

NORCOM

North Derbyshire, South Yorkshire and Bassetlaw Commissioning Consortium

policy on HYPERBARIC OXYGEN THERAPY FOR PATIENTS WITH ORAL CANCER

Report commissioned by: NORCOM Priorities Process

On behalf of: Primary Care Trust's in the NORCOM area

Produced by: Rotherham Primary Care Trust

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CONFLICTS OF INTEREST

None

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ABBREVIATIONS

COPD	Chronic Obstructive Pulmonary Disease
HBO	Hyperbaric Oxygen Therapy
ORN	Osteoradionecrosis

DEFINITIONS

Barotrauma: Injury of certain organs due to a change in atmospheric or water pressure.

Brachytherapy: Delivery of radiation treatment from a source placed near to or within the tumor.

Congenital Spherocytosis: A chronic disorder characterized by a preponderance of spherical red cells (erythrocytes) in the blood leading to anaemia and enlargement of the spleen.

National Specialised Services Definition Set: A set of definitions produced by national working groups to clearly define specialised services. Number 28 defines hyperbaric treatment services for adults.

Osteoradionecrosis: The death of bone cells as a result of irradiation.

Photodynamic Therapy: Treatment with drugs that become active when exposed to light.

Teletherapy: Delivery of radiation treatment from a source placed at a distance from the body.

1. AIM OF PAPER

- 1.1. This paper presents the Commissioning Policy on hyperbaric oxygen therapy (HBO) for patients with oral cancer for Primary Care Trusts in the NORCOM area.

2. BACKGROUND

- 2.1. In May 2000, the Trent Institute Working Group on Acute Purchasing conducted a review of the use of HBO in the management of patients with oral cancer. The Working Group built on the work previously done in 1992 by the Centre for Health Services and Policy Research (Canada).
- 2.2. The objective of the review was to determine whether HBO:
 - was effective in the prevention and treatment of osteoradionecrosis (ORN).
 - was effective in promoting wound healing
 - used prior to the placement of endosseous implants improved implant survival rates
 - use could lead to real or notional NHS resource savings
- 2.3. The review concluded that, whilst the use of HBO in the treatment of ORN appears to be effective, the evidence suggests it may not be necessary for all patients. The evidence for prevention of ORN is unclear and support for HBO prior to the placement of endosseous implants limited.
- 2.4. It is three years since the review. This policy has been produced following re-examination of the evidence contained in the review and any subsequent new evidence.

3. ORAL CANCER

- 3.1. Oral cancer is defined by ICD10 codes C00 (lip), C02 (tongue), C03 (gum), C05 (hard palate) and C06 (floor of the mouth and other unspecified areas).
- 3.2. It is a disease that becomes more common with age, showing a sharp rise in incidence after the age of 40.
- 3.3. Oral cancer is more common in men than women.
- 3.4. The disease is largely preventable. Principle risk factors are the use of tobacco, primarily through cigarette smoking, and alcohol consumption. The risks are enhanced when the two substances are used in combination.

- 3.5. The incidence of oral cancer in England in 1999 was 3.43 cases per 100,000 population. In the NORCOM area, 53 new cases were registered in 1999 giving an incidence of 2.98 per 100,000. The number of new cases registered in the NORCOM area rose slightly to 55 in 2000¹.
- 3.6. The incidence of ORN has declined since 1968 from 11.8%. One American study in 1986 reviewing 109 cases of patients receiving radiotherapy for head and neck cancer observed only three cases of ORN in the mandible², an incidence of 2.75%.
- 3.7. Review of survival rates suggests that the five-year survival rate for oral cancer has remained stable since 1950. The rate of mortality varies dependant upon the site of the cancer. Cancer of the lip has the lowest mortality. Rate of recurrence is variable. 90% of recurrence is within two years of the primary diagnosis. The salvage rate of previous treatment failure is poor.
- 3.8. Principally, treatment for oral cancer is surgery, radiotherapy or a combination of the two. Other options include cryosurgery, CO₂ laser surgery and photodynamic therapy.
- 3.9. Surgery consists of excision and reconstruction. Patients with advanced disease may be given postoperative radiotherapy. A small number of cases may require the insertion of osseointegrated implants for oral prostheses.
- 3.10. Radiotherapy is delivered either by an external beam from a machine (teletherapy) or from a radioactive source near to or within the tumour (brachytherapy).
- 3.11. Radiotherapy for oral cancer can lead to the development of ORN. As a result of irradiation, exposed bone may fail to heal. Treatment includes irrigation, antibiotics, reconstructive surgery and avoiding irritants.

4. HYPERBARIC OXYGEN THERAPY

- 4.1. HBO is used to recreate the steep oxygen gradient found in normal wounds, which is not present in irradiated wounds. Studies have shown this steep gradient to be necessary for the regeneration of capillaries in hypovascular areas.
- 4.2. The treatment can be used in four circumstances relating to oral cancer. These are for the treatment of ORN, the prevention of ORN, promoting wound healing and before and after osseointegrated implants.
- 4.3. The treatment is delivered in a decompression chamber of the type commonly used to treat divers with decompression sickness (the 'bends'). The patient receives 100% oxygen via a facemask or hood whilst under a pressure of up to 2.4 atmospheres.

- 4.4. Two types of chamber can be used. One (the multiplace chamber) is large enough to contain several individuals and allows patients to be supervised from within the chamber. The other (the monoplace chamber) can contain only one individual.
- 4.5. The Marx Protocols for the prevention and treatment of ORN have become the accepted standard of care. The protocols combine HBO with surgery both pre and post operatively.
- 4.6. For the prevention of ORN, 20 pre-operative treatments (dives) are given followed by 10 post-operatively. To treat established ORN, a 30/10 ratio is used.
- 4.7. A 'dive' lasts approximately 90 minutes.
- 4.8. The effects of treatment are usually noticeable after 8 dives. The effect plateaus at between 20 and 24 dives.
- 4.9. Risks and complications may be associated with the nature of the treatment environment or with therapeutic aspects.
- 4.10. The environmental risks include the potential for the oxygen rich atmosphere to become explosive and the risk of sudden loss of pressure resulting in decompression.
- 4.11. Common adverse effects of treatment include claustrophobia, middle ear barotraumas, oxygen toxicity, ear, sinus and tooth pain, pneumothorax and deafness.
- 4.12. The treatment is contra-indicated in patients with pneumothorax, severe COPD, optic neuritis, acute viral infection, upper respiratory infection, congenital spherocytosis, pregnancy, prior to middle ear or thoracic surgery and in patients with psychiatric problems.
- 4.13. There are no National Service Frameworks that relate to the use of HBO. The Marx Protocols provide a treatment regime but do little to identify those patients who would benefit most from treatment.

5. EVIDENCE BASE

- 5.1. Very few randomised controlled trials have been conducted to determine the efficacy of HBO. A large number of published research papers and a small number of case series studies are available.
- 5.2. Treatment of ORN
It is difficult to draw any conclusions regarding the value of HBO in treating ORN. The studies done are frequently retrospective case studies on small numbers of patients. The studies were conducted over long time periods and many were done in the 1970's and 1980's.

- 5.3. Dental care and radiotherapy treatment have improved. As a result the incidence of ORN has fallen.
- 5.4. There is more recent evidence that ORN can be effectively managed without using HBO.
- 5.5. Prevention of ORN
The evidence for using HBO to prevent ORN is also based on studies done in the 1980's. As ORN rates have fallen, the prophylactic use of HBO is unlikely to be cost-effective.
- 5.6. Dental Implants
There are no randomised clinical trials studying the use of HBO in promoting osseointegration. The evidence suggests the promotion of bone regeneration, however the level of radiation beyond which HBO is needed has not yet been conclusively established.
- 5.7. Wound Healing
There are very few studies of the use of HBO in head and neck wounds making the efficacy of the treatment difficult to establish.
- 5.8. The evidence summarised above was extracted from the Trent Institute Working Group on Acute Purchasing document 'The Use of Hyperbaric Oxygen in the Management of Patients with Oral Cancer' published in May 2000. No significant new evidence has since been published.
- 5.9. The evidence available does not give clear guidance regarding the commissioning of HBO therapy.

6. SERVICE PROVIDERS

- 6.1. The National Specialised Services Definitions Set number 28, Hyperbaric Treatment Services (Adult), details 22 providers of HBO.
- 6.2. Treatment facilities are classified by the British Hyperbaric Association, under one of 4 categories dependent on the facilities provided.
- 6.3. Category 1
Capable of receiving patients from any diagnostic category who may require advanced life support (ALS) either immediately or during treatment.
- 6.4. Category 2
Capable of receiving patients who are judged by the referring medical officer not to be likely to require ALS during treatment.
- 6.5. Category 3
Capable of receiving emergency referrals of divers and compressed air tunnel workers and providing elective treatment of residual symptoms of decompression illness.
- 6.6. Category 4
Capable of receiving elective and emergency referrals of patients judged by the referring medical officer not likely to require access during treatment (i.e. monoplace chambers).

- 6.7. Choice of Preferred Provider
To ensure all patients receive the appropriate level of care, the preferred provider must be able to provide adequate medical supervision. To ensure appropriate risk management, the treatment should be delivered by a consultant led, hospital based service with a category 1 chamber.
- 6.8. As patients must be available for treatment for between 20 and 30 days the preferred facility should be close to the NORCOM area.
- 6.9. The preferred service provider is the North of England Medical Hyperbaric Unit, BUPA Hospital, Anlaby Road, Hull. The facility is a hospital based, consultant led service with a category 1 multiplace chamber. Treatments are supervised by a nurse from within the chamber.

7. PATIENT NUMBERS FOR NORTH TRENT

- 7.1. It is estimated that approximately 5 patients per year from Primary Care Trusts in the NORCOM area may be considered for HBO treatment.
- 7.2. As the incidence of ORN has fallen, it is unlikely that the numbers of appropriate patients will rise significantly.

8. TREATMENT COSTS

- 8.1. The current cost of HBO therapy in Hull is £200 per dive. The cost has been calculated based on only one person occupying the chamber at once. Under the Marx Protocols, the total treatment cost for a 30/10 course is £8000.
- 8.2. The Hull facility almost invariably treats more than one patient in the chamber and so offers a discount of 50% making the cost £4,000.
- 8.3. Treatment is usually given from Monday to Friday, though the unit will open at weekends if it is clinically urgent to complete treatment prior to surgery.

9. CRITERIA FOR TREATMENT

- 9.1. The evidence for the use of HBO is inconclusive. As a result, requests for treatment should be assessed on a case by case basis in conjunction with specialist advice from Directors of Dental Public Health.
- 9.2. As a minimum, to be considered for HBO the following criteria should be met. Patients must:
- 9.2.1. Be diagnosed as having oral cancer **and**
 - 9.2.2. Have had extensive radiotherapy **and**
 - 9.2.3. Be diagnosed as having ORN **or**
 - 9.2.4. Be considered by the responsible OMFS consultant as being at serious risk of contracting ORN.
- 9.3. Appendix A shows a diagrammatic representation of the process for requesting funding for HBO treatment.

- 9.4. As the number of patients for whom the treatment is likely to be considered is small, all requests for HBO for patients with oral cancer should be considered by all three Directors of Dental Public Health, working as a virtual team. This will ensure a consistent approach across the NORCOM area.
- 9.5. A database of all cases considered, the criteria used and the outcome should be set up and maintained by the Director of Dental Public Health for Rotherham PCT.

10. FURTHER ISSUES

- 10.1. Due to the location of the preferred provider and the frequency of treatment, travel to the service may be of concern to some patients. Reimbursement of travelling expenses will be dealt with under existing commissioner policies. No special arrangements are proposed.

11. POLICY STATEMENT

- 11.1. The following statement sets out the position of Primary Care Trusts in the NORCOM area in respect of future referrals and funding requests for HBO for patients with oral cancer.
- (i) **As from 1st March 2004, all patients registered to Primary Care Trusts in the NORCOM area meeting the criteria in section 9 of this policy for HBO for oral cancer should have their treatment provided by a hospital based, consultant led service with a category 1 chamber.**
 - (ii) **As from 1st March 2004, all new referrals for HBO for NORCOM area residents should be made to the North of England Medical Hyperbaric Unit at the BUPA Hospital in Hull.**
 - (iii) **Requests for HBO should be considered on a case by case basis in conjunction with specialist advice from Directors of Dental Public Health using the process contained in Appendix A.**
 - (iv) **Requests for reimbursement of traveling expenses will be dealt with under existing policies.**
- 11.2. This policy will be reviewed in January 2006 or when further significant information becomes available, either from clinical trials or NICE.

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National Specialised Services Definitions Set Number 28

Hyperbaric treatment Services (Adult)

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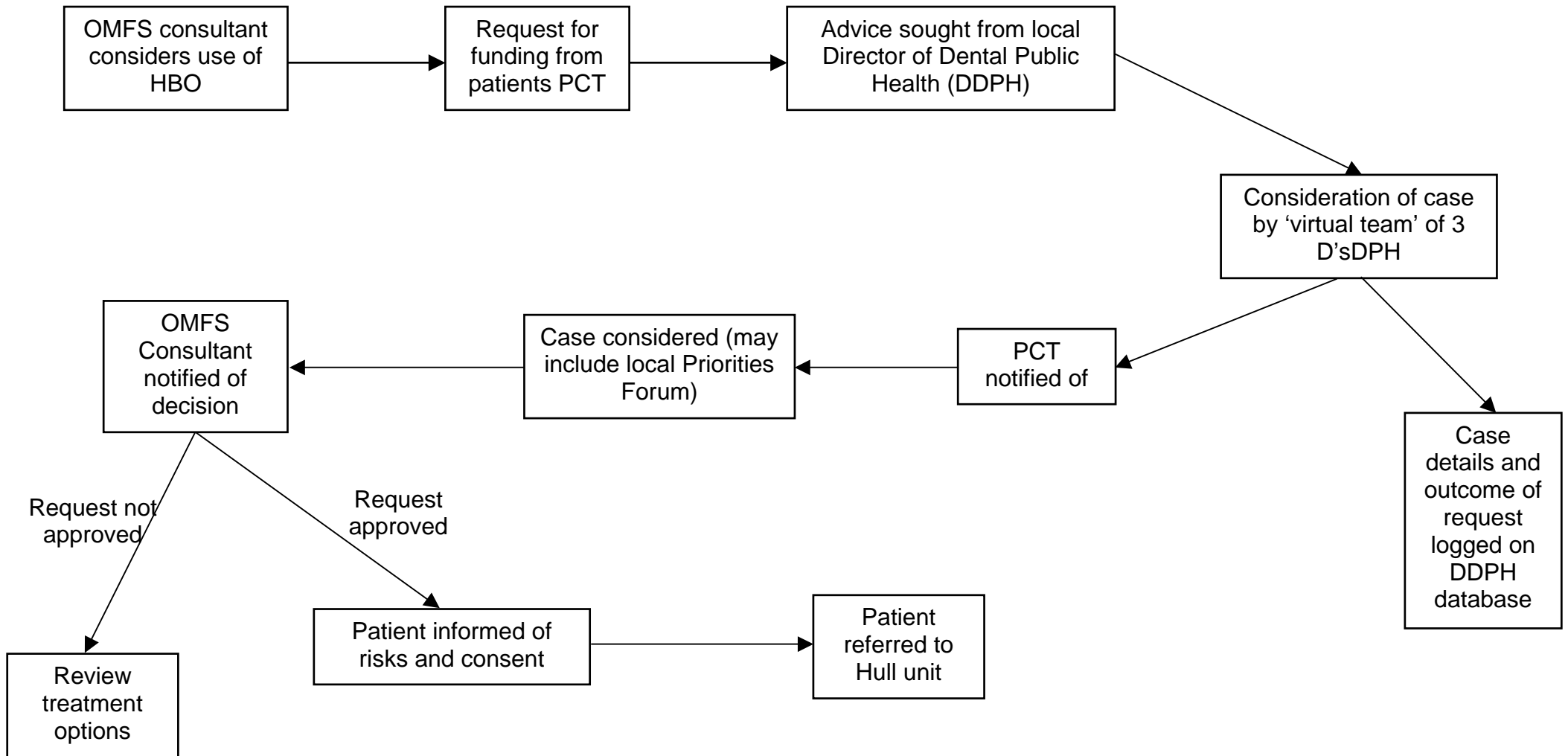
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HBO for Oral Cancer Pathway



HYPERBARIC OXYGEN

Patient Information

What is Hyperbaric Oxygen?

Oxygen makes up 21% of the air we breathe. Sometimes when people are ill they need more oxygen than this. Supplemental oxygen can be given through face masks, but even then some conditions require more oxygen to be in the patients system. This can be achieved by giving oxygen at 100% under greater than atmospheric pressure. Hyperbaric oxygen comes from two words – hyper meaning 'High' and 'baric' meaning pressure.

What is it used for?

In the chamber we treat both emergency and routine patients. Emergency patients have acute conditions such as carbon monoxide poisoning, decompression illness and severe infections. Routine patients come Monday to Friday to have treatment. They may have had, radiotherapy in the past or a chronic infection. In some instances radiotherapy can cause damage to the blood supply to tissue in the irradiated area. Hyperbaric oxygen greatly increases tissue oxygen levels and helps the body rebuild its blood supply into the damaged area. Low level of oxygen (also called hypoxia) is common of many non-healing wounds therefore we treat many people with different wounds.

Other things we use hyperbaric oxygen therapy for are: -

- Decompression sickness (the bends)
- Severe carbon monoxide poisoning
- Radiation bone necrosis
- Compromised skin flaps
- Refractory osteomyelitis (bone infections)
- Air or gas embolism
- Clostridial myonecrosis (gas gangrene)
- Necrotising fasciitis
- Severe haemorrhagic anaemia

Due to the nature of the conditions treated in the chamber we ask you to consider other patients privacy.

What will happen when I attend the unit?

The session times are held Monday to Friday, starting at either 09:30 till 11:30 or 13:00 till 15:00 hours. You may be given a preference as to which time to come but this will depend on spaces and availability.

You will be greeted by one of the members of the Hyperbaric team, which is made up of: -

- A Technical and Research Director
- A Medical Director
- Hyperbaric Nurse or Technician

The chamber is located within the hospital and can seat 7 people in comfortable chairs. A nurse will be with you at all times during your treatment. A routine treatment lasts approximately 2 hours.

Due to the nature of the treatment certain items are banned from the chamber such as any potentially flammable item.

- Cigarette Lighters
- Matches
- Batteries
- Mobile phones
- Non Diving Watches
- Pressurised containers
- Bleeps pagers
- Hearing aids
- Perfume or hairspray or hair grease (on patients)
- Perfume or hairspray (in a pressurised container)

We provide lockers to safely store your belongings and should you be unsure of the intrinsic safety of an item ask the staff or leave it in your locker.

What will my treatment feel like?

During the increase of pressure in the chamber you will experience some noise and warmth, and a fullness or feeling of pressure on your eardrums. Try not to worry – there will always be a nurse present in the chamber with you and you can ask them for help or information at any time.

This feeling or “pressure” on the ears is normal, similar to when in an aeroplane landing or when you travel through a tunnel on a train. This feeling is due to unequal pressure exerted on the eardrum. There are several methods to equalise the pressure in your ears. These range from yawning, drinking water, swallowing while pinching your nose, chewing gum. Singing a song sometimes helps and if it doesn’t it certainly amuses the Hyperbaric staff. This sounds complicated but is just holding your nose and trying to breathe out gently while keeping your mouth closed.

Your ears may pop or crackle as the pressure equalises, this is perfectly normal. **If you feel any pain or discomfort always communicate this immediately to the Nurse in the chamber.**

When at the desired depth you will wear a plastic hood and collar with 2 tubes. One hose connects you to the oxygen the other takes your exhaled breath away. You are still able to speak, read and wear glasses with the hood

on. The hood will be kept specifically for your use only for the duration of your treatment.

You will have a break during your treatment, when the hood will be removed for 5 minutes, during this time you can have a drink. However if you feel unwell or want to have a short break with the hood off, then let the nurse know. Toilet facilities are also available in the chamber, but it is normally best to use the toilet facilities in the hospital before entering the chamber. When coming for a session it is useful to bring something to read, as it helps to pass the time during treatment.

Side Effects

Side effects are very limited. You may experience some visual changes particularly if you wear glasses. You may develop changes in focusing eyes, this is normally due to Myopia – or short sightedness. This is normally a temporary change in sight and resolves quickly for the first two weeks after treatment has stopped and is normally fully resolved after 12 weeks of the treatment ending, - so don't change your glasses until at least eight weeks after treatment has finished.

How long will your treatment last?

After routine patients have finished their first 20 or 30 treatments, they normally have a break when they will see their consultant and often have surgery or dental procedures carried out. Once you have been seen by your consultant or had surgery / dental treatment, you will be ready for your final set of hyperbaric oxygen sessions. This normally consists of just 10 further treatment sessions.

Returning after treatment helps to aid wound healing, and allows your body to get maximum benefit from the oxygen therapy. Occasionally your consultant may ask you to attend for more than 10 sessions after treatment, but this will be discussed with you in Clinic.

You should contact the unit as soon as you have had surgery to resume treatment. Indeed you can phone the unit at any point if you have any problems during office hours.

Our telephone number is **01482 672462**

Costs?

If you have been sent to us by a NHS consultant, then your costs will be met by your local Primary Care Trust.

Where to find us?

The Chamber is located within the BUPA Hull and East Riding Hospital. There is good access by road from the M62 and A1079 going on to the A164. The unit is signposted from the M62 and the A164.

