

**Integrated Impact Assessment Report for Clinical Commissioning Policies**

<b>Policy Reference Number</b>	D11X02		
<b>Policy Title</b>	Hyperbaric oxygen therapy – Multiple indications		
<b>Accountable Commissioner</b>	Jacque Kemp	<b>Clinical Lead</b>	Mark Glover
<b>Finance Lead</b>	Peter Davies	<b>Analytical Lead</b>	Kath Everard
<b>Section A - Activity Impact</b>			
<b>Theme</b>	<b>Questions</b>	<b>Comments</b> (Include source of information and details of assumptions made and any issues with the data)	
A1 Current Patient Population & Demography / Growth	A1.1 What is the prevalence of the disease/condition?	A1. 1 Incidence of decompression illness (DCI) is easier to calculate than prevalence. Since this is an acute disorder from which 80% or more cases typically recover completely with prompt treatment, incidence probably gives a better measure than prevalence of the scale of the activity required of the hyperbaric service. Estimated incidence of decompression illness is 0.54 per 100,000 of the general population per year and likely to be slightly in excess of 300 per 100,000 of the diving population per year. This is based on an average of 293 divers treated with hyperbaric oxygen annually in FYs 2011/12 to 2013/14 in England from a population of divers which, in one estimate, comprises	

	<p>A1.2 What is the number of patients currently eligible for the treatment under the proposed policy?</p> <p>A1.3 What age group is the treatment indicated for?</p> <p>A1.4 Describe the age distribution of the patient population taking up treatment?</p>	<p>approximately 105,000 individuals in the whole United Kingdom. Population of England mid-2013 was 53.9 million.</p> <p>It is difficult to estimate the incidence of gas embolism arising from causes other than diving. Only 17 cases were notified to the hyperbaric community in UK over 10 years and only 5 were considered suitable for hyperbaric treatment, giving an incidence of treatable cases in the region of 0.80 per 100 million general population per year. There is a suspicion that this is an underestimate of actual need when compared to average annual figures from overseas (102 per 100 million in Paris, 272 per 100 million in Marseille, 18 per 100 million in Sydney and 17 per 100 million in Australia overall).</p> <p>A1.2 The whole population of England - 53 million. The HBOT service is aligned primarily to the treatment of emergencies, the most numerous cases of which are decompression illness and acute severe carbon monoxide poisoning.</p> <p>A1.3 All ages.</p> <p>A1.4 Decompression illness population mean age 35.2 years, median age 34.1, Interquartile range 28.3 to 41.3 years, minimum age 13.6 years, maximum age 73 years.</p>
--	--	---

	<p>A1.5 What is the current activity associated with currently routinely commissioned care for this group?</p> <p>A1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?</p> <p>A1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years?</p> <p>A1.8 How is the population currently distributed geographically?</p>	<p>A1.5 293 cases of decompression illness treated each year, 0.5 cases per year treated with gas embolism from non-diving causes and 61 cases of acute severe carbon monoxide poisoning treated per year.</p> <p>A1.6 There is no anticipated growth in the incidence of decompression illness, gas embolism or carbon monoxide poisoning.</p> <p>A1.7 There is no anticipated growth in the incidence of decompression illness, gas embolism or carbon monoxide poisoning.</p> <p>A1.8 Acutely presenting cases of decompression illness will arise at the time of exposure to a reduction in ambient pressure. Delayed presentations tend to arise in casualties who either are en route to, or have reached, their place of residence. As a result, the at-risk population is concentrated mainly in diving areas, most of which are coastal but some are inland, in areas of high population density and near to major international airports.</p>
<p>A2 Future Patient Population &amp; Demography</p>	<p>A2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely</p>	<p>A2.1 Yes. This policy excludes treatment for carbon monoxide poisoning from the current routine commissioning position. Regions also currently commission</p>

	<p>commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?</p> <p>A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).</p> <p>A 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details.</p>	<p>treatment for other selected conditions for which the policy now recommends no routine commissioning so access to hyperbaric oxygen therapy will reduce further still.</p> <p>A2.2 The diving population remains fairly static and accident rates are unlikely to rise. There is a possibility that current and planned research will establish HBOT as a cost-effective intervention for other indications which will extend the treatment to other populations but it is not possible to estimate the magnitude of this until the results of the studies are known.</p> <p>A2.3 The numbers of cases are small and, as a result, can be subject to large percentage variations between years. The geographical distribution of decompression illness depends mainly on diving location and place of residence of the individuals affected. It is not possible to rule out change completely, but significant variation is unlikely and would be expected to occur over a period longer than the 10 year horizon mentioned in K2.4.</p> <p>Research into the use of hyperbaric oxygen therapy for other conditions could widen the geography and demography of the patient population eligible for treatment and, therefore, increase activity. It is not possible to estimate the magnitude of any changes until the results of the studies are known.</p>
--	---	---

	<p>A2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?</p>	<p>A2.4 No change in patient numbers is expected except for the year-on-year variation and an allowance for underestimated incidence of gas embolism mentioned in K1.7.</p>
A3 Activity	<p>A3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet.</p> <p>A3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet.</p> <p>A3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet.</p>	<p>A3.1 Approximately 300 patients per year. Regular compressions will still be required to maintain equipment and staff competence for emergency treatment of DCI and Gas Embolism. NHS England might wish to consider how this spare capacity may be used to add to the evidence base for the indications which appear most promising, perhaps through NIHR funded trials or CtE</p> <p>A3.2 N/A</p> <p>A3.3 There is no 'best alternative'. ICU Patients might have to be transferred long distances to other international centres for treatment as the UK centres will not have the through-put, capacity or skills to provide the treatment. This might incur higher costs for the NHS.</p>
A4 Existing Patient Pathway	<p>A4.1 If there is a relevant currently routinely commissioned treatment, what is the</p>	<p>A4.1 There is no other option for treatment for DCI and gas embolism beyond HBOT. See service specifications for hyperbaric</p>

	<p>current patient pathway? Describe or include a figure to outline associated activity.</p> <p>A4.2. What are the current treatment access criteria?</p> <p>A4.3 What are the current treatment stopping points?</p>	<p>oxygen therapy NHS CB/D11 section 2.2 for a detailed description of the patient pathway which already includes HBOT.</p> <p>A4.2 Decompression insult severe enough to justify treatment as described within the United States Navy Diving Manual.</p> <p>Gas embolism - neurological and / or cardiovascular deterioration to an extent which threatens life or function after an incident in which gas could have been introduced into the venous or arterial circulation.</p> <p>Carbon monoxide poisoning – a history or signs consistent with exposure to carbon monoxide with loss of consciousness at any stage; persistent neurological symptoms; cardiac ischaemia or arrhythmias attributed to the toxic exposure. Also, all cases of pregnancy even if the mother is asymptomatic.</p> <p>A4.3 Following administration of the appropriate initial schedule of treatment, no more would be administered if there is no response to treatment; complete resolution of the deficit or plateau in response to treatment.</p>
<p>A5 Comparator (next best alternative treatment) Patient Pathway</p>	<p>A5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or</p>	<p>A5.1 There is no treatment option other than HBOT for decompression illness and gas embolism.</p>

	<p>include a figure to outline associated activity.</p> <p>A5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.</p>	<p>A5.2 N/A</p>
<p>A6 New Patient Pathway</p>	<p>A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy.</p> <p>A6.2 Where there are</p>	<p>A6.1 See service specifications for hyperbaric oxygen therapy NHS CB/D11 section 2.2 for a detailed description of this.</p> <p>Carbon Monoxide Poisoning and Necrotising Soft Tissue Infections have been removed from the list of emergency indications as NHS England has concluded that there is not sufficient evidence to support routine commissioning. This means that patients who satisfy the criteria for exceptionality (potentially saving life and/or limb) will in future have to follow the Individual Funding Request (IFR) Route, resulting in long delays and increased clinical risk.</p> <p>A6.2 Very few patients fail to</p>

	<p>different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.</p>	<p>complete the full prescribed treatment.</p> <p>Historical analyses show that 60% of decompression illness cases will have complete resolution after one treatment. 80% will have total resolution by the time they complete any additional treatments considered necessary.</p>
<p>A7 Treatment Setting</p>	<p>A7.1 How is this treatment delivered to the patient?</p> <ul style="list-style-type: none"> <li>○ Acute Trust: Inpatient/Daycase/ Outpatient</li> <li>○ Mental Health Provider: Inpatient/Outpatient</li> <li>○ Community setting</li> <li>○ Homecare delivery</li> </ul> <p>A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? <i>e.g. service capacity</i></p>	<p>A7.1 Acute Trust: Inpatient / Day case / Outpatient</p> <p>A7.2 Regular compressions will still be required to maintain equipment readiness and staff competence for emergency treatment of DCI and Gas Embolism. NHS England might wish to consider how this spare capacity may be used to add to the evidence base for the indications which appear most promising,</p>

		perhaps through NIHR funded trials or CtE This is of paramount importance in maintaining the viability and stability of this service.
A8 Coding	<p>A8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?</p> <p>A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)</p>	<p>A8.1 Anonymised registry database administered by an international hyperbaric research-focused consortium co-ordinated by Dartmouth-Hitchcock Medical Center USA and Kings College London UK</p> <p>A8.2 Possible relevant ICD10 codes include:  T70.3 - Caisson disease [decompression sickness]  Compressed-air disease Diver palsy or paralysis  T70.4 - Effects of high-pressure fluids  Traumatic jet injection (industrial)  T70.8 - Other effects of air pressure and water pressure, Blast injury syndrome  T70.9 - Effect of air pressure and water pressure, unspecified  O88.0 - Obstetric air embolism  T79.0 - Air embolism (traumatic)  Excl.: air embolism complicating abortion or ectopic or molar pregnancy (O00-O07, O08.2)  air embolism complicating pregnancy, childbirth and the puerperium (O88.0)</p>
A9 Monitoring	A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	A9.1 N/A

	<p>A9.2 If this treatment is a drug, what pharmacy monitoring is required?</p> <p>A9.3 What analytical information /monitoring/ reporting is required?</p> <p>A9.4 What contract monitoring is required by supplier managers? What changes need to be in place?</p> <p>A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?</p> <p>A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?</p> <p>A9.7 Do you anticipate using Blueteq or other</p>	<p>A9.2 The drug is medical oxygen or diver quality oxygen. The latter has more stringent limits for contaminants. The purity will be monitored in accordance with the specific requirements relevant to the provider's setting and all processes will be subject to inspection by the Care Quality Commission.</p> <p>A9.3 As detailed above</p> <p>A9.4 Standard monitoring including Quality Dashboard. Nothing specific to this service.</p> <p>A9.5 Dashboard in place</p> <p>A9.6 No</p> <p>A9.7 No</p>
--	--	---

	equivalent system to guide access to treatment? If so, please outline. <i>See also linked question in M1 below</i>	
Section B - Service Impact		
Theme	Questions	Comments (Include source of information and details of assumptions made and any issues with the data)
B1 Service Organisation	<p>B1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)</p> <p>B1.2 How will the proposed policy change the way the commissioned service is organised?</p>	<p>B1.1 Services are mostly in coastal locations. Informal networks already exist as providers co-operate to ensure that patients and emergency services receive immediate remote advice and that casualties are directed to the closest appropriate facility. The proposed service will deal primarily with emergency referrals directly from patients themselves and their companions, coastguard, ambulance trusts, emergency departments, primary care etc.</p> <p>B1.2 It is anticipated that provision for emergency treatments will remain the same.</p> <p>This is, however, a significant risk to the elements of the service delivering treatment for conditions that are currently funded for NHS patients but will not be routinely commissioned in future. The withdrawal of funding for these indications will potentially lead to some centres becoming unsustainable and reducing access for emergency treatments if these centres are forced to close. This risk could be considered as part of ongoing procurement</p>

		arrangements.
B2 Geography & Access	<p>B2.1 Where do current referrals come from?</p> <p>B2.2 Will the new policy change / restrict / expand the sources of referral?</p> <p>B2.3 Is the new policy likely to improve equity of access?</p>	<p>B2.1 Referrals for emergency treatments arise from acute primary and secondary care services or via direct access. Geographical dispersal of referrals reflects that of the at-risk population described at K1.8.</p> <p>B2.2 This restricts access for patients with indications that are currently commissioned in some units but not supported by the evidence review. The two indications recommended for routine commissioning in the policy proposition are currently commissioned from all units.</p> <p>B2.3 If the current policy proposition were implemented with no mitigating actions it would pose a threat to the viability of the emergency service.</p> <p>The activity associated with the treatment of emergency conditions will not be sufficient to maintain staff competency and equipment preparedness. There is a potential for reduced familiarity of staff with treatment procedures and patient care within a hyperbaric environment, which might lead to many staff falling below the accepted number of patient exposures required to maintain competency. This will impact on treatment efficiency and patient safety and might also impact on effectiveness of service delivery. Any future service must answer the need for training of personnel to ensure a sustainable service into</p>

	<p>B2.4 Is the new policy likely to improve equality of access / outcomes?</p>	<p>the future</p> <p>Mitigating actions will also be required to ensure that the policy changes do not undermine participation in NIHR portfolio research activities that are currently underway.</p> <p>B2.4 The new policy will ensure that HBOT is provided for treatments where NHS England accepts that there is evidence of effectiveness. This will ensure that the same criteria for treatment are applied across all eligible patients nationally.</p> <p>This policy is, however, more likely to reduce equality to access and outcomes (interpreted as requiring the same burden in order to access and receiving the same benefit as other patients with the same condition of identical severity) if applied without appropriate mitigations in place.</p> <p>Fewer centres will mean reduced capacity, possibly below historical surges in requirement, and greater distances to travel. If this results in a delay to treatment there is a risk of poorer outcome in progressive cases. This will magnify inequalities of access and outcome based on geographical location of the patient when symptoms arise. Careful consideration will need to be given to the configuration of centres which provides the greatest service resilience.</p> <p>Continued provision of the 24hr helpline for management of DCI would also need to feature in the mitigation plans.</p>
--	--	--

B3 Implementation	<p>B3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?</p> <p>B3.2 Is there a change in provider physical infrastructure required?</p> <p>B3.3 Is there a change in provider staffing required?</p> <p>B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?</p> <p>B3.5 Are there changes in the support services that need to be in place?</p> <p>B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p>	<p>B3.1 Yes, this needs to follow the implementation and procurement associated with the service review. Service stability and assurance of the safe and effective 24hr emergency service can only be achieved by the careful and detailed development of a mitigation plan. This will be outlined within the associated service review. Implementation of the policy proposition ahead of this would pose a severe risk to the service.</p> <p>B3.2 No</p> <p>B3.3 No. Staffing must continue to provide 24/7 access for emergency treatments</p> <p>B3.4 No. Intensive care is an established dependency.</p> <p>B3.5 N/A</p> <p>B3.6 N/A</p>
-------------------	--	---

	<p>B3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?</p> <p>B3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)</p>	<p>B3.7 If commissioned activity is restricted to the indications in the policy proposition, some providers will struggle to achieve the minimum number of chamber pressurisations that will ensure safe practice if only emergency treatments are commissioned and might, as a consequence, close.</p> <p>B3.8 Units will need to be commissioned to provide access for 24/7 service.</p>
B4 Collaborative Commissioning	B4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	B4.1 No
<b>Section C - Finance Impact</b>		
<b>Theme</b>	<b>Questions</b>	<b>Comments</b> (Include source of information and details of assumptions made and any issues with the data)
C1 Tariff	C1.1 Is this treatment paid under a national prices*, and if so which?	C1.1 No –. local prices

	<p>C1.2 Is this treatment excluded from national prices?</p> <p>C1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?</p> <p>C1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes?</p> <p>C1.5 is VAT payable (Y/N) and if so has it been included in the costings?</p> <p>C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?</p>	<p>C1.2 Yes.</p> <p>C1.3 Variation in pricing ranges from £25,200 to £8,790. This might be linked to disease severity and, therefore, the type, duration and number of hyperbaric treatments received. As the centres are in the main specific units, cross subsidy with other services is unlikely to explain price variation.</p> <p>C1.4 Procurement exercise anticipated when service review concludes. Currently benchmarking to establish pre-procurement financial arrangements.</p> <p>C1.5 N/A</p> <p>C1.6 N/A – specification isn't affecting current arrangements until procurement arrangements progressed.</p>
<p>C2 Average Cost per Patient</p>	<p>C2.1 What is the revenue cost per patient in year 1?</p>	<p>C2.1 C£15k (tbc)</p> <p>The proposed policy risks increasing the cost-per case for DCI and Gas embolism patients.</p>

	<p>C2.2 What is the revenue cost per patient in future years (including follow up)?</p>	<p>Most UK centres utilize multiplace Hyperbaric chambers, which can realistically only function cost-effectively at good occupancy levels.</p> <p>The staffing and maintenance costs of providing a consultant-led 24/7/365 Cat 1 service will remain virtually the same and capacity, which would otherwise have been utilised, will go unused.</p> <p>C2.2 Neutral to reduction – conditional on procurement arrangements.</p>
<p>C3 Overall Cost Impact of this Policy to NHS England</p>	<p>C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England.</p> <p>C3.2 Where this has not been identified, set out the reasons why this cannot be measured.</p>	<p>C3.1 Cost neutral worse case, reductions in volumes and procurement will deflate cost per case arrangements.</p> <p>C3.2 Exact volumes of emergency services are variable, rates can be confirmed by centres and NHS England Specialised Commissioning Hubs.</p>
<p>C4 Overall cost impact of this policy to the NHS as a whole</p>	<p>C4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs).</p> <p>C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole.</p>	<p>C4.1 Cost neutral to likely saving.</p> <p>C4.2 No cost pressures, specification and procurement likely to be neutral worse case.</p>

	<p>C4.3 Where this has not been identified, set out the reasons why this cannot be measured.</p> <p>C4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?</p>	<p>C4.3 N/A</p> <p>C4.4 N/A</p>
C5 Funding	C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified. <i>e.g. decommissioning less clinically or cost-effective services</i>	C5.1 N/A
C6 Financial Risks Associated with Implementing this Policy	<p>C6.1 What are the material financial risks to implementing this policy?</p> <p>C6.2 Can these be mitigated, if so how?</p>	<p>C6.1 <i>Nil – is however a risk of not endorsing policy.</i> Transferring patients by fixed wing pressurised emergency air ambulance to appropriate facilities abroad would incur significant cost. NHS England would also be responsible for the cost of general medical and intensive care administered around the hyperbaric treatment abroad. Poor outcome attributed to delay to treatment in iatrogenic air embolism raises the likelihood of a significant financial settlement.</p> <p>C6.2 Ensure that regular planned activity maintains equipment readiness and staff competence for emergency treatment of DCI and Gas Embolism.</p>

	<p>C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</p>	<p><i>C6.3 Policy will have no impact on emergency activity itself occurring, but the revised specification &amp; procurement unit rates will contain cost exposure.</i></p>
<p>C7 Value for Money</p>	<p>C7.1 What evidence is available that the treatment is cost effective? <i>e.g. NICE appraisal, clinical trials or peer reviewed literature</i></p> <p>C7.2 What issues or risks are associated with this assessment? <i>e.g. quality or availability of evidence</i></p>	<p><i>C7.1 No studies available but current English provider charges are generally lower than those charged by Scottish providers to English patients</i></p> <p><i>C7.2 Cost per case needs to be matched to provider overheads and to disease severity and, therefore, the type, duration and number of hyperbaric treatments received.</i></p>
<p>C8 Cost Profile</p>	<p>C8.1 Are there non-recurrent capital or revenue costs associated with this policy? <i>e.g. Transitional costs, periodical costs</i></p> <p>C8.2 If so, confirm the source of funds to meet these costs.</p>	<p><i>C8.1 e.g. Transitional costs, periodical costs</i></p>