Washington State Health Care Authority

FINAL Key Questions and Background

Hyperbaric Oxygen Therapy (HBOT) for Sudden Sensorineural Hearing Loss (SSNHL)

Background

SSNHL or sudden deafness is rapid loss of hearing with onset over a period of less than 72 hours. It involves a decrease in hearing of ≥ 30 decibels (dB) affecting at least 3 consecutive frequencies.[1] More than 90% of cases are idiopathic. It is accompanied by tinnitus in nearly all cases and vertigo in 30% to 60% of cases. The rationale for the treatment of SSNHL with HBOT is that the hearing loss may be caused by a hypoxic event in the cochlear apparatus; therefore, HBOT may reverse the oxygen deficit, increase oxygen pressures in the cochlea, and improve microcirculation. Notably, 32% to 62% of cases of SSNHL recover spontaneously, which complicates the evaluation of treatments for this condition.[1]

HBOT has also been studied as a treatment for acute acoustic trauma (AAT), which is a less common cause of SSNHL.[2,3] In AAT, exposure to a short-impact, acoustic impulse with an intensity of 90 to 130 dB for a duration of 1 millisecond causes the inner ear to become mechanically damaged with resulting microcirculation vasospasm and hypoxia of cochlear sensory cells occur.[4] Symptoms include high-frequency sensorineural hearing loss (4 kHz and higher) and tinnitus. Exposure to HBOT could provide increased oxygen to the cochlear apparatus, promoting healing. Thus, the rationale for HBOT for AAT is similar to the rational for idiopathic SSNHL.[4-6] AAT is primarily seen in military or law enforcement personnel, who are exposed to impulse noises from firearms.[4-6]

Policy Context

The State of Washington Health Care Authority selected HBOT for idiopathic SSNHL or AAT for a HTA because of medium concerns for safety and high concerns for efficacy and cost.

Scope of this HTA

The analytic framework (***Figure 1***), research questions, and key study selection criteria (***Table 1***) are listed in this section.

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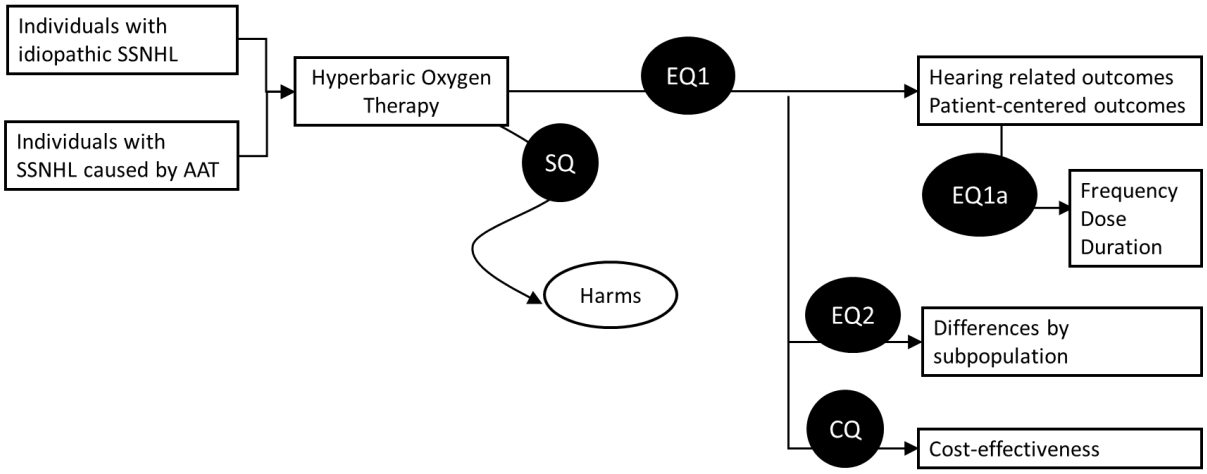
Figure 1. Analytic Framework Depicting Scope of this Health Technology Assessment



Abbreviations: AAT = acute acoustic trauma; CQ = cost question; EQ = efficacy question; SSNHL = sudden sensorineural hearing loss; SQ = safety question.

Research Questions

Efficacy Question 1. Is HBOT effective in improving patient-centered outcomes for individuals with idiopathic SSNHL or AAT?

Efficacy Question 1a. What is the optimal frequency, dose, and duration of HBOT treatment for idiopathic SSNHL or AAT?

Efficacy Question 2. What is the differential effectiveness and safety of HBOT according to factors such as age, sex, race or ethnicity, disability, comorbidities, treatment setting, hearing loss duration, severity, or type of hearing loss (e.g., idiopathic vs noise-induced or acute vs. chronic)?

Safety Question. What are the harms associated with HBOT for idiopathic SSNHL or AAT?

Cost Question. What is the cost effectiveness of HBOT for idiopathic SSNHL or AAT?

Studies investigating idiopathic SSNHL and AAT will be analyzed separately.

Study Selection Criteria

Table 1 provides the study selection criteria we will use to include studies in the HTA.

Table 1. Proposed Population, Intervention, Comparator, Outcome, Timing, and Setting for Health Technology Assessment on HBOT for idiopathic SSNHL or AAT

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Domain	Included	Excluded
Population	Adults or children with sudden idiopathic or noise-induced acute or chronic SSNHL. Acute acoustic trauma with SSNHL.	Adults or children with other forms of hearing loss.
Intervention	Hyperbaric oxygen treatment, delivered via a hyperbaric oxygen chamber, with or without steroid therapy or other medical management.	
Comparator	No treatment, other treatments, or sham HBOT treatments **EQ1a.** Varying HBOT protocols	No comparator group.
Outcomes	**EQ1 and EQ1a**. Patient-centered outcomes: • Hearing improvement • Hearing recovery • Return of hearing (> 25%, >50%, complete) • Improvement in pure-tone average (PTA) • Speech discrimination score • Depression • Functional status • Quality of life • Return to school or work **EQ2.** Differential effectiveness or safety by factors such as: • Age • Sex • Race or ethnicity • Disability • Comorbidities • Severity of hearing loss • Etiology (idiopathic vs. acute trauma) • Treatment setting **SQ.** Harms: • Barotrauma • Temporary visual disturbances • Oxygen toxicity • Other adverse events **CQ.** • Cost-effectiveness; cost-utility	• Inflammatory markers, such as neutrophil-lymphocyte ratio (NLR) and platelet-lymphocyte ratio (PLR). • Oxidative stress markers • Cost-effectiveness or cost-utility measures based on non-U.S. based costs
Setting	Any clinical setting in countries categorized as *very high*[a] on the 2022 UN Human Development Index	Countries categorized as other than *very high*[a] on the 2022 UN Human Development Index

Domain	Included	Excluded
Study Design	**EQ1, EQ1a, EQ2, SQ** Idiopathic SSNHL • Randomized controlled trial; AAT • Randomized controlled trial; controlled clinical trial; comparative cohort studies **CQ4** • Cost utility analysis or cost-effectiveness analysis performed from societal or payor perspective	• Editorials, commentaries, narrative reviews, letters, conference abstracts, case reports or case series. • Pre- post studies, case-control studies; non-comparative observational study designs; non-randomized studies of interventions • Qualitative studies • Relevant systematic reviews and meta-analyses will be excluded but may be manually searched to identify potentially eligible studies.
Language and Time Period	• English • No restrictions on publication date	• Any language other than English

Abbreviations: AAT = acute acoustic trauma; CQ = cost question; EQ = efficacy question, HBOT = hyperbaric oxygen therapy; SQ = safety question; SSNHL = sudden sensorineural hearing loss; UN=United Nations; US = United States.

Notes: [a] Countries identified as *very high* on the 2022 UN Human Development Index: Andorra, Antigua and Barbuda, Argentina, Australia , Austria, Bahamas, Bahrain, Barbados, Belarus, Belgium, Brunei Darussalam, Canada, Chile, Costa Rica, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Georgia, Germany, Greece, Hong Kong, China (SAR), Hungary, Iceland, Ireland, Israel, Italy, Japan, Kazakhstan, Korea (Republic of), Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Malaysia, Malta, Montenegro, Netherlands, New Zealand, Norway, Oman, Panama, Poland, Portugal, Qatar, Romania, Russian Federation, Saint Kitts and Nevis, San Marino, Saudi Arabia, Serbia, Seychelles, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Thailand, Trinidad and Tobago, Türkiye, United Arab Emirates, United Kingdom, United States, Uruguay.[7]

What is Excluded from this HTA

This HTA will not include studies conducted among healthy individuals or individuals with conductive hearing loss, or any kind of hearing loss other than idiopathic SSNHL or AAT. We will exclude studies that do not include a comparator or studies in which we cannot isolate the impact of HBOT (e.g., HBOT with steroid treatment compared with HBOT alone would not be included). We will not include intermediate outcomes such as inflammatory markers or oxidative stress markers. For idiopathic SSNHL, we will exclude comparative cohort studies for EQ1, EQ1a, EQ2, and SQ. We will exclude pre- post studies, case-control studies, non-comparative observational study designs, and qualitative studies since we believe a sufficient volume of trials and comparative cohorts are available, which will provide a more methodologically rigorous evidence based for informing coverage decisions. Relevant systematic reviews and meta-analyses will be excluded but may be manually searched to identify potentially eligible studies. For the CQ, we will exclude any non-U.S. based cost studies. Finally, we will exclude studies published in any language other than English for feasibility reasons.

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