HAWKINS SENATE STATEMENT

Thank you for giving me the opportunity to present the concerns that we have over the removal of Hyperbaric Oxygen Therapy (or HBOT) for non-diabetic chronic hypoxic wounds from the Medicare Benefit Schedule.

Firstly, we agree that the government should only pay for treatments proven to be safe, efficacious and cost effective.

We believe that HBOT fulfils the criteria and were surprised when the MSAC committee found otherwise.

ACCEPTED POINTS:

The fact is that when people have failed at least 3 months of standard wound care (and the average is 19.9 months) and you give them an appropriate course of Hyperbaric Oxygen Therapy, in the venous ulcer group, 68.3% are nearly or fully healed at 6 months.

Therefore 100% of people treated with HBOT have failed standard wound care.

This is not disputed by either MSAC or us.

DISPUTED POINTS:

What is disputed is that the MSAC report has stated that the same outcome would have occurred with standard wound care.

Logic dictates that if a wound has not healed within an average of 19.9 months, it is unlikely to get better in the subsequent 6 months. MSAC has no basis to support this 'assumption' (and I use their word), but they have made that assumption when comparing the two treatments: HBOT + Standard wound care vs standard wound care alone.

If you make that assumption, then no treatment modality could ever be assessed as cost effective as all that is being done is the addition the cost of HBOT without changing the outcome of the illness, which is what saves money and makes the treatment more cost effective.

ANALOGY – FOCUS ON THE CORRECT OUTCOME DATA:

To illustrate this; let's take a different example. Most people know that antibiotics help fight infections and are a cost effective treatment as they save lives. If you have a trial where you treat one group with INTENSIVE CARE alone for a serious infection and another group with INTENSIVE CARE + ANTIBIOTICS and you PREDETERMINE that both groups are going to have a 50% death rate then the antibiotics are not going to be a cost effective measure and according to MSAC logic, this should not be paid for. However, if you look at the ACTUAL DEATH RATES and see that INTENSIVE CARE has a 50% death rate and INTENSIVE CARE + ANTIBIOTICS has a 10% death rate, then antibiotics becomes very cost effective, as you reduce death rates by 40%.

Unfortunately MSAC has seemingly focused on the wrong outcomes when it had no data so predetermined healing rates for non-hyperbaric patients to be the same for HBOT patients with no justification or evidence.

COMPARATOR STUDY:

There is a comparator study by Louisa Gordon and colleagues in 2006 (which MSAC used for costing analysis) of Australian based high level wound care. She showed that of their group of patients in the first three months, 20 out of 56 patients healed (35%). These are the patients that would have not had HBOT in the first place. Subsequently in the next three months only a further 5/36 healed (13.9%). HBOT in contrast had a healing rate of 52.3% by the end of the hyperbaric treatment alone going onto 85.2% at 12 months for venous ulcers.

Why is this not good cost effective medicine when a years' worth of non-hyperbaric treatment costs the taxpayer in excess of $40,000.00 per annum (according to MSAC).

The additional cost of HBOT is, on average, $212.00 x 30 treatments ($6360.00) and the calculations when doing the correct healing rates (as Associate Professor Smart shall show) is a saving of more than $5000.00 per person NOT a cost vs standard wound care.

THE ISSUES:

So why did MSAC get it wrong? This is the third attempt at a review and it remains difficult for MSAC to assess a treatment that is a secondary treatment, that is, a treatment that is introduced after the failure of a prior treatment.

It is important to note that HBOT is only used after a person has failed standard wound care treatment for a period of at least 3 months.

So HBOT gets the 'difficult to cure' patients and then treats them with great success. You cannot compare the results to initiated standard wound care because they have already failed standard wound care.

But even with standard wound care, being equalised with HBOT, using Gordons' data they healed 44.6% venous ulcer patients at 6 months and HBOT had healed 68.3% and they started with the easy ones!

PROCEDURAL ISSUES AND MISINTERPRETED DATA:

There are also some concerns regarding procedural issues and misinterpretation of data.

The one randomised controlled trial that is quoted by Hammarlund and Sundberg in 1994 has been misinterpreted by the MSAC as they state that there was significant improvement in wound area in the HBOT vs placebo treatment at the 4 and 6 weeks mark and this improvement continues to the 18 weeks mark. They did not do an analysis at the 18 weeks mark because they had a significant drop out of patients. MSAC has stated that they have performed the analysis and found no statistical difference between the groups at 18 weeks.

Correspondence from Dr Christer Hammarlund (submitted as Appendix 8) states that this was never stated (at the 18 week mark) and statistical analysis was not done because that was

not the aim of the paper and he is somewhat surprised that it has been interpreted as a failure of HBOT, given, in his opinion, it was very positive for HBOT.

Also, the contradictions in the report (highlighted in Appendix 1) and the fact that there was significant dissent from the two expert committee members who, to my understanding, were also told that they did not need to vote to accept the report as the decision was already in the majority. This report has already been tabled twice (once as a reply to a question proposed by Senator Abetz in parliament and once here in the Department of Health and Agings submission as twice being a unanimous decision of the committee when clearly it is not. It is apparent that the objectivity of the MSAC committee was somewhat misleading and is therefore cause for concern.

LACK OF A FORMAL REVIEW PROCESS:

Finally, there is no way of contesting this document on the basis that there is no formal review process available. All we have is the report (and what's in it) and then Mr Richard Bartlett arranged an *ad hoc* review which was performed by the same committee members, which is hardly an independent review process. Mr Bartlett has been helpful and, at my formal request, tried to elicit an external assessment from someone in the NH&MRC. However, the verbal report in response was categorical agreement with the MSAC process. To this day, I have not received a formal reply or even acknowledgement of who conducted the review and what ~~the~~ questions were asked~~.~~

Ultimately, the MSAC ideal of safety, efficacy and cost effectiveness is a good one but the assessment of HBOT is flawed due to the inflexibility of the system in managing secondary treatments and the misinterpretation and mishandling of the data.

We would accept definitive evidence that proves that HBOT does not work in chronic non-diabetic wounds, but as it currently stands all the evidence available favours HBOT as a method of healing chronic non-diabetic wounds over standard wound care. The faster these wounds can be healed, the less cost to the taxpayer and, ultimately, the better outcome for the patient in the reduction of pain and suffering.

So the questions that we want to know the answers for are:

1) After three reviews, why is the MSAC system still getting the outcomes wrong with respect to HBOT?

2) Why should assumptions of equivalency be made when the default position for an already existing treatment modality be that if it has any evidence proving efficacy then it should remain until it is proven to be less efficacious?

3) If there is a new "level of proof" shouldn't that level be allowed to be proven prior to the removal of an MBS items or at least be equalised vs standard treatment until proof exists on way or the other? (which has been offered to the Department of Health and Aging)

4) Should there not be a defined process where the processes and statements can be challenged externally to the MSAC committee prior to the Minister making blanket decisions?

5) Is there not significant doubt about the whole process that mandates a moratorium of the cessation of funding until a proper pathway for assessing secondary treatments can be determined and the current RCT on venous ulcers can be completed?