THE WESLEY CENTRE FOR HYPERBARIC MEDICINE

16 November 2012

Supplementary Submission to

Standing Committee on Finance and Public Administration References Committee Inquiry into Medicare funding for Hyperbaric Oxygen Treatment

Introduction

- Wesley Centre for Hyperbaric Medicine wishes to provide the following supplementary submission to the above Inquiry in order to respond to submissions made by other witnesses during the hearing on 12 November 2012.

Gold Standard Evidence

- At no time did DoHA or MSAC consult the Wesley Centre for Hyperbaric Medicine as to the impact of their decision to remove Medicare funding for non-diabetic chronic problem wounds before the announcement in the 2012 Budget.
- At no time did MSAC raise the likelihood with ANZHMG that their prospective Wound Study would constitute an insufficiently high level of evidence to justify continued funding; not at the time of initiation in 2004, nor when updated of progress in 2006 (after which 13015 was recommended to continue), nor when updated of progress in 2008 (after which 13015 was again recommended to continue); then in 2011 randomised controlled trials (RCT's) become the "gold standard" of high level evidence against which efficacy was to be judged.
- Given this new definition of high level evidence (RCT's free of selection bias and clear comparator controls) the MSAC review of HBOT for non-diabetic non healing wounds could only reach one conclusion; there was one small, low powered 16 patient RCT (Hammarlund - designed to study wound size reduction, not efficacy) on which to draw; the conclusion – insufficient evidence to support efficacy; *such a conclusion was inevitable*.
- DoHA admitted "no study that is small is ideal, but it is the best available"; *again, a conclusion of insufficient evidence was inevitable.*
- For DoHA to claim that the Cochrane Collaboration came to the same view as MSAC *is mischievous*. The Cochrane Collaboration HBOT study referred to, analyses 9 RCT's (8 for diabetic foot ulcer and 1 non-diabetic – the Hammarlund RCT!); on the basis of this single, low powered RCT Cochrane too, found "*no evidence to confirm or refute*" efficacy; again there was no way they could find otherwise, *such a finding being inevitable*.
- Interestingly, a co-author of the Cochran Collaboration HBOT study, A/Professor Michael Bennett, is the same A/Professor Michael Bennett who was one of MSAC's two *dissenting expert clinicians* (along with A/Professor David Smart).

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- For DoHA to feign knowledge as to whether there are RCT's for Decompression Illness, Gas Gangrene and Necrotising Fasciitis, all of which Medicare funds, *is mischievous or deliberately evasive*; DoHA do have knowledge; MSAC has reviewed these three indications and funds them all, despite the absence of RCT's (because the sham arm of any RCT would result in death or permanent physical incapacitation); *it would appear that the levels of evidence required by MSAC are flexible and the decision whether to fund or not completely subjective, not objective as DoHA would wish us to believe.*

What MSAC does say?

- MSAC state that available evidence suggests HBOT does provide benefits, but the overall body of evidence is insufficient to determine whether HBOT is more effective than usual care; in plain language – this does not mean that HBOT is *less* effective;
- MSAC acknowledges the efficacy of lower level evidence in addition to positive clinical assessment; in plain language – in the clinical setting, *HBOT is delivering actual healing, alleviation of pain and improved quality of life*;
- MSAC state that clinical expert opinion believes evidence for HBOT efficacy is at least as good as that available for usual care; in plain language – usual care is no more or less effective than HBOT; and
- MSAC acknowledge it did not take into account the improvement in the patient's quality of life and suggests evidence of this may be substantial; in plain language – *the benefit of HBOT is underestimated and absent from the MSAC costing analysis*.

The coal-face consequences

- MSAC acknowledge HBOT is delivering clinical outcomes and is not proven less effective; only in the restricted terms of MSAC is it impossible to make any definitive comparison of relative effectiveness (based on RCT's). On such as basis, the Government has withdrawn public funding from a funded treatment, *but without any evidence that any alternative treatment is more effective*.
- MSAC state that clinical expert opinion is that the evidence in support of the use of HBOT is at least as good as that available for alternative treatments and therapies; *the ANZHMG wound study suggests <u>better than</u> alternative treatments and therapies*.
- This translates to a massive transfer of un-costed liability to the public health system and disenfranchisement of the 10.6 million Australians who currently hold private health insurance; without a Medicare number, the private health insurance funds do not provide a benefit to their members;
- For the patients disenfranchised by this decision, all of whose wounds do not respond to usual care, the future is bleak; unless they can self-fund, these patients will face continuing pain, suffering and reduction in quality of life, while the ever present threat of infection can lead to life threatening sepsis and amputation.

We have patients already suffering the consequences of this decision, unable to self-fund and consequently withdrawing from treatment. Accordingly, we hope that this Inquiry can recommend reversal of the Budget decision and reinstatement of Medicare funding for HBOT for non-diabetic chronic non healing wounds.

David Oliver
Executive Director.