Submission to the Senate Finance and Public Administration Reference Committee inquiry into Medicare Funding for Hyperbaric Oxygen treatment of chronic wounds.

I have been asked to make a submission to the Committee concerning the MSAC recommendation to cease Medicare funding of Hyperbaric Oxygen Therapy for the treatment of chronic non-diabetic wounds. Several weeks ago, the Australian Healthcare and Hospitals Association requested, at short notice, my opinion on this decision. I was provided with the MSAC Assessment Report of November 2011 and some of the material that the applicants had used in their request for a reconsideration. Based on that material, I concluded that the MSAC decision was inconsistent with much of the data in the Assessment Report and was wrong in both principle and practice. However I was not provided with the MSAC decision and its response to the reconsideration request in August 2012. What follows is based on that response as well as the earlier documents.

The decision

MSAC's decision was essentially based on two considerations:

(1) There was insufficient high-quality information to show that the addition of HBOT therapy to the comparator treatment ('usual care') was more effective than 'usual care' alone. The two options were therefore assumed to be of equal effectiveness.

(2) Costing studies showed that adding HBOT to the 'usual care' protocol increased cost.

(3) On cost effectiveness grounds, the additional cost could not be justified and public funding of HBOT should therefore be withdrawn.

Given MSAC's definition of high quality evidence – randomised control trials free of selection bias with clear comparator controls – such a conclusion was inevitable. The Assessment Report included only one small (16 patient) RCT study published by

Hammarland and Sundberg in 1994 and only five case series reports, three of which came from the Australian work requested by MSAC in 2004. However, the latter were dismissed as uncontrolled and of too poor a quality to be included, as was the bulk of expert opinion. The whole effectiveness review thus rested on a single study 18 years ago, the small size of which required a considerable difference in outcomes to reach statistical significance. MSAC's reply to the application for reconsideration (August 2012) concentrated on the absence of high-level RCT data, delays in recruitment for the sham-controlled trial that has recently commenced, the small number of centres committed to participation, flaws in the design of the trial and doubts about its completion within the three year period proposed.

The process

My own view is that, whatever the true position is, the results of one small RCT study that failed to demonstrate the benefits of HBOT statistically do not justify withdrawing public funding for an established therapy for which the Assessment Report showed some lower level evidence and clinical support. The assumption of equal effectiveness is just that – an assumption. not a fact, because 'the absence of evidence is not the evidence of absence'. Moreover, statistical hypothesis testing deals only with mean results and from a health service viewpoint, withdrawing funding may reduce access to services to some patients who would have benefited from the HBOT addition. Patient numbers are small – only about 160 annually. They are sick people, costing over $20,000 a year to treat. But removing the HBOT addition would save Medicare less than $400,000 annually in a total Medicare bill of over $16 billion, and even that is somewhat uncertain because of the complexity of the comparator scenarios. I understand that the public hospital providers will not significantly change their operations, so that the number of patients actually affected may be relatively small. My in-principle concerns are about a methodological dispute between MSAC and the HBOT providers affecting patient care on purely financial grounds.

There are clearly a number of issues over process. The MSAC 'reconsideration' document shows a growing exasperation with the HBOT providers over the design of the current trial, its scientific validity and the ability of interim funding to;

> "achieve its primary objective, namely, the production of evidence that can be used to support decision making. This view was informed by past experiences of MSAC in reviewing the outcome of interim funding decisions",

concern over the potential for interim funding to create;

> "a perverse incentive for applicants to rely on weak rather than strong evidence for the initial MSAC consideration."

and a number of issues over the need for agreement across all the affected parties on study design, data collection and data analysis, plus concerns over the effects on all parties if funding were subsequently withdrawn.

Although there would be technical difficulties (random allocation at a precise stage in the treatment process) and the trial could not, and should not, be managed by the HBOT providers alone, MSAC's recommendations are soundly based. However they appear not to have been shared by the HBOT providers who believe that discussions with MSAC prior to the 2004 review gave them to understand that a case series study would be adequate. Whatever the correct interpretation, there has obviously been a communication breakdown and there have been faults on both sides. As far as I am aware, MSAC has not formally communicated its requirements to the HBOT group who, in turn, appear not to have sought clarification or advice over a quite lengthy period.

This raises some questions about how MSAC obtains its information and conducts its reviews. Nearly all of its decisions relate to new technologies for which there are, by definition, no Australian data. Applications for approval come from the originators or users of the technology and the assessment process rightly includes ensuring that he information provided was collected and analysed independently and in accordance with the relevant scientific standards. The onus is on those seeking approval on either

commercial or professional grounds to demonstrate its clinical value and cost-effectiveness. But this is a review of an established therapy supported by the MBS for 20 years. The Assessment Report included expert clinical comments that queried whether the standard MSAC assessment process was suitable for such a review and the applicants' request for reconsideration (which I have not seen) apparently made similar comments.

That argument was rejected. I think that MSAC was wrong. The recommendation to de-fund HBOT might well turn out to be correct but the evidence used to support that is just as weak as the case would be to add it. However the consequences would be different. Removing funding on the assumption that nobody will be harmed is not the same as adding a payment on the assumption that somebody will benefit. Prudence requires that better information be obtained. The proposed trial should therefore proceed, subject to four conditions:

(1) that data quality and procedures are clearly set out and agreed upon, preferably under the management of an independent body in which both parties have confidence.

(2) that the present HBOT benefit continues for the period of the trial or two years, whichever is the less, so neither patients nor referring doctors have cost considerations in mind.

(3) that any ethical issues involved in deliberately continuing, for any length of time, treatment which has apparently failed, are satisfactorily addressed.

(4) that the nature of any subsequent review is clearly understood.

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That is my recommendation to the Committee

John Deeble

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