Hyperbaric Medicine's Effectiveness: Only in the Right Hands

In the right hands the practice of hyperbaric medicine offers meaningful benefits across a select range of acute and chronic conditions. Acute benefits are significant in that they can prove both life-saving [1, 2, 3, 4, 5, 6] and central nervous system sparing. [1, 7, 8] Such benefits extend to enhanced limb salvage rates, [9, 10, 11, 12] immediate support of critically ischemic tissues,[4, 5, 9] and improved control of major surgical infections. [3, 4, 5, 13] For elective conditions such as late radiation tissue injury, hyperbaric oxygen (HBO) therapy is uniquely disease modifying, in that it serves to overcome the pathological insult frequently to the point of injury resolution.[14, 15] This therapeutic effect is in distinct contrast to common alternatives which are invariably limited to management of symptoms or removal of affected organs, with attendant quality of life implications. In cases of deficient diabetic wound healing, careful patient selection and algorithmic-based dosing can induce otherwise elusive healing responses.[16, 17, 18 , 19] In the right hands patients enjoy these important gains in an exceedingly low risk and non-invasive setting. Finally, when delivered in the right hands, those who purchase health care will be encouraged that these improved clinical outcomes were provided on behalf of beneficiaries in a cost-effective manner.[4, 19, 20, 21, 22, 23]

Unfortunately, much of hyperbaric medicine's practice over the past decade has been provided in anything but the right hands. Rather, it has been essentially 'hijacked' by venture capitalists, private investment groups and others whose primary focus is profit, rather than clinical, maximization. They seek to achieve their goal through acquisition of a wound management company business model that, while purporting to represent best medical practice standards, is principally directed at increasing hyperbaric medicine referrals and intentionally prolonging respective courses of therapy. This approach not only contradicts best practice; it results in costly and ineffective delivery of care that is all too frequently medically unnecessary.[24] This finding of a failure to identify benefit, in essence, represents the distinction between treatment efficacy as demonstrated by well-designed controlled clinical trials [16, 17] and the ineffective provision (intentionally or otherwise) of that therapy.

This business model is implemented through wound management company-hospital partnerships. Management companies need such relationships as they are ineligible to directly bill Medicare and commercial health insurers for services rendered. Physicians who staff these centers are introduced to the practice wound care and hyperbaric medicine by respective management companies. It is during both this training and in follow-up clinical practice that they are encouraged to generate certain minimum numbers of hyperbaric referrals from their wound center patient populations. Not meeting expectations often results in physicians being 'red flagged' for failing management company perceptions of what is perceived as best practice, and identified as non-aggressive'. That a given physician did not see fit to render medically unnecessary care does not feature in management company algorithms. Rather, the company dictate is that a predetermined patient volume be generated, period. While management companies generate income from both wound care services and hyperbaric medicine treatments rendered, it is hyperbaric treatments that represent the lion's share of their revenue; hence great pressure to increase patient throughput.

The management company model centers on a 'chronic wound care' facility. Preferably, it is located on hospital property but not within the main hospital itself. Medical office buildings and other free-standing properties represent desired locations. In these settings, and by design, acutely-ill patients cannot gain therapeutic access. Isolating the very patients for whom HBO therapy has the most to offer maximizes management company and hospital profits. This is because inpatient provision of HBO therapy typically results in limited or no hospital, therefore management company revenue, requires highly trained (more expensive) clinical personnel, demands 24/7 coverage with its inherent staffing costs, and necessitates acquisition of specialized ancillary equipment, all of which would serve to negatively impact net revenue.

Sadly, this means that some 75% of the Food and Drug Administration approved and Undersea and Hyperbaric Medical Society recommended indications for HBO therapy, indications for which its immediate availability is imperative, are denied access. Consequently, huge swaths of the country including many major population centers are now devoid of this life saving, central nervous system-sparing and tissue-salving therapy.[25] This is because those centers that have historically provided uninterrupted urgent care access have all too frequently found it necessary to discontinue the 24/7 availability piece or close down their hyperbaric service altogether. Management companies continue to saturate the marketplace. This has resulted in competitive pressures from large numbers of local and regional management company operated wound centers diluting 24/7 facility outpatient revenue, the very revenue that serves to offset costs associated with provision of 24/7 and other inpatient care.

Medically unnecessary aspects of hyperbaric medicine stem from manipulation of patient diagnoses where actual clinical findings do not meet reimbursement criteria by those who purchase health care. There are several ready examples of such manipulations, the first being a patient with a chronic lower extremity wound. A common way to convert this patient's condition from a non-approved to an 'approved' use is to alter the chronic wound diagnosis to one of an acute peripheral arterial insufficiency. APAI is a reimbursable indication for HBO. However, an APAI is, as the name implies, an acute and generally limb-threatening condition if the offending thrombus or embolus is not promptly removed. HBO therapy may be employed, usually post-operatively, in selected cases. However, it is adjunctive to surgical standard of care, not a stand-alone treatment and certainly never related to the care of a chronic wound. It has been observed that many such patients receive as many as 40 to in excess of 100 hyperbaric treatments for problems wounds falsely coded as APAI.

Other false coding examples include billing the health care reimbursement system for non-existent (or previously surgically eradicated) chronic refractory osteomyelitis, filing claims for a complicated skin flap when no flap was employed, billing for an otherwise reimbursable diabetic foot wound when surgery has previously removed the lesion (often an infected toe) in question, and 'upcoding' the level of presenting diabetic wounds to meet reimbursement criteria. One final example is the billing for mandibular osteoradionecrosis that does not exist. Well intentioned hospital audits would not be expected to identify these fraudulent misrepresentations. Invariably, compliance personnel screen to ensure that a match exists between a physician diagnosis and resulting diagnosis code against respective insurer's approved diagnosis. What is commonly missing in this process is the clinical insight to match a patient's actual condition with that diagnosed by the physician.

To be balanced, diagnosis code manipulation is not limited to practitioners working within the above business model. It is also found in the delivery of HBO therapy by 'independent' practitioners, some of

whom were previously associated with investor-owned wound centers or others who sense ready profits from this process.

One telling metric that relates to the amount of inappropriate use of HBO therapy is the early response to the **CMS Prior Authorization for Non-Emergent Hyperbaric Oxygen** requirement.[26] The initiative was introduced by the government in 2015 *'…to address growing concerns about beneficiaries receiving non-medically necessary about (sic) non-emergent hyperbaric oxygen therapy*. This long overdue demonstration project has been implemented in Illinois, Michigan and New Jersey. These states were selected *'…because of their high utilization and improper payment rates for these services'*. A highly placed source advised this writer that for the month of August 2015, and involving some 30 managed hyperbaric facilities in one of the above states, not a single pre-authorization request had been approved.

This would certainly suggest that pre-authorization has already served to eliminate numerous cases of fraud, abuse and otherwise medically unnecessary HBO therapy within the Medicare system. However, in its present form, it will not identify the significant degree of abuse related non-existent APAI. One certainly hopes that when the results of this three year demonstration project are fully analyzed there will be an adoption of hyperbaric prior authorization on a nation-wide basis. One also hopes that non-governmental purchasers of health care who are likewise victims of fraud, abuse and medically unnecessary care will be prompted to implement similar initiatives.

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