Choices, 2015).

About current treatments

- If a diver develops an air embolism, the only effective treatment is immediate recompression treatment in a special pressurised room called a hyperbaric chamber.
- The diver should be given 100% oxygen and laid horizontally until they reach the hyperbaric chamber.
- Recompression treatment involves lying in a hyperbaric chamber, usually for several hours, and breathing a mixture of gases and oxygen under pressure. The high pressure can restore normal blood flow and oxygen delivery to the body's tissues and reduce the size of the air bubbles in the body.

- However, it is recognised that the evidence base supporting the use of HBOT in the treatment of decompression illness and gas embolus is not well developed and the rationale for treatment has been based on knowledge of the gas laws of physics, observational symptom resolution and the absence of a credible alternative. There is no relevant NICE guidance.

What we have decided

NHS England has carefully reviewed the evidence to treat decompression illness and gas embolisms with hyperbaric oxygen therapy. We have concluded that there is enough evidence to make the treatment available at this time.

2 Introduction

This document describes the evidence that has been considered by NHS England in formulating a proposal to routinely commission hyperbaric oxygen treatment for decompression illness and gas embolisms.

This document also describes the proposed criteria for commissioning, proposed governance arrangements and proposed funding mechanisms.

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.

3 Proposed Intervention and Clinical Indication

About decompression illness

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 Intervention:

The application of high environmental pressure (recompression) forces gas emboli to dissolve once more and discourages formation of new emboli. Slow, controlled decompression then allows the gas to be excreted safely through the lungs.

Administration of oxygen at a partial pressure significantly higher than 100 kilopascals (kPa) is known as hyperbaric oxygen therapy (HBOT). It takes place in a chamber. It was first introduced over 50 years ago for the treatment of decompression illness along with recompression as described, for example, by Goodman et al (1965).

There are a number of potential risks and side effects of HBOT. Most are often mild and reversible but some can be severe and life threatening (Leach, Rees & Wilmshurst, 1998). Overall, severe central nervous system symptoms occur in 1-2% of treated patients, symptomatic reversible barotrauma in 15-20%, pulmonary symptoms in 15-20%, and reversible optic symptoms in up to 20% of patients (Leach, Rees & Wilmshurst, 1998). Reversible myopia, due to oxygen toxicity on

the lens, is the commonest side effect and can last for weeks or months (Leach, Rees & Wilmshurst, 1998). Table 1 provides a summary of risks.

General	Claustrophobia, Reversible myopia, Fatigue, Headache, Vomiting
Oxygen Toxicity	Convulsions, Psychological, Lung, Pulmonary oedema haemorrhage, Pulmonary toxicity, Respiratory failure
Barotrauma	Ear damage, Sinus damage, Ruptured middle ear, Lung damage

4 Definitions

- **Crude mortality:** The crude death rate is the number of deaths occurring among the population of a given geographical area during a given year (usually expressed as per 1,000 persons of the mid-year total population of the given geographical area during the same year).
- **Iatrogenic:** relating to illness caused by medical examination or treatment.
- **Neurological sequelae:** neurological symptoms and signs that appear or reappear after a period of days to weeks
- **Prospective study:** A research study in which the health or other characteristic of patients is monitored (or 'followed up') for a period of time, with events recorded as they happen. This contrasts with retrospective studies.
- **Retrospective study:** A research study that focuses on the past and present. The study examines past exposure to suspected risk factors for the disease or condition. Unlike prospective studies, it does not cover events that occur after the study group is selected.
- **Randomised controlled trials:** a study in which a number of similar people are randomly assigned to 2 (or more) groups to test a specific drug, treatment or other intervention.

5 Aims and Objectives

This policy proposition considered the evidence underpinning the use of HBOT for

decompression illness and gas embolism.

This policy proposition aims to define NHS England's commissioning position on HBOT as part of the treatment pathway for adults undergoing treatment for decompression illness and gas embolism where this is the responsibility of NHS England specialised commissioning teams.

The objective is to ensure evidence based commissioning with the aim of improving outcomes for adults and improve access to the procedure as soon as possible after the onset of symptoms.

6 Epidemiology and Needs Assessment

Between 2011/12 and 2013/14, there was an average of 293 divers and 2 cases of gas embolism who were treated with hyperbaric oxygen per year (NHS England, 2015).

7 Evidence Base

Summary of Evidence

NHS England commissioned a review of the published evidence on the use of HBOT treatment for decompression illness and gas embolisms. To aid in the search for clinically relevant literature, experts in the field of HBOT guided the development of a PICO (Population, Intervention, Comparison, Outcome) framework. Key findings were:

This evidence review identified one randomised controlled trial (RCT) (in Bennett et al 2012) and five retrospective studies (Hadanny et al 2015, Lee et al 2015, Xu et al 2012, Sayer et al 2009, Koch et al 2008) of recompression with or without HBOT in patients with decompression illness (DCI) or decompression sickness (DCS), and one prospective study of HBOT in patients with iatrogenic gas embolus (IGE) (Bessereau et al 2010).

Most studies presented findings in broad categories such as complete recovery, partial recovery or no improvement, with varying or no definitions of these categories. These were assessed at time points ranging from immediately after

treatment to one year after discharge from hospital.

The most commonly used recompression schedule was US Navy Table 6 (USN T6) or Royal Navy Table 62 (RN T62), but most studies included patients in whom a number of other schedules were also used and three studies used different schedules specified in other countries.

The rate of complete recovery immediately after one session of HBOT (USN Table 5 or T6) in 195 patients with Type I DCS was reported to be 33%, with 92% of patients reporting complete recovery without further treatment on telephone follow-up one month later (Lee et al 2015).

Recovery at discharge from hospital was reported in several studies. In one, complete recovery after treatment (the majority with USN T6) for DCI was reported in 67% of 168 patients at discharge, and 82% of 164 patients at 4-6 week follow-up (Bennett et al 2012). An overall 'good' outcome at discharge was reported in 96% of more than 650 patients treated for DCI with four main schedules, most commonly RN T62 (Sayer et al 2009). Complete recovery at discharge was found in 89.8% of more than 5000 patients with DCI treated with one of four recompression schedules, but it was not clear whether all of these included HBOT (Xu et al 2012).

In patients with IGE who had a single session of HBOT, crude mortality at discharge from an intensive care unit (ICU) was 12%, at hospital discharge 16%, at six months 17.6% and at one year 21% (Bessereau 2010).

There was no evidence comparing the effects of recompression with or without HBOT in different groups of patients. The only patient factor found to be related to outcomes of DCI or DCS was severity of initial symptoms, but the studies did not provide evidence on whether patients with more or less severe symptoms had a greater or lesser benefit from HBOT. Koch et al (2008) reported significantly worse mean outcome scores in 42 patients with more severe DCS-II, than in 225 patients with less severe DCS-II ($p < 0.001$), all of whom received hyperbaric treatments according to German Navy guidelines. Xu et al (2012) found a significant relationship between whether patients had mild ($n=3831$), moderate ($n=1124$) or severe ($n=314$) DCI and rate of complete recovery both after initial recompression therapy ($p < 0.001$) and at hospital discharge ($p < 0.001$). However, it was not clear to what extent this

analysis had adjusted for confounders.

In 125 patients with IGE, neurological sequelae at one year were found to be associated with the patient having a Babinski sign ($p=0.0007$) or focal motor deficit ($p<0.0001$) at presentation, and mortality at one year with the patient having a Babinski sign ($p=0.04$) or acute renal failure ($p=0.03$). However the relevance of these signs in planning treatment for such patients is not clear (Bessereau et al 2010).

There was no evidence demonstrating that any particular treatment schedule was more or less beneficial than any other.

The evidence on whether outcomes varied with delay in receiving treatment was mixed. The odds ratio (OR) for residual symptoms immediately after treatment was significantly higher (OR 3.31, 95% CI 1.08-10.13) in patients who had treatment for Type I DCS more than 96 hours after the appearance of symptoms compared with those who had treatment within 24 hours (Lee et al 2015). However, the longer term clinical significance of this outcome was unclear. Complete recovery 10 to 14 days after treatment with various recompression schedules (most commonly USN T6) was reported to be 78% in 128 divers with DCS who had recompression within 48 hours, and 76% in 76 divers who had recompression more than 48 hours after surfacing ($p=0.955$, no significant difference between early and delayed recompression) (Hadanny et al 2015). In contrast, Xu et al (2012) found a significant relationship ($p<0.0001$) between complete recovery and the number of hours' delay between symptom onset and recompression treatment in over 5000 Chinese divers, but it was not clear whether this analysis adjusted for confounders.

Overall the majority of patients with DCI or DCS in all studies were deemed to have a good outcome. However, it is not possible to define in what way and to what extent the outcomes were influenced by recompression treatment with or without HBOT as all the patients in these studies received some form of recompression with or without HBOT and there were no comparisons with patients who did not receive these treatments. In the study of patients with IGE, mortality and morbidity rates were reported to be high but the contribution of HBOT to outcomes was not clear.

Three studies reported data on safety or adverse effects. In Bennett et al (2012),

during initial recompression three out of 179 patients experienced aural barotrauma, two had premonitory signs of cerebral oxygen toxicity and one had persistent nausea. Xu et al (2012) reported symptoms of oxygen toxicity during initial recompression in nine (0.17%) of 5269 divers with DCI. Out of 125 patients with IGE, one experienced seizures during HBO, which resolved on shifting the patient from pure oxygen to air (Bessereau et al 2010).

No studies were identified which considered cost-effectiveness.

The studies were generally of poor to moderate quality, and none were designed to answer questions about the effect of adding recompression with or without HBOT to supportive treatment.

The evidence is insufficient to draw any conclusion about the impact of HBOT in DCI, DCS or IGE.

Conclusion

Following on from the seminal publication in 1965 by Goodman and Workman, a Cochrane review (Bennett, 2012) and two Health Technology reports (AETMIS, 2001; Mitton, 1998) 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.

Recompression has been an established treatment in these indications for many years. For instance, in 1889, Ernest Moir introduced air recompression to treat DCI and the mortality in his team of compressed air workers fell from 25% to 1.7%. As a result, studies comparing supportive treatment with or without recompression are likely to be deemed unethical. However, the evidence identified here demonstrates uncertainty around the contribution of HBOT in these conditions, and there appears to be insufficient evidence on which to base clear recommendations for commissioning. Further research may be considered justifiable, provided it is well-designed and conducted to answer the questions of interest.

Delivery of recompression in the UK

In 1965 Goodman and Workman reported on two series of casualties with

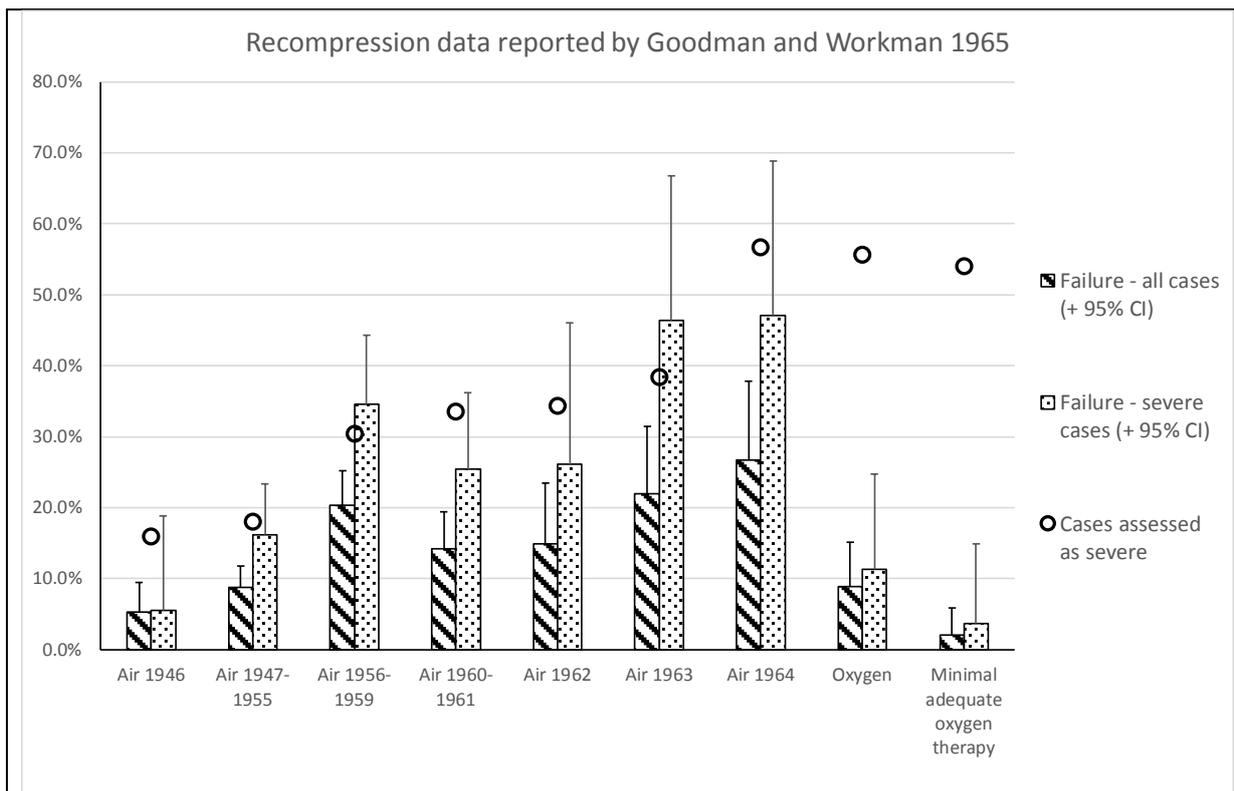
decompression illness.

One series had been treated with air recompression between 1945 and 1963. Serious cases were treated with regimes of 18 hours and 38 hours duration respectively and gave the casualty a fixed maximum inspired oxygen partial pressure of 127 kPa.

In the second series covering 1963 to 1965, patients were treated for shorter durations (but at least 64 minutes) and variable maximum inspired partial pressure of oxygen which did not exceed 283 kPa. After analysing responses to depth and time to resolution of symptoms, the authors proposed a minimal adequate treatment from which they developed US Navy Tables 5 and 6 which are of 135 minutes and 285 minutes duration respectively and both give the casualty a fixed maximum inspired partial pressure of oxygen of 283 kPa.

The graph (Figure 1) shows the increasing rate of failure of initial treatment (defined as recurrence or incomplete resolution of symptoms) observed in casualties treated with air tables over the period 1945 to 1963 and the comparator results obtained with the shallow oxygen tables.

Figure 1: Recompression data reported by Goodman and Workman 1965



Goodman and Workman's data are consistent with much lower treatment failure rates using the shallow 100% oxygen tables compared to outcomes achieved with air recompression tables for diving casualties of similar severity. These results proved convincing to the clinical community worldwide and thus, there are few if any services that do not offer recompression with 100% oxygen or gas mixtures which contain a higher fraction of oxygen than is found in air.

NHS England has concluded that there is sufficient evidence to support a proposal for the routine commissioning of this treatment for the indication.

8 Proposed Criteria for Commissioning

Decompression Illness

Inclusion criteria

1. Patients satisfying all of the following criteria are eligible for hyperbaric oxygen therapy:

a. a history of decompression, with or without an inert gas burden, within the 72 hours prior to onset of symptoms or signs

AND

b. all reasonable efforts commensurate with the urgency of the situation have been taken to exclude causes other than bubble-mediated disease

AND

i. a history of one or more of the following persisting at the time of assessment:

1. Limb Pain

2. Pain presenting in a thoracolumbar dermatomal distribution (Girdle Pain)

3. Subjective or objective Neurological deficit

4. Audiovestibular symptoms or signs

5. Cardio-pulmonary symptoms or signs

6. Cutaneous symptoms or signs (pruritis, rash, discoloration)

7. Lymphatic symptoms or signs (painful or swollen lymph nodes, regional oedema)

8. Constitutional symptoms or signs (such as headache, fatigue, malaise, nausea, vomiting and anorexia) severe enough to affect quality of life or function.

OR

ii. omitted more than 20 minutes of planned decompression (not including safety stops) and remain asymptomatic and can present at a hyperbaric facility within 60 minutes of the decompression insult.

OR

iii. a history clearly consistent with arterial gas embolism, are now asymptomatic with no abnormal neurological signs, and for whom there is no other obvious cause, if they can present at a hyperbaric facility within 6 hours of the decompression insult.

2. Exclusion criteria

A patient is not eligible for hyperbaric oxygen therapy if:

a. a reason other than bubble-mediated disease for the signs or symptoms

is identified

- b. they have an untreated tension pneumothorax

3. Point at which HBO is appropriate for management of the condition

- a. Treatment is appropriate as soon as it is established that the inclusion criteria are fulfilled and that there are no exclusions.

Gas embolism

1. Patients satisfying all of the following criteria are eligible for hyperbaric oxygen therapy:

- a. a history of an event which could plausibly have introduced gas into a blood vessel

AND

- b. all reasonable efforts commensurate with the urgency of the situation have been taken to exclude causes other than bubble-mediated disease

AND

- i. a history of one or more of the following persisting at the time of assessment:

- 1. Subjective or objective Neurological deficit
- 2. Cardio-pulmonary symptoms or signs

OR

- ii. a history clearly consistent with arterial gas embolism, are now asymptomatic with no abnormal neurological signs, and for whom there is no other obvious cause, if they can present at a hyperbaric facility within 6 hours of the decompression insult.

2. Exclusion criteria

- a. A patient is not eligible for hyperbaric oxygen therapy if:
 - i. a reason other than bubble-mediated disease for the signs or symptoms is identified
 - ii. they have an untreated tension pneumothorax

3. Point at which HBO is appropriate for management of the condition

- a. Treatment is appropriate as soon as it is established that the inclusion criteria are fulfilled and that there are no exclusions.

9 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 Service Specification for Hyperbaric Oxygen Therapy (All Ages) (Service Specification Number: D11/S/a) which can be found:

(insert link)

10 Proposed Governance Arrangements

All centres performing HBOT must be recognised by NHS England as one of their listed centres for HBOT and specifically in accordance with the published service specification: Hyperbaric Oxygen Therapy (All Ages)

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

- 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 with written evidence to the BHA or Regional Commissioners 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.

11 Proposed Mechanism for Funding

Funding and commissioning of hyperbaric oxygen therapy for decompression illness and gas embolism will be managed through the relevant local NHS England specialised commissioning team.

Reimbursement for treatment will be dependent on activity being reported via SUS

and is dependent on the completion of the National Hyperbaric Oxygen Registry Database.

12 Proposed Audit Requirements

As outlined in the service specification and collected on the national registry:

- 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.

13 Documents That Have Informed This Policy Proposition

The British Hyperbaric Association. Health & Safety for Therapeutic Hyperbaric Facilities. A Code of Practice. 2000, ISBN 0 9527623 2 3

The Cox Report: A Code of Good Working Practice for the Operation and Staffing of Hyperbaric Chambers for Therapeutic Purposes. Published by the Faculty of Occupational Medicine. (The Cox Report.) May 1994, ISBN 1 8732409 9 6

14 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.

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Draft for consultation