North of England Medical Hyperbaric Services Limited

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Quality Report

Spire Hull and East Riding Hospital
Lowfield Lane
Anlaby
Hull
HU10 7AZ
Tel: : 01482 659471
Website: www.hullhyperbaric.co.uk

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This report describes our judgement of the quality of care at this hospital. It is based on a combination of what we found when we inspected and a review of all information available to CQC including information given to us from patients, the public and other organisations.

Summary of findings

Letter from the Chief Inspector of Hospitals

North of England Medical Hyperbaric Services Limited has been providing a service at the current location for 17 years. The hyperbaric unit was located within the Spire Hull and East Riding hospital. The unit provided hyperbaric (high-pressure) oxygen therapy for a range of conditions. The service was available to NHS and private patients of all ages and to military personnel.

We inspected the service on the 16 September 2015 as part of our pilot phase for independent health care services. As this was a pilot phase, we will not publish a rating. The team inspected the full hyperbaric service at this inspection.

Are services safe at this service

People were protected from avoidable harm and abuse. There had been no serious incidents reported in the last year. Staff were aware of safeguarding procedures but some staff were overdue training. There was a potential service risk in relation to medical support, as it was delivered primarily by one doctor (the medical director) with the assistance of two other doctors on the rare occasion the MD was not available. Additionally there was no paediatric consultant to oversee the treatment of children.

Are services effective at this hospital/service

Due to the specialised nature of the service there was limited evidence available of the effectiveness of the service. There was no national bench marking and the service did not audit individual patient outcomes following treatments. There was no appraisal and performance review process for staff. We saw some recent local audits, which had all been carried out for the first time just before our inspection. The consent policy did not indicate who would carry out a capacity assessment in the event of a patient needing one. There was no reference to Deprivation of Liberty Safeguards in the policy.

Are services caring at this hospital/service

We found the staff at the hyperbaric unit to be compassionate and caring. We observed staff and patients interacting positively together before, during and after treatment. Staff built up a relationship with patients over the course of treatment and learned more about them as individuals. We found this enabled staff to give supportive, holistic care and to advocate for patients. Patients said staff were compassionate, looked after all their needs and nothing was too much trouble.

Are services responsive at this hospital/service

Hyperbaric facilities are few in number in England. There was therefore a potential inequality in the distance a patient would need to travel for treatment, however this was related to nationally commissioned services and not the provider.

The timing of the morning and afternoon sessions provided flexibility for elective patients. Staff told us the average wait from referral to treatment was two months. We found this to be longer than some other hyperbaric units. Staff told us they were committed to ensuring patients were treated fairly and equally regardless of their circumstances.

We found emergency access to the service was good. Staff could be called in and the unit opened within an hour.

Are services well led at this hospital/service

We found there was no clear vision or set of values for the North of England Hyperbaric Medical Services. The provider told us there was no need for a written strategy as staff demonstrated the values by the work carried out.

We found no performance framework to identify, assess, monitor, and respond to performance issues.

Summary of findings

There was a small team at the unit and the chamber staff seemed to work well together with positive attitudes towards good quality care. Both the technical director and nurse manager were visible and approachable. Staff told us they did not receive an annual appraisal. There were no staff surveys, staff meetings or ways the staff could be formally involved in developing the service. We were told there was "informal management" of staff. There were no formal management meetings or clinical governance processes; we were told the three senior staff saw each other very frequently and communicated by email and telephone.

Our key findings were as follows:

- The facilities were clean and infection control processes were in place.
- The staff at the hyperbaric unit were compassionate and caring.
- Staffing was adequate for the service provided and responsive to patient's individual needs. However, there were potential risks with regard to paediatric consultant cover and medical emergency cover.
- There was a lack of formal recorded HR and management systems in place including a lack of evidence of staff completing mandatory training.
- There was sufficient equipment to ensure staff could carry out their duties. Processes were in place for monitoring and maintaining most equipment however, the emergency resuscitation equipment was not checked in accordance with national guidance.
- There was no formal written vision or strategy for the service.

There were also areas of poor practice where the provider needs to make improvements. Importantly, the provider must:

- Follow recognised guidelines including the British Hyperbaric Association (BHA) guidelines and the European code of good practice for hyperbaric therapy and implement actions arising from the BHA audit including: having written medical designated responsibilities for the doctor and ensuring the potential risk of lack of formal on-site medical support/cover is mitigated;
- Ensure all staff are up to date with appraisals, mandatory training, dive medicals, advanced life support training and that Disclosure and Barring Service certificates are up to date.

In addition the provider should:

- Develop a strategy and vision for the service and involve the staff in this process.
- Develop a performance framework to identify, assess, monitor, and respond to service and staff performance issues.
- Take action to ensure the emergency resuscitation equipment is checked on at least a weekly basis.
- Ensure a paediatric consultant oversees the hyperbaric treatment of children.

Professor Sir Mike Richards
Chief Inspector of Hospitals

Overall summary

There was a small team of staff at the unit who all seemed to work well together. We found the technical director and nurse manager to be knowledgeable and skilled. They had a positive ethos towards good quality care. Both the technical director and nurse manager were visible and approachable.

We found the staff at the hyperbaric unit to be compassionate and caring. We saw staff had empathy and were aware of the whole care experience for patients, not just their hyperbaric treatment in isolation. The timing of the morning and afternoon sessions meant that most patients did not have to travel very early or return home late. There was flexibility for elective patients to attend sessions to fit in around their own routine.

We found emergency access to the service was good. Staff could be called in and the unit opened within an

Summary of findings

hour. Staff told us the average wait from referral to treatment was two months. We found this to be longer than some other hyperbaric units, which employ more staff and hence have more treatment sessions. The average wait for treatment in such other units was approximately two weeks.

There was no clear vision or set of values for North of England Hyperbaric Medical Services. This meant staff could not understand their role in achieving the vison for the service, and there was no way to monitor progress towards delivering any goals. The technical director told us there was no need for a strategy as staff demonstrated the values by the work carried out. We found no performance framework to identify, assess, monitor, and respond to performance issues. Staff told us they did not receive an annual appraisal. There were no staff surveys, staff meetings or ways the staff could be involved in developing the service.

Staff told us there was a strong focus on patient safety. Environmental audits commenced in August 2015 and were due to take place on a monthly basis. Maintenance records indicated staff carried out checks on a daily basis, for example, the oxygen and carbon dioxide levels within the chamber. However, we found the resuscitation equipment inside the chamber such as the 'medic' bag and airway bag were only checked on a monthly basis.

Staff were expected to complete mandatory training in their substantive posts outside the service. The nurse manager kept records of when mandatory training was due or completed by staff; however, we saw that mandatory training was out of date for several of the 10 staff. There was a potential service risk in medical support to the service highlighted in an external 2014 report and confirmed at inspection. The NHS England service specification indicated a paediatric consultant should oversee the treatment of children; we found this was not the case at North of England hyperbaric unit.

North of England Medical Hyperbaric Services Limited

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Detailed findings

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Background to North of England Medical Hyperbaric Services Limited

North of England Medical Hyperbaric Services limited (NEMHS) was privately owned and managed by the technical and research director. NEMHS has been providing a service at the current location for 17 years.

The hyperbaric unit was located within the Spire Hull and East Riding private hospital. The unit provided hyperbaric (high-pressure) oxygen therapy for a range of conditions. The service was available to NHS and private patients of all ages and to military personnel.

Hyperbaric oxygen treatment involves breathing pure oxygen at higher than atmospheric pressures in an enclosed chamber. The atmospheric pressure was equivalent to being up to 40 feet under water. Hyperbaric therapy was used to treat a variety of medical conditions. These included decompression illness sustained after diving, the treatment of radiation tissue injury, treatment of necrotising wounds, carbon monoxide poisoning and gas embolism (air bubbles in the blood vessels). Treatment was available 24 hours a day all year round for emergency and elective patients. Elective patients received treatment every weekday for between four to six weeks.

Consultants, the coast guard, emergency departments, other emergency services, senior physiotherapists, and GPs referred patients to the service. Most patients were treated through a contract with NHS England before elective treatment commenced. Most elective patients could access the service within 1 – 2 hours from home. However, emergency patients could be referred from anywhere within England dependent on availability, clinical need and transport requirements. The unit treated all age groups.

There are CQC inspection frameworks for single speciality services such as hyperbaric services which were being tested in wave 1 (April 2015 – September 2015). Until October 2015, we were in the pilot phase for the single specialty services list and therefore we will not publish a rating. The team inspected the full hyperbaric service at this inspection.

There were no special reviews or investigations of the hospital by the CQC at any time previously. There had been no previous CQC inspections. The registered manager had worked at the service for nine years and been the manager for six years.

Our inspection team

Our inspection team was led by Professor Juliet Beal, National Nursing Advisor and inspectors from the Care Quality Commission.

Detailed findings

How we carried out this inspection

We carried out the inspection on the 14 and 15 September 2015. We talked with four patients and seven members of staff, including the owner / technical director, the nurse manager, medical director and chamber staff.

We observed how patients were being cared for and reviewed patients' clinical records. Prior to the announced inspection, we reviewed a range of information we had received from the service.

Facts and data about North of England Medical Hyperbaric Services Limited

The service is available 24 hours per day 365 days per year.

The chamber was a category 1 unit, as defined by the Cox report categories (The Faculty of Occupational Medicine, Cox report 1994) which meant facilities should be capable of receiving patients in any diagnostic category, who may need advanced life support either immediately or during Hyperbaric oxygen treatment. It was a multi-place chamber (space for more than one person at a time); there was space for seven people in two compartments. Staff could lock in and lock out of the chamber. It was equipped for staff to look after critically ill patients if required.

In 2014, an overall number of 114 patients were treated. This included 42 patients treated for decompression injury after diving, nine other non-diving emergencies, and 63 elective patients. The number of treatments carried out last year was 1863.

The most common elective treatments at NEMHS were for radiation tissue injuries, necrotising soft tissue infections, failing skin grafts, and other problem wounds.

Controlled drugs were not held or routinely used within the service. If they were required in an emergency, they could be obtained from the hospital within which the service is based. The matron of the hospital was the Controlled Drugs Accountable officer for this service.

The overall management structure of the unit consisted of the technical director, the medical director, (who was the consultant) and the nurse manager. Nine other staff were employed on a part time basis; these staff were dual trained in hyperbaric medicine as chamber operators (with technical skills to operate the chamber) and as chamber attendants (where they would stay in the chamber with patients for the duration of the treatment).

Are services safe?

Our findings

There had not been any serious incidents related to hyperbaric treatment in 2015. People were protected from avoidable harm and abuse.

Environmental audits commenced in August 2015 and were due to take place on a monthly basis. There was no other infection control information available from previous years.

Maintenance records indicated staff carried out checks on a daily basis. However, the resuscitation equipment inside the chamber such as the 'medic' bag and airway bag were checked on a monthly basis. We found records to be legible and concise. The consultant completed a pre-treatment assessment, and a basic nursing assessment was completed during this time.

We saw that mandatory training was out of date for several of the 10 staff. Staff records indicated one staff member had not completed advanced life support since 2006. This should be completed on a four yearly basis according to the Resuscitation Council. The British Hyperbaric Association (BHA) guidelines indicate a doctor should be "in the vicinity of the chamber"; we were told a doctor was never more than 10 minutes away.

Staff told us that children undergoing treatment were cared for during treatment by a registered children's nurse. NHS England states units must "ensure that children treated at the unit have their care overseen by a paediatric consultant". We did not find that this happened at NEMHS.

There was a potential service risk in relation to the medical support, especially out of hours, as it was delivered primarily by one doctor (the medical director) with the assistance of two other doctors on the rare occasion the medical director was not available.

Incidents

- There had not been any serious incidents related to hyperbaric treatment in 2015. Staff told us an accident book was in use to record incidents.
- There had been an incident in 2014 when a staff member got chemicals in their eyes when changing a scrubber canister. (Scrubber canisters were in use to filter carbon dioxide from the air inside the chamber). The incident was reported and the staff member appropriately treated. Staff told us eye protection was available to use but it was not clear if this was worn at the time. Staff told us they had learned from this event by verbal reminders to wear eye protection.
- Staff reported a further incident in 2014 when a patient suffered minor ear trauma because of pressure. This was one of the possible consequences of hyperbaric treatment and was reported appropriately.
- The incident reporting policy indicated the nurse manager and technical director were responsible for reviewing any incidents.
- We did not find evidence of investigations after something went wrong. Lessons were learned as staff were communicated with verbally when they next came to work and actions agreed.

Duty of Candour

- The incident reporting policy did not include any reference to duty of candour.
- Staff told us they were aware of the need to be open and honest with patients if something went wrong.

Cleanliness, infection control and hygiene

- There had been no incidence of a healthcare infection in the 12 months before our inspection.
- The room and chamber looked visibly clean.
- Environmental audits commenced in August 2015 and were due to take place on a monthly basis. Hence, it was not possible to determine if staff would be made aware of monthly audit results, as only one audit had taken place just before our inspection. There was no other infection control information available from previous years.
- We looked at the weekly, fortnightly, monthly and quarterly cleaning schedules of the environment and equipment and saw these records were up to date. Staff cleaned chairs in the chamber at the end of each day. Equipment was cleaned on a fortnightly, monthly or quarterly basis dependent on its use. For example, the main locks on both scrubbers were emptied, cleaned and refilled each fortnight.
- Exhaust valves were sent to a third party for ultrasonic cleaning. Floor plates were lifted every quarter to enable cleaning to take place.
- Hoods were labelled with the patient's name, and kept for the duration of their treatment. After treatment was complete, the hoods were sent for sterilisation and the oxygen tubing was disposed of.

Are services safe?

- We noted storage of staff bags and belongings under the floor plates. After our inspection, the technical director told us this was "perfectly acceptable".

Environment and equipment

- The chamber was situated in a room off a main hospital corridor. There were lockers for patients to store valuables. Toilets and dining facilities were situated nearby within the main hospital.
- The chamber was well lit; there was emergency generator back up. There were small porthole windows to reduce the feeling of claustrophobia.
- There was two-way communications into and from the chamber via speakers which were used throughout treatment. The chamber operator monitored patients via windows and close circuit television (CCTV).
- We saw valid public and employers liability insurance certificates, which were bespoke for the unit. Fire prevention certificates were included in the overall fire plan of the hospital, and were issued in April 2014 following assessment.
- The maintenance records indicated staff carried out checks on a daily basis, for example the oxygen and carbon dioxide levels within the chamber.
- An appraisal by the British Hyperbaric Association (BHA) in April 2014 noted there were no specific checks in place to prevent delivery of oxygen deeper than 18m. We spoke with staff about this and they told us alarms had been subsequently fitted to alert them to this.
- The resuscitation equipment inside the chamber such as the 'medic' bag and airway bag were checked on a monthly basis. We did not see a risk assessment to indicate the reason for monthly checking. The Resuscitation Council (UK) recommends the frequency of equipment checks will depend upon local circumstances but should be at least weekly.
- Other emergency equipment for intravenous infusions and emergency chest drains were not kept in the unit but were available from the critical care unit nearby within the hospital.
- Staff told us emergency equipment inside the chamber, such as the ventilator and defibrillator, was suitable for use under high air pressure.
- We were shown up to date service schedules for the mechanical aspects of the chamber. A third party company was responsible for the maintenance of the chamber; the technical director and provider was the managing director of that approved company.

Medicines

- Staff told us that medicines were not stored within the unit; if any drugs were needed in an emergency, they would be obtained from the ward or critical care unit next door.
- The consultant told us that oxygen was not prescribed using a standard prescription sheet. We saw in patient records that the "Marx treatment protocol" was documented for elective patients. (This is a widely accepted and documented indication for hyperbaric oxygen in chronic radiation injury, developed by Marx, 1985)
- The oxygen protocol used for diving decompression injury is known as 'Table 6'. This was developed by the United States Navy, and is used worldwide as a guide for decompression after diving.
- We observed oxygen treatment recorded on individual log sheets.
- An appraisal by the BHA in April 2014 found the ambient oxygen levels in the chamber were too high at 24%. They recommended reducing the levels to 22.5% to minimise the risk of fire, which was done. Staff told us the ambient levels were usually 20-21% and some oxygen leakage was inevitable during treatment sessions. This could happen when patients removed their hoods to have a break half way through treatment. An alarm would sound if the oxygen levels exceeded 24%. We saw oxygen monitors outside and inside the chamber.

Records

- There was an up to date 'Information lifecycle management and patient records' policy (August 2015). This meant staff were able to follow up to date directions.
- The BHA appraisal in 2014 noted the security of medical records could be improved. Patient records had been kept in the hyperbaric unit inside a locked cupboard, action had been taken and a key safe had been installed to keep the key separate. In-patient notes were kept on the ward next door.
- We saw the elective patient pathway contained a description of Caldicott and information governance information which helped inform staff of the requirements. We were told the technical director was

the Caldicott guardian for the unit. (A Caldicott guardian is a senior person responsible for protecting the confidentiality of patient and information and enabling appropriate information-sharing).

- We were shown electronic patient records which were securely accessed by unique staff log in.
- Staff collated anonymous patient data and sent this electronically to NHS England. This data included a record of the number of treatment sessions and utilisation of the chamber. This was used to record use of the chamber and therapeutic treatment of patients.
- We looked at 11 paper patient records. These were legible and concise. There was a pre-treatment assessment completed by the consultant. A basic nursing assessment was completed during the pre-assessment visit and an outpatient care plan recorded for each patient at each treatment session.
- We found evidence of on-going assessment and patient reassurance in records.
- Staff maintained a comprehensive treatment log for each patient; this included the planned number of sessions, the oxygen level they had received, the length of treatment and which protocol had been used.
- We did not see any 'do not attempt cardio pulmonary resuscitation' (DNACPR) forms in the records. It was not known how DNACPR decisions were communicated by referrers such as GP's or hospital consultants.

Safeguarding

- We saw an up to date safeguarding children policy, which had been written by a registered children's nurse. There was a policy for the protection of vulnerable adults. This had been written by the nurse manager and verified by the technical director who was the units safeguarding manager.
- Staff told us of safeguarding alerts they had done; for example, when a child sustained a decompression diving injury.
- Three staff out of 10 were overdue vulnerable adults training and two staff were overdue safeguarding children training. There were 88% of staff trained in safeguarding children level 2. Information given to us before the inspection showed one person was trained to safeguarding children level 3, but it was not clear what position this person held.

Mandatory training

- Staff were expected to complete mandatory training in their substantive posts. The nurse manager kept records of when mandatory training was due or completed by staff. The unit did not have targets for completion of mandatory training.
- We saw that mandatory training was out of date for several of the 10 staff. For example, Fire training was out of date for nine staff; moving and handling training was out of date for eight staff; five staff were overdue information governance training. Four staff were overdue mental capacity act training;
- Staff records indicated one staff member had not completed advanced life support since 2006. This should be completed on a four yearly basis according to the Resuscitation Council.
- The nurse manager told us the unit did not provide mandatory training or registration checks for the staff. They were expected to complete this in their other place of work and inform the hyperbaric unit manager when this was done.

Assessing and responding to patient risk

- We were given a risk assessment index which included several potential risks associated with treatment; for example oxygen toxicity, convulsions, unconsciousness, confusion, ear/ sinus pain, transient eye disturbance, cross infection, perforated eardrum, nose bleeds, pneumothorax, and cardiac arrest. However, no evidence was provided as to how these risks would be mitigated or managed.
- The consultant and nurse manager reviewed elective patients in a scheduled pre-assessment clinic. This included recording medical and basic social history. The nurse manager and consultant told patients of the risks associated with treatment. Pre-admission testing took place as indicated by NICE guidance. This included MRSA screening and eyesight evaluation.
- Staff informed patients that eye problems returned to a pre-treatment state usually after three months. The BHA audit of 2014 noted the elective patient pathway described how to monitor eyesight. There was a recommendation to add further information regarding the time, 'trigger' points and supervision of fitness to drive to the eyesight monitoring protocol. The provider decided not to do act on this recommendation, as it was felt they could advise patients on an individual basis.

Are services safe?

- Staff told us NHS England, as commissioners of the service, required a report from the unit about eyesight problems sustained by patients. Staff told us this had not been done by the time of our inspection, but it was unclear when it was requested.
- The BHA guidelines indicate discharge planning should begin at pre assessment, especially for patients who require follow on care. We did not see any evidence of discharge planning, however the patients we saw receiving treatment were all out patients and seemed to be independent.
- Staff told us patients were able to take a five-minute break inside the chamber, remove their hoods and have a drink during the two-hour session. This helped to minimise the risk of oxygen toxicity.
- The BHA guidelines indicate a doctor should be "in the vicinity of the chamber". We spoke with the consultant about this. They told us a doctor was never more than 10 minutes away. They said patients reach a 'depth' of nine metres after 15- 30 minutes and a doctor would not be present unless there was an unexpected emergency. The resident medical officer of the Spire hospital would be called in this situation.
- Staff told us about 40 patients a year received emergency treatment.
- The children's nurse showed us a comprehensive risk assessment and plan for children who require treatment.
- We observed BHA guidelines being followed. For example, according to guidelines, patients may not start treatment without appropriate consultant assessment; during our inspection a patient was referred for emergency treatment, we were told the nurse manager and consultant would go to assess the patient (who was in a nearby hospital) the next morning.
- The consultant told us if there was an emergency which involved a ventilated patient, an anaesthetist would be "immediately available", however, they may be in theatre at the hospital.

Nursing and other staffing

- There were 10 staff including the nurse manager employed on a part time basis. They came from a variety of backgrounds including critical care nursing, operating department practitioners, paramedics and anaesthetic practitioners. The staff were all trained to both operate the chamber or attend patients during treatment.
- There was a 'bank' of four staff that could be called upon to work extra shifts. Staff showed us information which showed 33 extra bank shifts had been worked over the three months prior to our inspection.
- Staff told us there was usually three staff on duty each day. During our inspection there were three plus one on the Monday, three staff on Tuesday, four plus one on Wednesday, (this was the day the team were expecting CQC). For the remainder of the week and all the next week three staff were planned for each day.
- There had been a high rate of sickness (14.1%) for the three months preceding our visit: this was predominantly from one person being not available for work for this period. Staff told us that children undergoing treatment were cared for during treatment by a registered children's nurse who was on the bank staff.
- Three staff were planned for each session. Staff told us this was to mitigate against emergency situations.

Medical staffing

- There was one anaesthetic consultant who also was in the role of medical director who worked at the unit. They were not employed by the service but were paid on a case-by-case basis.
- While there were three doctors named on the BHA appraisal of 2014, but there were no human resources (HR) records or contracts regarding these staff.
- The consultant told us they provided out of hours cover. When we asked about cover for holidays, the consultant told us they did not take holidays. The consultant told us they could respond "quickly" in the case of an emergency as they lived nearby. They said they were contactable 24 hours a day and the resident medical officer of Spire hospital could ring them at any time.
- The consultant was a trained anaesthetist and worked at a nearby hospitals. We asked about the possibility of the consultant having to leave his other duties in order to respond to a hyperbaric emergency. We were told the other hospitals were "very understanding".

Are services safe?

- The consultant told us it was unlikely another doctor would be called upon, and it had never been necessary to do so. We were told in a 'dire' emergency, the consultant neurologist from Spire hospital would be called upon.
- The consultant told us he saw the patients in pre-assessment, but not again after that as they were treated on an out- patient basis.
- The European code of good practice for HBOT therapy indicates during any session a hyperbaric physician forms part of the minimum team for multiplace chambers (European code of good practice for hyperbaric oxygen therapy, 3.3). This code of practice indicates "During any session the functions involved are:

Supervision of the treatment (medical aspect and safety of operations)".

- The code states "The location of the individual members of the minimum team is the responsibility of either the duty physician or duty supervisor, however the whole nominated team should remain in the facility and immediately available". We were not assured the doctor would be immediately available at this hyperbaric unit.
- NHS England states units must "ensure that children treated at the unit have their care overseen by a paediatric consultant". We did not find that this happened at North of England medical hyperbaric services.

Major incident awareness and training

- The nurse manger wrote an 'Emergency preparedness and resilience policy' in August 2015. This was in the form of a statement rather than a full policy.
- The BHA appraisal of 2014 noted the operations manual lacked bailout advice and guidance. We checked the manual but it was not clear if this had been updated. We saw there was a shutdown protocol for evacuation in the event of an emergency.
- During the week of our inspection there was a major power failure within the Spire hospital; the unit were asked not to take patients for one day. Staff told us no patients were disadvantaged because of this.
- There were back-up generators in the event of a power failure during treatment.
- The technical director told us staff were trained in annual deluge and fire hose simulation. Practice drills were carried out on a regular basis in order for staff to be ready to use them if it became necessary. Information provided to us before the inspection showed that two staff members were overdue this training which had expired in June 2015 for one staff member and February 2015 for the other.
- Other information provided to us showed seven of the chamber staff were overdue annual fire training. Fire training for three staff members had expired in January, seven months before our inspection. One staff members training had expired in March 2014.
- The BHA appraisal in 2014 noted more detail was required for three potential emergency situations. These were a fire in the chamber, a fire in the building and loss of communications. We checked the operations manual but it was not clear if extra detail had been added.

Are services effective?

Our findings

The unit opened routinely five days a week between 9pm and 5pm and provided two, two-hour elective treatment sessions each day. There was seven day, 24 hour availability for emergency treatment. As a category 1 facility, ventilated patients could be accommodated and staff told us sedated, ventilated patients would be overseen by a trained anaesthetist. The technical director told us as a member of the British Hyperbaric Association, the unit complied with standards such as the Health and Safety at Work Act, and the Diving at Work regulations.

All of the chamber attendants or chamber operators were professionals who worked in a variety of other roles on a part time basis. Staff completed external training before acting as chamber operators and attendants. The technical director told us they were assured of staff competency as most had worked there for 10 years. Two staff had expired disclosure and barring (DBS) checks, they expired in November 2014 (these should be renewed every 10 years). We found the service did not actively monitor patients' outcomes beyond the minimum requirement for submission to NHS England. They were not using information to further develop the service.

There was no appraisal and performance review process. The provider told us these were not formalised as they all worked closely together and saw each other every day. We found there were no arrangements for clinical supervision, one to one meetings or appraisals of any staff.

The technical director told us peer reviewed literature was used to benchmark the treatment given by staff at the unit. The consultant confirmed this approach and told us that staff do not benchmark on a national or local level, as they were part of a close network of hyperbaric oxygen treatment providers and the treatment was the same worldwide. Staff told us there was no written process for time to treatment targets for elective patients. They said the average time after referral was about two months.

We saw recent audits, which had all been carried out for the first time just before our inspection. The consent policy did not indicate who would carry out a capacity assessment in the event of a patient needing one. There was no reference to Deprivation of Liberty Safeguards (DOLS) in the policy.

- In order to be a member of the BHA the unit had to comply with standards such as the Health and Safety at Work Act, and the Diving at Work regulations.
- We were told peer reviewed literature was used to benchmark the treatment given by staff at the unit. They said care was "protocol driven" from both the Royal Navy and United States Navy. The treatment 'tables' used were underpinned by recognised international diving guidance.
- The consultant confirmed this approach and told us "our practices don't change due to the nature of our work", that staff do not benchmark on a national or local level, as they were part of a close network of hyperbaric oxygen treatment providers and the treatment was the same worldwide.
- NHS England commissioned the service to treat diabetic foot ulcers. NICE recommends hyperbaric oxygen treatment is not used to treat such wounds unless this forms part of a clinical trial (NICE recommendation 55). Staff told us diabetic foot ulcers could be classed as 'problem wounds', which could meet NICE guidance.
- Staff told us there was no written process for time to treatment targets for elective patients. They said the average time after referral was about two months.
- There was no set response time for emergency treatment. Senior staff told us literature suggested divers respond better the sooner they were treated for decompression injury.
- We found the unit did not follow evidence-based care in relation to children having their care overseen by a paediatric consultant.
- As a category 1 facility, ventilated patients could be accommodated and staff told us sedated, ventilated patients would be overseen by a trained anaesthetist.
- We found the service did not actively monitor patients' outcomes beyond the minimum requirement for submission to NHS England.
- We saw there was no process to audit the effectiveness of any policies.
- Staff showed us results of recent audits. These had all been carried out for the first time just before our inspection. These included documentation, infection control, records and an environmental audit; 100% was achieved for all of these. The nurse manager who wrote the policies carried out the audits; a peer audit did not take place.

Evidence-based care and treatment

Are services effective?

- Staff told us the BHA planned to carry out an audit every three years. We noted the BHA appraisal in 2014 did not comment that the hyperbaric unit did not have an audit programme. BHA guidelines indicate a 'rolling programme' of audit should be in place.
- Staff told us they had witnessed significant wound healing but there was no audit of the effectiveness of treatment.
- The unit submitted data to NHS England as part of two clinical audits for 'patent foramen ovale' and diving compression injury treatment. This was required as part of the commissioning process.
- Staff followed NICE risk guidelines in caring for patients who needed closure of 'patent foramen ovale'. This is a heart defect that creates a passage in a wall that normally separates the left and right upper chambers of the heart. If gas bubbles form after diving, the bubbles are carried to the right side of the heart. In divers with 'patent foramen ovale', the bubbles could pass through the opening, bypassing the lungs. This contributes to the risk of decompression injury. NEMHS referred such patients to a cardiology specialist.
- The nurse manager told us some inpatients remain under the care of the hyperbaric staff. This included patients who have attempted suicide by carbon monoxide poisoning. After treatment, Hyperbaric Oxygen Treatment staff remained with the patient on the ward and monitored them closely for several hours until they were either transferred to another care facility or discharged.

Nutrition and hydration

- Staff told us patients were able to take a cold drink into the chamber with them to have during the break in treatment. One patient told us it would be nice if they could have warm drinks at this time.
- There were no facilities inside the room to give patients food or drink. Patients could obtain these from the hospital restaurant within the same building.

Pain relief

- As the majority of patients were elective, they brought their own pain relief in to the unit with them. Their property was in a locker during treatment so keys would have to be passed via the airlock for staff to obtain them if required.
- None of the patients we spoke with had required pain relief during treatment. One patient told us they had experienced pain in their ears. They told us staff paused the pressure increase and reminded them how to relieve the pressure in their ears.

Patient outcomes

- Staff told us they submitted outcome data on both a quarterly and annual basis to NHS England and to the BHA.
- The standard contract for NHS England required the unit to comply with key generic outcome measures. These included:
  - compliance with national access and time to treatment targets (staff told us there were no set targets);
  - contribution to and compliance with national audits and guidelines including NICE guidelines;
  - pre and post treatment quality of life measures, (staff told us patients were invited to complete a quality of life questionnaire before treatment and three months after treatment);
  - the percentage of divers returning to a pre morbid state;
  - the average time from referral to treatment;
  - the percentage of patients who felt information was adequate and they felt safe.
- We saw patients fitting their own neck collars, hoods and tubing inside the chamber. Staff inside the chamber checked to make sure the hoods were fitted securely. (Oxygen was given through a clear plastic hood that has a rubber seal at the neck. The process allowed oxygen to be absorbed by all body cells and tissues, even those with blocked or reduced blood flow. The increased flow of oxygen stimulated function to damaged cells and organs).
- We saw that the unit complied with key service outcomes, for example, a dashboard of treatment schedules was maintained. Compliance was demonstrated in other ways including patients being kept informed about reasons for treatment.
- Staff told us in an emergency the timescales for 'time to treat' patients may be prolonged due to factors entirely outside of the unit's control.
- The consultant sent a discharge letter to each patient's GP with a summary of the treatment they had received.

Are services effective?

- The consultant told us patients were referred to an ear, nose and throat (ENT) specialist if pressure related ear problems continue after treatment has stopped.

Competent staff

- All of the chamber attendants or chamber operators were professionals who worked in a variety of other roles on a part time basis. Their backgrounds included critical care, operating department practitioners, paramedics and anaesthetic practitioners.
- Staff completed external training before acting as chamber operators and attendants.
- The nurse manager had worked at the unit for nine years, and had been the manager for six years. They worked at the unit four days a week and at a critical care unit one day a week.
- Staff told us when a new team member began work at the unit they work through an induction workbook. There was no set date for completion of this, as the number of sessions worked each week varied, staff who worked three days a week could potentially become competent more quickly than those who worked less days.
- The nurse manager told us competencies were not rechecked as a routine process, as procedures did not change. There was no way to identify if staff skills had changed. (An exception to this was if a staff member was away from work for an extended time they had a revised induction period).
- The technical director told us they were assured of staff competency as most had worked there for 10 years and been closely observed.
- Staff told us they had opportunities to attend relevant conferences or learning events.
- Chamber staff had an annual 'dive medical' to ensure they were fit to work inside the chamber. The dive medical for one staff member expired in November 2014.
- We saw information provided by the unit prior to our inspection showed two of the ten staff had expired professional registration, this ran out in August 2014. After our inspection, senior staff told us the information they had provided was inaccurate and staff always had in date professional registration. Two staff had expired disclosure and barring checks, they expired in November 2014 (these should be renewed every 10 years).
- The consultant told us they did not go into the chamber so did not need to be dive trained, nor have a diving medical.
- The consultant told us they kept their own patient records as part of the General Medical Council (GMC) medical appraisal process.
- We found BHA guidelines were not followed in the case of written medical designated responsibilities for a hyperbaric unit. The consultant told us it was not necessary to have written responsibilities, as they were the only doctor. We had a discussion with the registered children's nurse and it was clear they could demonstrate knowledge and competence.

Appraisals and clinical supervision

- The technical director told us they were responsible for the performance of the nurse manager and consultant. However, there was no process for appraisal and performance review to take place. The technical director told us this was not necessary as they all worked closely together and saw each other every day.
- We found there were no arrangements for clinical supervision, one to one meetings or appraisals of any staff.
- None of the staff had had an appraisal: information sent to us by the unit before our inspection showed 100% of chamber staff appraisals were "pending".

Multidisciplinary working

- We were told of multidisciplinary working with other services within Spire hospital such as cardiology, psychiatric services and the 'Embrace' specialist children's transport team.
- We observed positive multidisciplinary working with ambulance crews.

Seven-day services

- The unit opened routinely five days a week between 9pm and 5pm and provided two, two-hour elective treatment sessions each day.
- There was seven day, 24 hour availability for emergency treatment.
- Supporting diagnostic services such as X ray or CT scans were available on site through the Spire hospital.
- Cover was arranged by a system of availability, there was no on call rota.

Are services effective?

- In the event of an out of hours emergency, the Spire hospital ward staff contacted either the consultant, nurse manager or designated other person.
- The registered children's nurse arranged emergency paediatric treatment. They told us if they were not available, the child would have to go to a different treatment centre.

Access to information

- There were electronic patient records which were securely accessed by unique staff log in.
- Additionally paper records were used to record care and treatment of patients and these were readily accessible to staff.

Consent, Mental Capacity Act and Deprivation of Liberty Safeguards

- The nurse manager wrote a consent policy in August 2015. The policy included reference to the Mental Capacity Act.
- The policy did not indicate who would carry out a capacity assessment in the event of a patient needing one. There may be rare instances when patients who have attempted suicide by carbon monoxide poisoning either lack capacity and/ or may decline treatment.
- The policy stated if there was any doubt a patient lacked capacity, the legal department should be contacted. We found this an inappropriate measure as capacity assessments should be carried out by a clinician or social worker. The policy did not indicate that best interest decisions would be made in an emergency.
- There was no reference to Deprivation of Liberty Safeguards (DOLS) in the policy, nor who would complete a DOLS authorisation form. The nurse manager told us staff would refer to the safeguarding trainer or Spire hospital matron if they had queries about DOLS.
- Senior staff obtained verbal and written consent for treatment in pre assessment clinic.

Are services caring?

Our findings

We found the staff at the hyperbaric unit to be compassionate and caring. We observed staff and patients interacting positively together before, during and after treatment.

Staff spoke about patients in a sensitive manner. They built up a relationship with patients over the course of treatment and learned more about them as individuals. We found this enabled staff to give supportive, holistic care and to advocate for patients.

We spoke with four patients who said staff were compassionate, looked after all their needs and nothing was too much trouble. Patients told us of situations where staff had helped patients obtain professional support during a period of bereavement. We saw staff had empathy and were aware of the whole care experience for patients, not just their hyperbaric treatment in isolation.

Compassionate care

- We found the staff at the hyperbaric unit to be compassionate and caring. We observed staff and patients interacting positively together before, during and after treatment.
- Staff spoke about patients in a sensitive manner. They built up a relationship with patients over the course of treatment and learned more about them as individuals. We found this enabled staff to give supportive, holistic care and to advocate for patients.
- We spoke with four patients on a face-to-face basis. They told us staff were compassionate, looked after all their needs and nothing was too much trouble.
- Comments we heard from patients included “All the staff are kind and experts in what they do” and “This is very calm and caring after some of the NHS places I have been to”.
- We were shown patient feedback forms and noted the following comment; ‘It was a delight and tremendous relief to be looked after so professionally, meticulously and competently in quite worrying circumstances. In my view… a fantastic team of caring and motivated individuals. Cannot think of a single way my treatment could have been improved and I feel lucky to have landed in their hands’.

Understanding and involvement of patients and those close to them

- Senior staff told us patient surveys were completed and sent to NHS England. The unit had received very positive comments.
- Patients told us staff were approachable and would make time to explain anything to them.
- We saw that staff recognised when patients needed additional support. Patients told us of situations where staff from the unit contacted other health professionals on patients behalf to clarify appointments in other services. One patient told us staff had helped them with housing issues.

Emotional support

- Patients told us of situations where staff had helped patients obtain professional support during a period of bereavement. Another patient told us staff had helped them to gain confidence in asking for food to be puréed when dining out.
- We saw staff had empathy and were aware of the whole care experience for patients, not just their hyperbaric treatment in isolation.

Are services responsive?

Our findings

Hyperbaric facilities are few in number in England. There was therefore a potential inequality in the distance a patient would need to travel for treatment; however this was related to nationally commissioned services and not the provider.

The timing of the morning and afternoon sessions provided flexibility for elective patients. Staff told us the average wait from referral to treatment was two months. We found this to be longer than some other hyperbaric units. Staff told us they were committed to ensuring patients were treated fairly and equally regardless of their circumstances.

We found emergency access to the service was good. Staff could be called in and the unit opened within an hour.

Service planning and delivery to meet the needs of local people

- Hyperbaric facilities are few in number in England. There was therefore a potential inequality in the distance a patient would need to travel for treatment, however this was related to nationally commissioned services and not the provider. Hyperbaric units are typically located close to areas where cases of decompression illness were more prevalent as in the case for the North of England unit.
- The unit was located near the coast and as such responded to diving emergencies. Patients were also referred from hospitals and other care providers in the North of England. There was a large 'catchment' area but most patients were within one to two hours' drive from the unit. Staff told us patients and relatives sometimes stayed in nearby guesthouses to reduce travelling.
- The timing of the morning and afternoon sessions meant that most patients did not have to set off very early or return home late. There was flexibility for elective patients to attend either a morning or afternoon session on weekdays.
- The company owned a multi person vehicle and a driver was employed to provide dedicated transport for some patients. Staff told us this helped with treatment compliance and supported patients.
- The unit opened routinely five days a week between 9pm and 5pm and provided two, two-hour elective treatment sessions each day.
- There was seven day, 24 hour availability for emergency treatment.

Access and flow

- We found emergency access to the service was good. Staff could be called in and the unit opened within an hour.
- Staff told us the average wait from referral to treatment was two months. We found this to be longer than some other hyperbaric units which employ more staff and hence more treatment sessions. The average wait for treatment in another such unit was two weeks.
- Staff told us treatments were rarely cancelled or rearranged. During the week of our visit, there has been a major power failure at the hospital and the hyperbaric staff were asked not to take patients for one day. We were told no patients were disadvantaged; another session would be planned for them.
- We were told critically ill patients would be repatriated after treatment to an appropriate care facility via ambulance. Appropriately qualified professionals from the unit would support them during the transfer.

Meeting people's individual needs

- There was no waiting area for patients, a two seater wooden bench was provided. Patients told us it did not affect their care as they waited in the hospital dining room until the treatment session was due to begin.
- Space was limited inside the chamber. Seats were removable to enable space for a trolley or bariatric wheelchair.
- There was a small 'lip' at the entrance, which could act as a trip hazard for less able patients.
- The second smaller chamber was accessible via an air lock, through which staff or patients had to step if they needed to go in. There was a portable toilet in the smaller chamber and staff could pass items in or out of the chamber via a smaller air lock.
- Staff told us if necessary, they would carry out an extra daily treatment sessions to meet the needs of individuals, for example patients with a learning disability. Patients with hearing loss had to remove hearing aids before treatment (because of the fire risk with battery-operated items), so staff were used to finding ways to support communication, such as writing on paper during treatment.

Are services responsive?

- Staff told us parents could go into the chamber with children who were being treated, and carers could accompany patients if necessary.
- Staff told us about the work they had done to meet the needs of claustrophobic patients. Visits to the chamber could take place before treatment, and patients could go in and out of the chamber with the door open to increase their tolerance of the space.
- There was a newly written equality and diversity policy, which contained the nine protected characteristics of the equality act. These included age, disability, sexual orientation, race, and religion or belief. Staff told us they were committed to ensuring patients were treated fairly and equally regardless of their circumstances.
- We saw the consent policy included reference to obtaining professional interpreters for patients whose first language was not English.
- Emergency paediatric treatment was arranged with the registered children's nurse. They told us if they were not available for the duration of the treatment, the child would have to go to a different treatment centre.
- One staff member told us they took a holistic approach and considered other risks to patients. For example if a patient had a problem wound, staff would ensure the patient had pressure-relieving equipment at home.
- We noted there was a very basic website, which did not provide any information about treatment, opening times, contact numbers or other patient information.
- Staff told us patients were given written information at the pre assessment visit. We learned that the leaflets were only available in English.
- We observed toys and games to help children undergoing treatment. Magnetic pictures were stuck to the inside of the chamber and pictures were placed on windows to make the experience friendlier for children.
- There was an agreement with the Spire hospital in the event of patients requiring acute care or diagnostic services, the two organisations would co-operate for the benefit of the patient.
- After treatment for diving injury, patients received discharge information which included contact details for the unit should any concerns arise. They were also given advice regarding treatment they received, and advice on symptoms to be aware of following treatment

Learning from complaints and concerns

- Before our inspection, we saw the unit had a draft complaints flowchart. There were no timescales included for responses to complainants.
- We did not see any patient information displayed near or in the unit, which would inform patients how to make a complaint if they chose to do so.
- We noted the unit had not received any complaints in 2014, but did not have a ratified process for ensuring any complaints could be dealt with satisfactorily.
- It was not possible to tell if learning from complaints or concerns could take place.

Are services well-led?

Our findings

The leadership, governance and culture did not always support the delivery of high quality person centred care.

We found there was no clear vision or set of values for the North of England Hyperbaric Medical Services. This meant staff might not understand their role in achieving the vison for the service, and there was no way to monitor progress towards delivering any goals. The provider told us there was no need for a written strategy as staff demonstrated the values by the work carried out.

We found no performance framework to identify, assess, monitor, and respond to performance issues. Staff told us they did not receive an annual appraisal. There were no staff surveys, staff meetings or ways the staff could be involved in developing the service.

There was a small team at the unit and the chamber staff seemed to work well together. We found the technical director and nurse manager to be knowledgeable and skilled. They had positive attitudes towards good quality care. Both the technical director and nurse manager were visible and approachable.

The technical director told us there was "informal management" of staff. There was no specific job description or set responsibility for the consultant. The British Hyperbaric Association (BHA) guidelines state there should be a written structure of responsibility for medical staff members. The technical director told us there were no formal management meetings or a clinical governance process as the three senior staff saw each other very frequently and communicated by email and telephone. The BHA had appraised the service, a small number of areas were not complaint with BHA guidelines.

We noted almost all the clinical policies had been written the month before our inspection. As the management structure was small, the nurse manager wrote all the new policies and the technical director approved them. There was no way to audit the effectiveness of any policies, nor report this back to staff or patients.

Vision and strategy

- We found there was no clear vision or set of values for North of England Hyperbaric Medical Services. This meant staff might not have understood their role in achieving the vison for the service, and there was no way to monitor progress towards delivering any goals. No SMART (specific, measurable, achievable, realistic, timely) targets were set.
- The provider told us there was no need for a written strategy as staff demonstrated the values by the work carried out.

Governance, risk management and quality measurement

- We found no performance framework to identify, assess, monitor, and respond to performance issues. Performance management allows actions to be taken which help achieve aims of a service. Performance can be aligned to corporate priorities, and in turn improve services and outcomes for patients.
- There was no specific job description or set responsibility for the consultant. We were told it was not necessary, as they were the only permanent doctor. The BHA guidelines state there should be a written structure of responsibility for medical staff members.
- The BHA appraisal audit in April 2014 found "a potential service risk in their medical support", as it was delivered primarily by the medical director with the assistance of two other doctors on the rare occasion the medical director was not available.
- The provider did not have formal management meetings or a clinical governance process as the three senior staff saw each other very frequently and communicated by email and telephone. The senior team told us they felt arrangements were satisfactory, and noted if they felt the need for a more structured meeting in the future this would be addressed.
- Senior staff told us there were links to the medical advisory committee of Spire hospital, but found no evidence of discussion related to hyperbaric services in documents shown to us.
- The BHA guidelines state hyperbaric services should have a robust clinical governance structure in place.
- We noted almost all the clinical policies had been written the month before our inspection. As the management structure was small, the nurse manager wrote all the new policies and the technical director approved them. There was no way to audit the effectiveness of any policies, nor report this back to staff or patients.

Are services well-led?

- We saw the development plan for 2014-2018 produced following the BHA appraisal visit in 2014. There were 18 points for action, which included changing text and descriptions in the elective patient pathway. The majority of which were completed at the time or our inspection.
- Senior staff had made the decision not to act on two of these action points. These were firstly adding information about "trigger points and supervision of fitness to drive to the eyesight monitoring protocol". The second point was "adding specific details about ear equalisation training to elective patient pathway". Senior staff documented they would be able to advise patients on an individual basis and use the patient information leaflet.
- Hyperbaric services in England are few in number and the BHA was made up of a network of colleagues who worked in hyperbaric units. The service was a member of the BHA, which appraised them each three years. The technical director was on the project board of the BHA and the consultant was a member of the BHA clinical reference group. The BHA audit of 2014 did not pick up that the service had no clinical audit programme.
- The technical director had a number of roles including, the managing director of the third party company who maintained the chamber, treasurer of BHA, the safeguarding manager and acted as the Caldicott guardian for the hyperbaric service. We were not assured the potential for managing any conflicts of interest was robust.

Leadership

- We found the technical director and nurse manager to be knowledgeable and skilled. They had positive attitudes towards good quality care.
- Both the technical director and nurse manager were visible and approachable.
- The technical director told us there was "informal management" of staff.
- Whilst we found it appropriate that staff informed the nurse manager when they had completed mandatory training in their other employment, we found a lack of formal human resource (HR) processes including professional registration of staff.

Culture within the service

- There was a small team at the unit and the chamber staff seemed to work well together.
- Staff seemed surprised when we asked them if they felt valued. They did not appear to have considered this. They told us there was a strong culture of promoting safety.
- Patients told us they felt at the heart of the service and we found a friendly culture in the workplace.
- We found that the senior staff had a close, informal working relationship and had worked together for a number of years; this close relationship may have reduced the opportunity for challenge and scrutiny of decisions.

Public engagement

- Patients were encouraged to complete a survey after their treatment. Staff collated results were sent them to NHS England.
- Senior staff told us patients contacted them by phone or in writing, but there was no 'formal' way for patients to provide views of the service, for example via the website or participating in patient engagement meetings.

Staff engagement

- Staff told us they did not receive an annual appraisal. There were no staff surveys, staff meetings or ways the staff could be involved in developing the service.
- One staff member told us there was a communication book, but only three people used it. They told us the team was small and this resulted in "a lot being assumed".

Innovation, improvement and sustainability

- The technical director told us it was more difficult to plan for sustaining the service due to the 12-month block contract arrangements with NHS England.
- The unit had been involved in research programmes with the Royal Marsden Hospital and Hull University, including the Hyperbaric Oxygen for the Prevention of Osteoradionecrosis Trial. This was a research programme looking at ways to use hyperbaric oxygen to prevent jawbone damage in head and neck cancer. Other research undertaken looked at the use of high-pressure oxygen for radiotherapy side effects (the HOT II Trial).
- The technical director told us they hoped to develop their service in line with the coastguard maritime

Are services well-led?

contract changes. Helicopters would be used for long-range rescue of divers and the director was considering innovative use of a transportable hyperbaric chamber as part of a rescue service.

Outstanding practice and areas for improvement

Areas for improvement

Action the hospital MUST take to improve

- The provider must ensure that duty of candour is incorporated in to appropriate policies and procedures and staff have an awareness of it.
- The provider must follow recognised guidelines including the British Hyperbaric Association (BHA) guidelines and the European code of good practice for hyperbaric therapy and implement actions arising from the BHA audit including: having written medical designated responsibilities for the doctor and ensuring the potential risk of lack of formal on-site medical support/cover is mitigated;
- The provider must ensure all staff are up to date with appraisals, mandatory training, dive medicals, advanced life support training and Disclosure and Barring Service certificates are up to date.

Action the hospital SHOULD take to improve

- The provider should take action to ensure the emergency resuscitation equipment is checked on at least a weekly basis.
- The provider should take action to develop a strategy and vision for the service and involve the staff in this process.
- The provider should develop a performance framework to identify, assess, monitor, and respond to service and staff performance issues.
- Ensure a paediatric consultant oversees the hyperbaric treatment of children.

This section is primarily information for the provider

Requirement notices

Action we have told the provider to take

The table below shows the legal requirements that were not being met. The provider must send CQC a report that says what action they are going to take to meet these requirements.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 20 HSCA (RA) Regulations 2014 Duty of candour The incident reporting policy did not include any reference to duty of candour. The provider must: 1. ensure that duty of candour is incorporated in to appropriate policies and procedures and; 2. ensure staff have an awareness of it.

Regulated activity	Regulation
Treatment of disease, disorder or injury	Regulation 17 HSCA (RA) Regulations 2014 Good governance The provider was not acting on recognised guidelines specifically in relation to: no written medical designated responsibilities for the doctor and a lack of formal on-site medical support/cover. The provider must follow recognised guidelines including the British Hyperbaric Association (BHA) guidelines and the European code of good practice for hyperbaric therapy and implement actions arising from the BHA audit including: 1. having written medical designated responsibilities for the doctor and; 2. ensuring the potential risk of lack of formal on-site medical support/cover is mitigated.

Regulated activity	Regulation

This section is primarily information for the provider

Requirement notices

Treatment of disease, disorder or injury

Regulation 18 HSCA (RA) Regulations 2014 Staffing

There was no appraisal and performance review process for staff. Staff had not received appraisals, some training was overdue and there was a lack of evidence that all the appropriate checks were in place including Disclosure and Barring Service certificates.

The provider must ensure all staff are up to date with appraisals, mandatory training, dive medicals, advanced life support training and Disclosure and Barring Service certificates are up to date.