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To Whom it may Concern

Community-based hyperbaric treatment

I have been asked to write in support of the use of hyperbaric treatment for children with brain injury as part of the ongoing debate in Denmark. There is no doubt that it is correct for health officials to raise concerns as their medical advisors will have little knowledge of the principles involved. Unfortunately medical schools, at least in the West do not provide training in the use of oxygen as a treatment or the medical aspects of barometric pressure. This has resulted in a climate of professional distrust and many doctors fear using this important modality, especially as it is incorrectly linked to deep sea diving and some even think that hyperbaric oxygen treatment may cause decompression sickness when it actually removes nitrogen from the body. Most countries in the West do not even provide hyperbaric oxygen treatment for carbon monoxide the most common poison and as a result there are many unnecessary deaths. The recent discovery that oxygen is directly involved in the control of over 300 genes has provided a new understanding of its unique role in healing. Of the greatest importance is the control of inflammation by oxygen and its role in the release of stem cells. (*Oxygen and the inflammatory cell. Nathan C. Nature 2003;422:675-76. Thom SR, Bhopale VM, Velazquez OC, et al. Stem cell mobilization by hyperbaric oxygen. Am J Phys Heart Circ Physiol 2006;290:1378-86*) This science is now being incorporated into the treatment of sports injuries. As I have been asked to provide a professional opinion it will be helpful to provide my credentials in the field and then detail the situation in the UK.

Background

Until my retirement in 2008 I was Professor of Hyperbaric Medicine in the University of Dundee and Director of the Wolfson Hyperbaric Medicine Unit. Working in Ninewells Hospital and Medical School I was involved in research and the provision of clinical hyperbaric oxygen treatment. I have been an external examiner at the University of Copenhagen and I have provided support for commercial diving operations in the Danish Sector of the North Sea. My C.V., which lists 132 clinical and scientific publications, is available on request. Under my University contract I was also allowed to work in the industrial sector and I have been involved internationally in oilfield commercial diving and to a lesser extent in aviation medicine since my appointment as Senior Lecturer in 1975. I have continued to work as a consultant to several international diving contractors, to the UK Health and Safety Executive and to the oil companies Exxon- Mobil, Shell and BP. Since 1982 I have also been honorary consultant to the charitable MS Therapy Centres of the UK and Ireland which not only provide treatment for Multiple Sclerosis (MS) patients but also for children with cerebral palsy and autism. I was involved in their inauguration in 1982 and have since been responsible for providing medical cover. The 64 charitable community centres are mainly operated by trained lay operators working to a Code of Practice accepted by the UK Department of Health.

Regulation of Hyperbaric Facilities in the UK

In 1999 concerns about the regulation of private healthcare arose from recognition that maternal mortality and death rates in cardiac surgery in private hospitals were significantly higher than in the National Health Service (NHS). There were also concerns about failures in

private cosmetic surgery. The Private and Voluntary Health Care Regulations 2001 and the resulting Care Standards Act covered hyperbaric chambers because a number of private facilities had been set up around the country to treat diving accidents without adequate provision for acute care. The regulations also included the 64 MS hyperbaric oxygen treatment centres that had been operating in the community since 1982. Because of the very substantial data on safety from the MS community based chambers, the provision of home based treatment was also allowed under the regulations. I became the advisor to the Healthcare Commission (now the Care Quality Commission) on Hyperbaric Medicine and, as a result, the community based single compartment chambers were classified as 'Category 3' with Category 1 and 2 being reserved for high pressure chambers operating over 2 atmospheres absolute (ata). Category 3 chambers are limited to a maximum working pressure of 2 ata and are termed barochambers.

A new Code of Construction and Working Practice was drawn up in consultation with the Health and Safety Executive, the NHS and the UK Fire Services. This drew attention to the universal acceptance of pressurised aircraft as low pressure single compartment chambers equipped with oxygen breathing equipment. The safety standards for barochambers exceed those of aircraft by a very substantial margin; for example the test pressure of commercial aircraft is 1.6 times their operating pressure, whereas clinical hyperbaric chambers are tested to a minimum of 5 times their maximum operating pressure. Aircraft can never be made fail-safe because of gravity and the pressure hull is subject to the constant stresses of take off and landing. Chambers used for MS and CP children use compressed air with oxygen provided by masks or hoods reducing the risk if a fire should occur. It should be noted that there is no risk of fire if there is no source of ignition. Because of the exemplary safety record of the UK facilities operating Type 3 barochambers they were formally removed in 2008 from Healthcare Commission regulation.

The Evidence Base and the UK Experience

The experience of the 64 MS Therapy centres indicates the intrinsic safety of both the equipment used and of hyperbaric treatment. There has been no engineering failure recorded and in excess of 2.5 million hyperbaric oxygen treatment sessions have been provided without a single significant incident to over 20,000 patients. There have been mild cases of ear squeeze, just as there are in aircraft operation but they are easily dealt with by a slight reduction in pressure. The engineering of the chambers prevents the rapid decompression rates found in diving. All the UK centres have always been fully insured and no claim has been made in relation to patient treatment in their 29 years of operation.

It should also be noted that the treatment is supported by Class 1 evidence from a randomized controlled trial; *Fischer BH, Marks M, Reich T. Hyperbaric-oxygen Treatment of Multiple Sclerosis: A Randomized, Placebo-Controlled, Double-Blind Study. N Eng J Med 1983; 308:181-186.* The treatment also reduces progression of the disease. *D J D Perrins , P B James. Long-term hyperbaric oxygenation retards progression in multiple sclerosis patients IJNN 2005;2: 45- 48.*

The MS Therapy centres have also been involved in the treatment of children with cerebral palsy again in the community and this is allowed by the government under the Care Standards Act. This application is also supported by a published trial in the Lancet. *Collet JP, Vanasse M, Marois P, et al. Hyperbaric oxygen for children with cerebral palsy: a randomised multicentre trial. Lancet 2001;357:582-586.* Because of the inexperience of the investigators the group claimed to be a control group actually received compressed air at 1.3 ata . This raises the plasma oxygen tension by about 50% which, because it cannot be regarded as a placebo, rendered it invalid as a controlled group. However, to quote the

Lancet paper, both the oxygen and the compressed-air groups showed “substantial clinical improvement” despite *all other treatment* such as physical therapy and drugs being stopped six weeks before and during the study. Improvements were seen in both groups “for all dimensions” but the author’s plea for further research has not been heeded. However, over the last ten years many parents in the USA and the UK have treated their children in both the MS Therapy centres and at home confirming the findings reported in the Lancet paper.

Conclusions

The clinical evidence base supports using both air and oxygen at pressures in excess of normal barometric pressure in the treatment of a number of neurological conditions, including cerebral palsy. Given that equipment used is properly engineered to accepted standards, e.g. ASME/PVHO, Lloyds, CE etc and operators receive proper training this is an effective and extremely safe modality. With suitable training this treatment can be provided by parents in the home. I have not charged for this report and it may be distributed freely.

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