

HERC Coverage Guidance – Indications For Hyperbaric Oxygen Therapy Disposition of Public Comments

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Commenters

Identification	Stakeholder
A	Emeritus Physician and Clinical Professor of Medicine, Seattle, WA <i>[Submitted April 21, 2014]</i>
B	Medical Director, Springfield, OR <i>[Submitted June 1, 2014]</i>
C	Medical Director, Wound Healing and Hyperbaric Medicine, Adventist Medical Center, Portland, OR (appointed expert) <i>[Submitted June 30, 2014]</i>

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Public Comment Grouped by Commenter

Ident.	#	Comment	Disposition
A	1	According to one website (biomedexperts.com), I am the #1 expert in the world on carbon monoxide (CO) poisoning, based upon the fact that I have more published more papers in the medical literature on the topic (46) than anyone ever has. I understand that you are considering elimination of reimbursement for hyperbaric oxygen treatment of CO poisoning. I am writing to tell you that I believe that would be a mistake.	Thank you for taking the time to comment.
	2	Last year, I served as the Clinical Expert for the State of Washington Health Technology Assessment of hyperbaric oxygen therapy. You may find it interesting that we did not even consider three commonly treated diagnoses where hyperbaric oxygen is considered proven, primary treatment -- decompression sickness, arterial gas embolism, and CO poisoning.	Thank you for providing this information, along with the transcript of the WA HTA meeting.
	3	<p>I understand that your group is going back and re-evaluating yet another time clinical studies that are now over a decade old. You will not find the answer in meta-analyses such as that done by the Cochrane Group or the American Society of Emergency Medicine. All clinical trials in the area have had some flaws, some more than others. They have all used different endpoints (some clinically irrelevant) and have had varying degrees of follow-up (some even using questionnaires self-administered by the patient at home when they would not return for re-evaluation). All have also used different protocols for treatment of hyperbaric and control patients (one hospitalizing control patients not receiving hyperbaric treatment for three to six days of oxygen by mask, something that is not even done at their own institution or any other hospital in the world).</p> <p>There is no surprise that averaging six totally different studies yields no firm conclusions and the usual recommendation that “more good quality studies are needed.” Well, it has been over a decade since Weaver published his clinical trial as lead article in the <i>New England Journal of Medicine</i>. No trials randomizing hyperbaric oxygen with normobaric oxygen are underway at this time, to my knowledge. I would probably be aware of it if there were any.</p>	HTAS is aware of this controversy, and has elected not to make a recommendation regarding coverage or non-coverage of HBOT for CO poisoning.
	4	In the meantime, what is a managing physician to do? When you get severe CO poisoning tonight because of malfunction of your furnace and are taken to the emergency department, the physician there may call a regional or national expert in hyperbaric medicine for advice. Do you want the expert to say, “I don’t know what to do because I am waiting for more high quality clinical trials to be performed and published”? Of course not. You would want the expert’s opinion based upon his or her synthesis of the data available. And that opinion might be to give hyperbaric oxygen in selected cases.	See comment #3

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	5	The most common hyperbaric treatment performed for CO poisoning in the US is one treatment, followed by up to two additional treatments if the patient remains symptomatic. The treatment is typically done as an outpatient and the goal is prevention of chronic brain injury. The alternative is oxygen by mask in the emergency department until the patient's blood carbon monoxide level is normal and the patient is asymptomatic (usually 6-12 hours).	Thank you for this information.
	6	The most similar experimental approach to this common practice was the study by Weaver and that is why most experts in the field use it for guidance instead of meta-analyses that give no management recommendations and simply call for additional research. Weaver demonstrated that a practical hyperbaric protocol reduced the incidence of chronic brain sequellae by 50% at one year, as compared to oxygen at sea level pressure.	There were methodologic problems with the Weaver study, as noted in the coverage guidance. Because of this controversy, HTAS has removed any reference to this condition in the coverage recommendations.
	7	<p>I am sure that the cost of treating patients with CO poisoning with hyperbaric oxygen does not even show up on your state budget radar screen. Of an estimated 50,000 emergency department visits for CO poisoning in the US annually, only about 1,500 (3%) are treated with hyperbaric oxygen. The rest are treated in emergency departments (which may actually be more expensive in some situations, depending on the hospital's emergency department hourly charge for occupancy of a room).</p> <p>My speculation is that you are talking about less than \$20,000 annually for hyperbaric oxygen treatment of selected carbon monoxide-poisoned patients in Oregon. Is your group willing to deny that and accept the responsibility that you are instead allowing you citizens to develop chronic brain injury because "more well designed clinically studies are needed"? I hope not.</p>	<p>Thank you for this information</p> <p>See comment #3; HTAS is not recommending against coverage for CO poisoning.</p>
B	1	Thank you for the opportunity to provide public comment regarding hyperbaric oxygen therapy (HBOT). This is a subject of considerable concern to the citizens of Oregon.	Thank you for taking the time to comment.
	2	Attached is a review published in the prestigious <i>British Medical Journal</i> regarding evidence based medicine and the effectiveness of the parachute. Although it was written as satire, it points out a crucial concept relevant to your current endeavor defining indications for HBOT.	HTAS is aware of the parachute example, and in fact, it has been referenced by public commenters for a variety of previous topics that HTAS has considered.
	3	Higher levels of evidence are based on large scale human Randomized Controlled Trials (RCT), which we believe reflects medical reality. But, as the <i>BMJ</i> article symbolizes, not everything in reality can be reduced to such large scale RCT's for many reasons, not the least of which is the ability to collect large control populations, with very similar characteristics, willing or ethically appropriate to forgo a recognized treatment in the name of science. That is to say, there are simply not sufficient numbers of people willing, nor should be selected, to jump out of an airplane without a parachute in order to prove the value of the parachute for those who do. That does not negate the effectiveness of the parachute.	HTAS is aware of this and agrees that RCTs are not always feasible. When they are not can be considered feasible is a matter of common sense to some, but a matter of opinion to others. Indeed, whether or not a clinical trial is reasonable is explicitly considered in the guidance development framework attached to every coverage guidance (see pages 30-36). In the parachutes example, clearly no one would disagree with the feasibility of performing a RCT.

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	4	<p>We have the same difficulty with HBOT. There is a paucity of level 1A evidence for HBOT, not for lack of interest or motivation, but due to the practical and ethical impediments to producing a good RCT. In the case of the diabetic foot ulcer, for example, how can we possibly find a large cohort stratified for consistency in diabetes control, medications required for that control, medical comorbidities, obesity, smoking history, arterial disease, degree of neuropathy, quality of footwear, access to medical care and socioeconomic factors, all of which directly impact the outcome of the wound as confounding variables. Rather than negate the value of lower levels of evidence, especially experimental studies which are at the bottom of the “evidence pyramid”, this is an inherent, hidden detraction of higher levels of evidence, including an RCT. It is erroneous to equate a well-designed RCT in an animal model with “poor” evidence.</p>	<p>HTAS is not entirely clear on the point that the commenter is making. We agree that stratifying a cohort based on a number of factors known to influence the outcome of procedure is challenging, but can usually be accomplished statistically in the analysis. A well designed RCT in the animal model is not “poor evidence”, but has limited applicability in humans.</p>
		<p>The second point I will try to make is the problem of consolidating the entire spectrum of skin grafts and flaps into a single diagnostic category. There is a vast difference between a split thickness skin graft, a large, complex myocutaneous surgical flap, and a traumatic compromised tissue flap. It is erroneous to compare these as the same condition in assessing the effectiveness of HBOT for “grafts and flaps”.</p> <p>It is here where the parachute problem becomes especially pertinent. In my experience treating patients with HBOT, one of the most urgent needs for this therapy is in a woman with breast reconstruction in which the nipple/areolar complex becomes compromised postoperatively. Hyperbaric oxygen is the treatment of choice as the nipple/areola becomes dusky, purple, dying and, I might add, physically and psychologically irreplaceable tissue. This is an emergency situation, but does not threaten life or limb. You will never see any RCT supporting the effectiveness of HBOT in this situation. The evidence will always be, at best, deductive and based on experimental models, low level “poor” evidence. But I can assure you that if this situation arises with you or a loved one, you ARE going to want HBOT and you are going to want it NOW. It would be erroneous for the State of Oregon to disallow, or even delay in any way, insurance coverage of this crucial treatment of a potentially devastating disfigurement on the basis of lack of evidence that will never exist. Although considerably more rare, the same may be said of sudden blindness in acute central retinal artery occlusion, or deafness in acute sensorineural hearing loss. Carbon Monoxide poisoning is yet another example where human RCT studies will never exist.</p>	<p>The coverage guidance document currently recommends coverage of HBOT for compromised flaps and grafts. Is the commenter suggesting that coverage NOT be recommended for some subset of flaps and grafts? If so, which subset is not defined.</p> <p>Central retinal artery occlusion is not addressed in this coverage guidance.</p> <p>See comments A3-7 regarding CO poisoning.</p> <p>Regarding acute sensorineural hearing loss, the appointed expert provided additional information, referencing a 2012 Cochrane review and the AAO practice guideline. This information was reviewed by HTAS at their April meeting, and is repeated in comment #C4.</p>
	5	<p>I appreciate the due diligence being done by the Oregon Health Evidence Review Commission. I know you will read this with due consideration. I hope you will all enjoy the parachute</p>	<p>Thank you for your comment.</p>

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		“study”, but understand the seriousness of its underlying message.	
C	1	Thank you for the opportunity to provide additional comments regarding the OHA technology assessment on hyperbaric oxygen therapy. In large part, I have no disagreement with the recommendations of the technology assessment. I appreciate all of the work that has gone into the review by the OHA, and I will make this as brief as possible.	Thank you for your comment.
	2	There are three indications for which the HERC assessment does not recommend hyperbaric medicine that are all indications that have been reviewed and approved by the UHMS (thermal burns, refractory osteomyelitis, acute idiopathic sudden sensorineural hearing loss). The current UHMS indications book uses AHA criteria and not GRADE methodology, so it is difficult to use GRADE to argue for the use of HBOT. Dr. Murad’s paper comparing the AHA criteria with GRADE is very informative, but has limitations in that it asks one single question and one single outcome for each hyperbaric indication. This limits the ability of a heterogenous body of literature to provide high quality, consistent answers for a single patient population.	HTAS does not disagree regarding the use of GRADE in this instance. HTAS has incorporated the Murad review into this coverage guidance.
	3	I am currently chair of the UHMS Clinical Practice Guideline Oversight Committee, and Dr. Murad is a member of the oversight committee as well. We are currently undertaking a more detailed review of all of the indications for HBOT using GRADE methodology, so we will shortly have a better ability to provide a more direct answer for these indications. My request would be for the HERC take these new publications under consideration (after they are published) in order to update their guidance documents.	HTAS will be sure to review this additional information when this coverage guidance is updated.
	4	Until then, please consider the comments regarding ISSHL that I have already been submitted to the committee. In brief, the Cochrane review on ISSHL did find that there was a significant improvement in the decibel level of hearing gain, but questioned the clinical significance of that improvement. I have provided the WHO definitions for hearing loss, showing that there was a significant improvement from moderate and severe hearing loss to minimal hearing loss, which does not require the use of hearing aids. Additionally, the American Academy of Otolaryngology and Head and Neck Surgery recommends HBOT for ISSHL (CPG attached), as there are no other treatment options that have had a similar improvement in hearing, which can be life-altering.	<p>The reference provided is a process document outlining the methods used by the AAO to develop their practice guidelines. The AAO practice guideline on ISSHL was previously submitted by the commenter, and response was provided in another document (HBOT Supplemental Review: Additional Review of Evidence Provided by Public Commenter) and already reviewed by the committee. Commenter’s previous statements regarding amount of hearing improvement demonstrated in the Cochrane review, and WHO hearing loss definitions, are correct, and are repeated below for ease of consideration:</p> <p>“for patients with severe hearing loss (61-80 dB loss) as defined by the World Health Organization (WHO), the improvement was 37.7 dB. For patients with moderate hearing loss (41-60 dB), the</p>

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			<p>improvement in hearing was 19.3 dB. Using the WHO grades for hearing impairment, this represents a significant improvement from both of these categories to the slight hearing loss (26-40 dB) category (see attached slides courtesy of Heather Murphy-Lavoie, MD), which does not usually require a hearing aid. Considering that the costs of hearing aids are between \$1500-3000 per pair, need to be replaced every few years, and do not provide fully functional hearing, a limited course of HBOT (\$2000-5000 for a series of 10 sessions) may be a more cost effective and superior clinical result.”</p> <p>The previous response to this comment is repeated below:</p> <p>The American Academy of Otolaryngology Clinical Practice Guideline (Stachler 2012) states the following with regard to use of HBOT for sudden hearing loss:</p> <p>“Value judgments: Although hyperbaric oxygen therapy (HBOT) is not widely available in the United States and is not recognized by many US clinicians as an intervention for ISSNHL, the panel felt that the level of evidence for hearing improvement, albeit modest and imprecise, was sufficient to promote greater awareness of HBOT as an intervention for ISSNHL.”</p> <p>The authors of the guideline reference the SR included in the WA HTA report (Bennett 2007), and in summarizing this review, state the following:</p> <p>“Although the chance of a 50% improvement was not significantly increased following HBOT, the chance of a 25% increase was. Data indicated that a physician would need to treat 5 patients with HBOT therapy to improve 1 person’s hearing by 25%. Whether this is truly clinically significant is debatable.”</p> <p>A literature search performed by the guideline authors identified one additional RCT published after the date of the SR which found no significant difference between HBOT and the control arm in the percentage of patients who regained hearing either</p>

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			<p>moderately or completely. The authors conclude with the following:</p> <p>“Given the small number of patients in the trials reviewed, methodological shortcomings, and poor reporting, the reported findings of benefit should be interpreted cautiously. The substantial cost, the potential adverse effects (including barotrauma), a question of the clinical significance of reported benefits, and the confounding effect of cointerventions (steroids, antivirals, rheologic agents) make it difficult to weigh benefits and harms.”</p>

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References Provided by Commenters

Commenter	References
A	(1) Weaver, L. K., Hopkins, R. O., Chan, K. J., Churchill, S., Elliott, C. G., Clemmer, T. P., et al. (2002). Hyperbaric oxygen for acute carbon monoxide poisoning. <i>New England Journal of Medicine</i> , 347(14), 1057-1067.
B	(1) Smith, G., & Pell, J. P. (2003). Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials. <i>Bmj</i> , 327(7429), 1459-1461.
C	(1) Rosenfeld, R. M., Shiffman, R. N., Robertson, P. (2013). Clinical Practice Guideline Development Manual, Third Edition: A Quality-Driven Approach for Translating Evidence into Action. <i>Otolaryngology -- Head and Neck Surgery</i> 148: S1-S55.