

Considered Judgement Form

This form is a checklist of issues that may be considered by the Purchasing Guidance Advisory Group when making purchasing recommendations.

Meeting date: 9 Dec 2004

Topic: Hyperbaric Oxygen Therapy (HBOT)

1. General information

Hyperbaric oxygen therapy (HBOT) may be defined as the therapeutic administration of 100% oxygen at environmental pressures greater than one atmosphere absolute (ATA). Administration involves placing the patient in an airtight vessel, increasing the pressure within that vessel, and giving 100% oxygen for respiration. In this way it is possible to deliver a greatly increased partial pressure of oxygen to the lungs, blood and tissues. The mechanisms of HBOT treatment include the reduction of intravascular bubble volume, increasing tissue oxygenation, vasoconstriction and other potential beneficial effects e.g. killing certain anaerobes, promoting osteoclast and osteoblast growth. Use of the therapy has been reported for a wide variety of more than 130 medical conditions. It has been successfully used to treat medical conditions such as decompression sickness and gas embolism. However, for many other conditions, the use of HBOT appears to lack scientific validation of effectiveness.

Fire hazard appears to be the most common cause of fatal accidents during HBOT treatment. Other adverse effects include ear barotrauma, claustrophobia, reversible myopia, oxygen toxic effects on brain and lung, and decompression illness. Safety issues need to be considered when purchasing hyperbaric oxygen therapy services. HBOT is not a completely benign treatment

In New Zealand, hyperbaric chambers were facilitated in Auckland, Wellington, Christchurch and Dunedin hospitals in the 1970s and 1980s. Today, hyperbaric oxygen therapy services are only available in Christchurch Hospital, Royal New Zealand Navy Hospital and a private clinic in Auckland.

In 1999, ACC was asked by clinicians to provide national funding for hyperbaric oxygen treatments in New Zealand. Dr Nicholas Kendall reviewed the evidence for the effectiveness of using HBOT for a number of clinical conditions in relation to injury, and produced an evidence report for ACC purchasing decisions in 2001³. Since then, new studies on the use of HBOT have been published. ACC has also been asked to fund the use of HBOT for other conditions, e.g. traumatic brain injury and wound care. In response to these changes and requests, the Evidence Based Healthcare Advisory Group (EBH) and Healthwise in ACC decided to review and to update the evidence report for purchasing decisions and HBOT contract updating.

After discussions with the corporate medical advisor and programme manager in hyperbaric oxygen services, it was agreed that this work would only focus on medical conditions that are likely to be covered under the New Zealand's accident compensation scheme.

The following conditions were chosen for assessment in the project: decompression sickness, gas embolism, skin grafts and flaps, crush injury, acute traumatic peripheral ischaemia, suturing of severed limbs, thermal burns, carbon monoxide poisoning, gas

gangrene, chronic refractory osteomyelitis, diabetic wounds, radiation-induced soft tissue injury and osteoradionecrosis, necrotising soft tissue infections, sport related soft tissue injuries, traumatic brain injury, stroke, cerebral palsy, sudden deafness and acoustic trauma, dental implant following radiotherapy, and periodontitis.

Search strategy: A range of OVID databases were searched in September 2003 and May 2004 (updating search) for published randomised studies on hyperbaric oxygen therapy and the conditions targeted for this review. A secondary hand search of citations and a search for related information from Internet sources were also conducted.

Selection criteria: All randomised studies, including randomised controlled studies and randomised crossover studies

2. Results, evidence statement and purchasing recommendations

2.1 Decompression sickness and gas embolism

Decompression sickness is a condition associated with rapid changes in the ambient atmospheric pressure. It is caused by gas bubbles that are formed in the blood or tissues due to rapid decompression e.g. ascent from diving.

Air or gas embolism is the symptom complex caused by the entry of air into the circulatory system. The condition can occur accidentally during diving, traffic accident, surgery or other medical procedures.

For both conditions, HBOT is believed to reduce the bubble volume and therefore to help the re-establishment of blood flow. In addition, the oxygenation of ischaemic tissue or organs and the reduction of brain and spinal cord oedema by using HBOT are likely to improve clinical outcomes.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
There is an absence of randomised controlled studies to look at the effectiveness of HBOT for decompression sickness and gas embolism.
2. Cost
3. Clinical impact
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none">• Don't purchase• Don't purchase at this stage, but the decision will be reviewed when new evidence available• Purchase subject to special controls: case-based approval• Purchase
6. Evidence Statement
There is an absence of randomised controlled studies to look at the effectiveness of HBOT for decompression sickness and gas embolism. However, HBOT is the primary or standard treatment for these conditions. The use of HBOT for these two conditions appears effective in clinical practice especially when early treatment is administered.
7. Purchasing Recommendations
Hyperbaric oxygen should be purchased for the treatment of decompression sickness and gas embolism.

2.2 Skin grafts and flaps

HBOT is not necessary and not usually recommended for the support of normal, uncompromised skin grafts or flaps. However, following preoperative or postoperative irradiation or in other cases where there is decreased microcirculation or hypoxia, it has been suggested that HBOT may be useful to improve skin graft survival.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
One randomised controlled study published in 1967 was identified. Favourable results were reported that the HBOT intervention group achieved statistically significant higher graft survival than the control group. However, this study has considerable weaknesses. Basic information about patients studied (e.g. age, gender, the cause of the lesion) and methodology (e.g. method of randomisation, whether blinded assessment) were not clearly reported.
2. Cost
Treatment in this area is associated with significant costs.
3. Clinical impact
Diabetic patients may be a group who may benefit from this treatment.
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none">• Don't purchase• Don't purchase at this stage, but the decision will be reviewed when new evidence available• Purchase subject to special controls: case-based approval• Purchase
6. Evidence Statement
<p>The number of randomised studies that look at clinical effectiveness of using HBOT for skin graft remains very small. There may be some potential clinical benefits of using HBOT for skin graft as suggested by the study included. Nevertheless, the considerable weaknesses have to be taken into account. The effectiveness of using HBOT for skin graft cannot be concluded from the randomised study. There is a need for more well-designed new randomised controlled studies with clearly defined study populations.</p> <p>Evidence from RCTs for the use of HBOT to support skin grafts and flaps appears to be insufficient to justify routine use. Purchasing decision may need to take into account the high cost of skin graft and the potential clinical benefits of using HBOT for the condition into account.</p>
7. Purchasing Recommendations
Purchase subject to special controls: case-based approval. ACC are encouraged to monitor and follow-up all approved cases.

PGAG Discussion:

There have been no requests to fund HBOT for skin grafts or flaps, however it may be carried out in the acute care setting and therefore paid through public health acute contract. Most likely referrals would be for diabetic claimants with non-healing ulcers. The criteria for which cases to treat will be at the discretion of the clinician, approval to fund is sufficient rather than stating specific patient groups who may benefit.

2.3 Crush injury, acute traumatic peripheral ischaemia and suturing of severed limbs

Even though the causes and individual characteristics of these conditions can be different, the unifying factors of ischaemia and oedema are presented in different degrees after injury. HBOT may have beneficial effects on these conditions by (a) increasing oxygen delivery, (b) reducing oedema, (c) improving oxygenation of the environment in the injury zone, and (d) protecting tissue from reperfusion injury. Therefore, HBOT is considered as a useful adjunct treatment for the above conditions.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
One RCT of reasonable quality of study was found that investigated the clinical effectiveness of HBOT for moderate or severe crush injury. Statistically significant effects of HBOT on the two relevant clinical outcomes were reported: (a) complete wound healing, and (b) the need for new surgical procedures, e.g. skin flaps and grafts, vascular surgery or amputation
2. Cost
3. Clinical impact
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none">• Don't purchase• Don't purchase at this stage, but the decision will be reviewed when new evidence available• Purchase subject to special controls: case-based approval• Purchase
6. Evidence Statement
The included RCT suggests there is a clinically important benefit for the use of HBOT for patients with moderate to severe crush injury. While there is no randomised evidence examining the use of HBOT specifically with severed limbs or in acute traumatic peripheral ischaemia, a clinical benefit remains possible. The use of HBOT for these latter two conditions may be appropriate, but any decision should be made with reference to the ability to respond to therapy, the severity of injury and timing for initiation of treatment.
7. Purchasing Recommendations
Purchase

PGAG Discussion

Requests for HBOT for this type of injury will not come to ACC for approval as they will be funded under public health acute funding.

2.4. Thermal burns

The local response to burn injury involves direct tissue coagulation and microvascular reactions in the surrounding tissue that may result in extension of injury. The zone of coagulation or complete capillary occlusion may progress rapidly after injury. Ischaemic necrosis quickly follows. Oedema develops in the injury area as well as in distant organs and soft tissues. Adjunctive HBOT treatment is considered to be useful in maintaining microvascular integrity, reducing oedema and promoting wound closure.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
Four randomised studies were identified. The randomised studies identified have significant weaknesses, e.g. small sample size, problems in randomisation and study population. No significant benefit was found in the study with the largest sample size. There is a need for more well designed randomised controlled studies to investigate the clinical effectiveness and cost effectiveness of using HBOT as an adjunctive treatment for thermal burns especially for complex burn injuries.
2. Cost
3. Clinical impact
Very few cases, subacute/chronic cases 3-12 months post burn. Referrals from specialist burns units, likely to part of a clinical pathway.
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none"> • Don't purchase • Don't purchase at this stage, but the decision will be reviewed when new evidence available • Purchase subject to special controls: case-based approval • Purchase
6. Evidence Statement
There is insufficient evidence to support the routine use of HBOT in the treatment of thermal burns.
7. Purchasing Recommendations
Purchase subject to special controls: HBOT should not considered as routine use for thermal burns, but may be considered for severe cases.

PGAG Discussion:

Funding for HBOT in the treatment of burns is likely to become a bigger issue for ACC, with possible changes to the funding of burns services

2.5. Carbon monoxide poisoning

Traditionally, the toxic effects of carbon monoxide poisoning are considered as due to a hypoxic stress of carboxyhaemoglobin (COHb) formation, which reduces the capacity of the blood to carry oxygen to the tissues. Even though major cardiac injury can primarily be explained by CO-induced hypoxic stress, COHb level does not correlate well with the development of neurological injuries of carbon monoxide poisoning. Recent investigations have recognised that there are other mechanisms of the toxic effects, probably including CO-induced oxidative stress, binding to myoglobin and hepatic cytochromes, and peroxidation of brain lipids. HBOT is originally considered for CO poisoning treatment since it has been found to increase the rate of COHb elimination. However, other possible beneficial effects on the pathophysiology of central nervous system injury are likely to be relevant.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
Six RCTs were included. One study has notable strengths in methodological quality and provides good evidence to support the effectiveness of using hyperbaric oxygen therapy in patients with acute CO poisoning. However, it is worth to note that patients enrolled in the study were mostly the result of accidental poisoning rather than deliberate suicide attempt, and the duration of exposure to carbon monoxide may be different between groups.
2. Cost
3. Clinical impact
Patients with carbon monoxide poisoning may be treated up to 4-5 weeks after poisoning, however the vast majority are treated within 24-36 hours. The papers included in this review reported intervention with 24 hours of poisoning. Patients are treated on the basis that carbon monoxide is neurotoxic and treatment can reverse the potential adverse effects.
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none">• Don't purchase• Don't purchase at this stage, but the decision will be reviewed when new evidence available• Purchase subject to special controls: case-based approval• Purchase
6. Evidence Statement
There appears to be good evidence to support the use of hyperbaric oxygen therapy for patients with severe acute carbon monoxide poisoning. To ensure HBOT is effectively used in patients with acute CO poisoning, further studies are needed to identify the patients who are at high risk of developing delayed and/or permanent neurological sequelae of carbon monoxide poisoning, and to determine the optimal dose including the timing of the use of HBOT.
7. Purchasing Recommendations

Purchase, for patients who are clinically poisoned with carbon monoxide.

2.6. Gas Gangrene

Gas gangrene is a fulminating myonecrotic infection caused by the clostridial species of bacteria which, untreated, characteristically has a rapidly fatal outcome. Accidental trauma appears to be the main cause of gas gangrene with 50% of cases resulting from the contamination of traumatic wounds. The principle therapeutic mechanism of HBOT is considered to be through the action of oxygen free radicals in degrading or slowing production of toxins produced by the clostridial bacteria.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
No randomised study was found that used HBOT for this condition.
2. Cost
3. Clinical impact
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none">• Don't purchase• Don't purchase at this stage, but the decision will be reviewed when new evidence available• Purchase subject to special controls: case-based approval• Purchase
6. Evidence Statement
While there is no RCT investigating the use of HBOT for gas gangrene, a clinical benefit remains possible. The use of HBOT in adjunct to surgical techniques and antibiotic therapy has been widely accepted in clinical practice.
7. Purchasing Recommendations
Purchase, as adjunctive treatment for the condition

2.7 Chronic refractory osteomyelitis

Refractory osteomyelitis is chronic osteomyelitis which has persisted or recurred after appropriate interventions have been performed or where acute osteomyelitis has not responded to accepted management techniques. Generally, the infections are secondary to an open wound from an open injury to bone and surrounding soft tissues. HBOT may assist in the treatment of osteomyelitis by the promotion of fibroblast activity.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
No randomised study was found that reported using HBOT for the condition.
2. Cost
3. Clinical impact
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none">• Don't purchase• Don't purchase at this stage, but the decision will be reviewed when new evidence available• Purchase subject to special controls: case-based approval• Purchase
6. Evidence Statement
The effectiveness of HBOT for chronic refractory osteomyelitis remains unknown.
7. Purchasing Recommendations
Don't Purchase

2.8. Diabetic wounds

Diabetes mellitus remains as a significant risk factor for impaired wound healing. It adversely affects wound healing probably by two principal mechanisms: atherosclerosis and defective cellular and humoral immunity. Diabetic wounds appear to be an important cause of non-traumatic amputations. HBOT may promote wound healing in diabetes patients through increasing oxygen tensions to the levels that are necessary to enable fibroblast replication, development of a collagen matrix and the ingress of capillaries into avascular areas.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
Four RCTs included. Most included studies indicate clinical benefits from the use of HBOT for diabetic wounds, specifically a reduction in the probability of major amputation and the promotion of wound healing. However, these studies have considerable weaknesses in methodological quality. There is still a need for well-designed randomised controlled trials for this application in the future.
2. Cost
3. Clinical impact
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none">• Don't purchase• Don't purchase at this stage, but the decision will be reviewed when new evidence available• Purchase subject to special controls: case-based approval• Purchase
6. Evidence Statement
Most included studies indicate clinical benefits from the use of HBOT for diabetic wounds, specifically a reduction in the probability of major amputation and the promotion of wound healing, these included studies cannot identify the subgroup of individuals with diabetic foot lesions who are most likely to benefit from HBOT. These studies also have considerable weaknesses in methodological quality and did not investigate harm of prolonged treatment. Until large clinical trials of high methodological rigour can do so, it is prudent to recommend that HBOT can be considered as an adjunctive treatment for selected diabetic patients, e.g. for diabetic patients for whom conventional management fails to achieve improvement in wound healing, or for diabetic patients who appear to be at high risk of amputation.
7. Purchasing Recommendations
Purchase, for selected patients e.g. for diabetic patients for whom conventional management

fails to achieve improvement in wound healing, or for diabetic patients who appear to be at high risk of amputation.

PGAG Discussion

It is important to ensure that before patients are considered for this treatment they have adequate diabetic control.

2.9. Radiation-induced soft tissue injury and osteoradionecrosis

Hyperbaric oxygen therapy has been proposed for the prevention and treatment of many conditions where there is hypoxia to the tissues, including radiation-induced tissue injury. HBOT may enhance neovascularisation in irradiated and other hypoxic tissues.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
Six randomised controlled studies were included.
One included study indicates that there is no improvement in neurophysiological outcomes using HBOT for patients with radiation-induced brachial plexopathy.
In another study, the interim results from HORTIS indicate clinical benefits of using HBOT for radiation induced proctitis.
The randomised study reported by Marx in 1985 provided relevant evidence for the using HBOT to prevent osteoradionecrosis in patients at high risk, however, the study provided limited evidence to support using HBOT for patients diagnosed with osteoradionecrosis.
The other three studies have significant weakness, e.g. very small sample size or with very poor description on study methodology.
2. Cost
3. Clinical impact
Don't currently see many cases, but may see an increase as part of "treatment injury" claims.
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none"> • Don't purchase • Don't purchase at this stage, but the decision will be reviewed when new evidence available • Purchase subject to special controls: case-based approval • Purchase
6. Evidence Statement
Some evidence was found supporting the use of HBOT to prevent osteoradionecrosis in the patients at high risk. As suggested by some included studies, clinical benefits of using HBOT to treat osteoradionecrosis and some radiation induced soft tissue injuries remain possible. There is a need for well-designed and well-conducted RCTs on the topic
7. Purchasing Recommendations
Purchase subject to special controls: case-based approval, e.g. for osteoradionecrosis, radiation induced proctitis

PGAG Discussion

Case based approval allows the situation to be carefully monitored.

2.10. Necrotising soft tissue infections

Necrotising soft tissue infections are caused by aerobic, anaerobic and mixed bacterial floras. Some of the infections appear to be the results of a synergistic combination of organisms. Mortality of the conditions can be very high from 20% up to 70 or 80%. Hyperbaric oxygen therapy is considered as a useful adjunctive treatment to surgery and antibiotics

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
No randomised controlled study was found on necrotising soft tissue infections
2. Cost
3. Clinical impact
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none">• Don't purchase• Don't purchase at this stage, but the decision will be reviewed when new evidence available• Purchase subject to special controls: case-based approval• Purchase
6. Evidence Statement
There is an absence of randomised controlled studies to look at the effectiveness of HBOT for necrotising soft tissue infections; however, the clinical benefits cannot be ruled out. The use of HBOT in adjunctive to surgical techniques and antibiotic therapy has been considered as an accepted adjunct in the clinical practice.
7. Purchasing Recommendations
Purchase, as an adjunctive treatment for the condition.

2.11. Sport related soft tissue injuries

There has been an increasing demand to use HBOT in sports medicine in recent years. HBOT has been used for sport related soft tissue injuries such as ankle sprains, acute strains of the foot and lower leg, and delayed-onset muscle soreness (DOMS). The hypothesis is that HBOT will improved pain and swelling through reactive vasoconstriction and resolution of tissue oedema, resulting in a more rapid return to athletic activity.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
Seven randomised studies were included. All these studies have some weaknesses in the study design, including using human models, small sample sizes and unclear methods of randomisation. In general, the studies reported no significant benefits of using HBOT for sport-related soft tissue injuries.
2. Cost
3. Clinical impact
Mainly used to enhance performance.
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none">• Don't purchase• Don't purchase at this stage, but the decision will be reviewed when new evidence available• Purchase subject to special controls: case-based approval• Purchase
6. Evidence Statement
There appears to be no substantial evidence to support using HBOT for sport-related soft tissue injuries.
7. Purchasing Recommendations
Don't purchase

2.12. Traumatic brain injury (TBI)

Traumatic brain injury is a major cause of death and disability throughout the world. HBOT can have effects on hyperoxygenation, reduction in cerebral blood flow (CBF) by cerebral vasoconstrictions, reduction in intracranial pressure and improvement in glucose metabolism. These effects may have potential clinical benefits for patients with acute brain injury. The use of HBOT for chronic brain injury is based on the theory of inactive cells that have the potential to recover. According to the theory, the availability of oxygen or high oxygen concentrations to these cells stimulates the cells to function normally.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
Four RCTs were included. These studies have weaknesses in study design and present conflicting results in mortality measured. Even though one study reported reduction in mortality in the intervention group, there appears to be no clear evidence to indicate that using HBOT could improve function recovery for patients with acute brain injury. No randomised study was found on patients with old brain injury.
2. Cost
3. Clinical impact
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none">• Don't purchase• Don't purchase at this stage, but the decision will be reviewed when new evidence available• Purchase subject to special controls: case-based approval• Purchase
6. Evidence Statement
The evidence to support the use of HBOT for patients with traumatic brain injury appears to be very weak. The clinical effectiveness of this application remains inconclusive until well-designed randomised controlled studies are conducted.
7. Purchasing Recommendations
Don't purchase at this stage, but the decision will be reviewed when new evidence becomes available

2.13. Stroke

One strategy to treat acute ischaemic stroke is to improve the cellular and metabolic disturbances of focal brain ischemia. HBOT may have potential benefits for the condition, for example hyperoxygenation and reduction in cerebral oedema. However, the use of HBOT for acute ischaemic stroke has been debated in terms of its effectiveness.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
Seven RCTs were identified and five included in the analysis. None included studies found significant clinical benefits of using HBOT for patients with acute stroke.
2. Cost
3. Clinical impact
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none">• Don't purchase• Don't purchase at this stage, but the decision will be reviewed when new evidence available• Purchase subject to special controls: case-based approval• Purchase
6. Evidence Statement
Five randomised-controlled trials do not show significant clinical benefit of HBOT for acute stroke patients.
7. Purchasing Recommendations
Don't purchase

2.14. Cerebral palsy

Cerebral palsy (CP) refers to a group of disorders of body movement and muscle co-ordination caused by lesions or defects of the brain acquired in pre-natal or early life. Conventional therapies and interventions have not achieved the degree of functional improvement and independence that patients and their parents/caregivers desire. A number of approaches including hyperbaric oxygen therapy have been proposed. The use of HBOT for cerebral palsy may be based on the untested theory that “inactive cells” in the brain can be stimulated by oxygenation to function normally.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
Two RCTs were identified. The favourable findings from parental reports on using HBOT for children with cerebral palsy were only found in a poor quality and unpublished study. These results are very likely to be subject to observational bias. A well-designed study shows that HBOT does not improve the condition of children with cerebral palsy. Incidence of ear barotrauma was particularly high in the two studies that used HBOT to treat children with cerebral palsy: 34.6% in the Cornell study and 47.4% in Collect’s study.
2. Cost
3. Clinical impact
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none">• Don’t purchase• Don’t purchase at this stage, but the decision will be reviewed when new evidence available• Purchase subject to special controls: case-based approval• Purchase
6. Evidence Statement
There appears to be inconsistent evidence to support using HBOT for children with cerebral palsy, even though more studies may be needed to confirm this finding further
7. Purchasing Recommendations
Don’t purchase

2.15. Sudden deafness and acoustic trauma

Sudden deafness can be considered as an emergency condition with unknown specific cause in most cases. The suggested causes included viral infection, autoimmunity, vascular pathologies, ototoxic drugs and trauma. Acoustic trauma often occurs in the military occupations with common causes of gun shooting and explosions. The condition is usually characterised by high frequency hearing impairment and tinnitus. The use of HBOT for sudden deafness and acoustic trauma may be based on the assumption that an increased oxygen tension in the inner ear may have potential benefits for the conditions.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
Five RCTs were included. These studies have significant weaknesses in study design and provide inconsistent results in relation to the effectiveness of using HBOT for sudden deafness and acoustic trauma.
2. Cost
3. Clinical impact
Anecdotally HBOT for sudden deafness and acoustic trauma doesn't work.
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none">• Don't purchase• Don't purchase at this stage, but the decision will be reviewed when new evidence available• Purchase subject to special controls: case-based approval• Purchase
6. Evidence Statement
There appears to be insufficient evidence to support the use of HBOT for sudden deafness or acoustic trauma.
7. Purchasing Recommendations
Don't purchase

2.16. Dental implant following radiotherapy and peridontitis

Missing teeth are a common complication of radiotherapy. Dental implants offer one way to replace missing teeth and associated tissues. HBOT has been used to improve the success of implant in patients who received radiotherapy. However, the use of HBOT for this condition remains a controversial issue. HBOT may also be used to treat severe periodontitis. The mechanism of the treatment is unknown, but may be based on the assumptions that HBOT inhibits the growth of anaerobes and increases gingival blood flow.

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency
No randomised study was found to look at the effectiveness of using HBOT for dental implant following radiotherapy
2. Cost
3. Clinical impact
4. Equity, Maori/Pacific Health, Acceptability
5. Possible Purchasing Options
<ul style="list-style-type: none"> • Don't purchase • Don't purchase at this stage, but the decision will be reviewed when new evidence available • Purchase subject to special controls: case-based approval • Purchase
6. Evidence Statement
The clinical benefit of using HBOT for dental implant following radiotherapy and peridontitis remains unknown.
7. Purchasing Recommendations
Don't purchase

Glossary

1. Effectiveness, Volume of Evidence, Applicability /Generalisability and Consistency

Comment here on:

- the extent to which the service/product/ procedure achieves the desired outcomes. Specific reference needs to be made to safety. Report number needed to treat and harm where possible,
- any issues concerning the quantity of evidence and its methodological quality and the extent to which the evidence is directly applicable or generalisable to the New Zealand Population,
- the degree of consistency demonstrated by the available evidence.

Where there are conflicting results, indicate how the group formed a judgement as to the overall direction of the evidence

2. Cost

Comment on:

- any economic costs associated with this service, product or procedure

3. Clinical impact

Comment on:

- the clinical impact eg size of population, magnitude of effect, relative benefit over other management options, resource implications, balance of risk and benefit

4. Equity, Maori/Pacific Health, Acceptability

Comment on the extent to which:

- the service, product or procedure reduces disparities in health status (equity of access, resources, health outcome),
- is consistent with the treaty of Waitangi and encourages Maori/ Pacific participation in providing and using service, product and procedures, and
- is consistent with values and expectations of New Zealanders.

5. Purchasing Options

List the possible purchasing options.

6. Evidence Statement

Summarise the advisory group's synthesis of evidence relating to this service, product or procedure, taking the above factors into account, and indicate the evidence level that applies.

7. Recommendations

What recommendation(s) does the advisory group draw from this evidence?