16 November 2012

Australian Healthcare & Hospitals Association
Supplementary Submission to

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

Introduction

- The Australian Healthcare & Hospitals Association (AHHA) and the Australian and New Zealand Hyperbaric Medicine Group (ANZHMG) wish to provide the following supplementary submission to the Standing Committee on Finance and Public Administration References Committee in order to respond to comments made at the hearing by the Consumer Health Forum and the Department of Health and Ageing.

MSAC failed to reach an evidence-based conclusion

- Ms Carol Bennett (CEO Consumers Health Forum) told the Committee that "*health consumers …. strong[ly] support …. basing health decisions on independent, validated evidence about what is effective. CHF has adopted this principle of basing decisions on evidence of effectiveness, including cost-effectiveness, as the touchstone for the development of our policy positions in relation to government and taxpayer funded health services*". She said: "*In considering the safety, effectiveness and cost effectiveness of this treatment, MSAC found there is insufficient evidence to justify public funding of this treatment for this particular condition*".
- Professor Ward also said that: "*There was not sufficient evidence to convince the committee that this was effective".*
- However, these statements are not true. In this case, MSAC failed to reach an evidence-based conclusion to underpin its recommendation to defund Medicare funding for HBOT of non-diabetic chronic wounds (an established therapy since 1984). The whole MSAC effectiveness review rested on a single 18 year-old Randomized Control (RCT) Study, the small size (16 patients) of which required a considerable difference in outcomes to reach statistical significance (published by Hammarland and Sundberg undertaken in 1994). That does NOT mean that HBOT is less effective; only that, in strictly scientific terms, it is impossible to make any definitive comparison of relative effectiveness.
- Also the conclusions reached by MSAC about the Hammarlund and Sundberg (1994) paper are different to the interpretation of the papers by the authors. They declare that the paper was designed to look at wound size reduction and NOT healing because of the low number of treatments and also the 18 week follow up can not be extrapolated as to healing rates as that was not the intention of the paper. Using this paper as the sole determinant of removal of funding based on incorrect interpretation is a dangerous precedent and this makes the ANZHMG papers the best available evidence for wound healing which is positive for wound healing by HBOT.
- Five case series reports, three of which came from the Australian work requested by the MSAC in 2004, were dismissed as uncontrolled and of too poor a quality to be included, as was the bulk of expert opinion sought by the MSAC, despite the MSAC Assessment Report acknowledging the effectiveness of HBOT according to the lower level evidence. Accordingly, the MSAC rejected the data from the Australasian Wound Study that was set up following the MSAC's own recommendations in 2003-4.
- MSAC instructions (April 2003) to develop a national wound study based on a collection of data based on outcomes were acted on by the ANZHMG in good faith over the following years. The study involved prospective enrolment of more than 400 patients with strict entry criteria in

which patients had failed three months of standard care and were referred to HBOT as a second-line treatment. The costs have been borne by the individual ANZHMG and the public teaching hospitals of Australia. The study is yet to be published, because the last 12-month follow-up is due to be completed early in 2014.

- It is of great concern that this data was not accepted by MSAC in 2012. The opportunity to correct the process was available to MSAC. There had been communications between AHHA and MSAC in relation to the data: Stephen Blamey in 2006 and Bill Matthews in 2008 relating to an update of that study.
- An update including the published results of the ANZHMG wound study (interim 3 year results in 2006) was provided to MSAC in 2007. MSAC accepted this update and allowed an extension of the 3C item number for a further three years. If MSAC had concerns about the quality of this data then they should have provided feedback to ANZHMG and AHHA at that time. This represents a complete failure of process.

Incorrect statements regarding MBS expenditure

- Both the Consumers Health Forum and the Department of Health and Ageing incorrectly reported that, since 2000, *the treatment of non-diabetic chronic wounds by HBOT has cost $11 million of MBS funding*. This is wrong.
- The total expenditure for MBS item 13015, extending from 2001 through to 30 June 2012, was $10.6 million. However, according to the department's own figures in the MSAC report, 44 per cent of the amount went to non-diabetic problem wounds and 56 per cent of the amount went to the soft tissue radiation injury: 154 patients were treated annually for non-diabetic problem wounds and 189 patients were treated annually for soft tissue radiation injury. Therefore the actual expenditure on non-diabetic wounds is actually 44 per cent of $10.6 million or $4.7 million over 11 years - an average of $427,000 per annum.

Questions arise about how MSAC obtains its information and conducts its reviews

- Ms Carol Bennett (CEO Consumers Health Forum) told the Committee that: "*Decisions have to be made about expenditure that on balance achieves the greatest overall health benefit, after factoring in the merits of competing treatments and procedure"*. However, MSAC's assessment role relates to new technologies and was inappropriate for this review of an established therapy in which a very high level of evidence for the treatment of interest was expected without any corresponding assessment or requirement for the alternative funded therapies. Very few existing therapies would pass such an unbalanced assessment.

Conclusion

- MSAC provided instructions to hyperbaric medicine specialists to undertake data collection regarding outcomes of hyperbaric oxygen therapy for non-diabetic problem wounds. Despite having the opportunity to revise this instruction when ANZHMG and AHHA forwarded data updates and the 2006 interim study results, MSAC took no action. In 2012 MSAC has rejected the data from the study that was commenced following its own recommendations in 2003. This is a clear denial of natural justice.
- The decision to withdraw CMBS funding for the HBOT of chronic non-diabetic wounds (CMBS 13015) in the 2012-13 Commonwealth Budget effective 1 November 2012 was made, in the view of AHHA, on the basis of flawed decisions by the MSAC. Its Assessment Report 1054.1 (November 2011) and subsequent Reconsideration (2 August 2012) were wrong in both principle and practice and inconsistent with Medicare principles. The result is that the MSAC has recommended withdrawal of public funding from an existing funded treatment but has provided no evidence that any alternative treatment is effective.
- The AHHA and the ANZHMG are seeking reversal of the decision announced in the 2012-13 Commonwealth budget to withdraw CMBS funding. Already patients are affected by this decision to cut funding.

AHHA letters to the Minister

The Senate Committee requested copies of all letters sent to the Minister on this issue. They are attached:

- 12 July 2012
- 19 August 2012
- 15 October 2012

Prue Power AM
Chief Executive
Australian Healthcare & Hospitals Association