Chapter 2

Withdrawal of Medicare funding for HBOT

Introduction

2.1 The following discussion canvasses issues that have been brought to the committee's attention regarding the withdrawal of Medicare funding for Hyperbaric Oxygen Treatment (HBOT) for non-diabetic wounds. The withdrawal of funding occurred as result of a Government decision, based on recommendations by the Medical Service Advisory Committee (MSAC), in its third formal assessment of the use of HBOT for non-diabetic wounds. Significant issues that have been brought to the committee's attention include whether the assessments have been fair as well as the impacts on patients of the treatment being withdrawn.

MSAC assessments of HBOT

2.2 As noted in chapter 1, MSAC formally reviewed HBOT for wound treatment for non-diabetic patients on three occasions: 2000, 2003 and 2011. A number of concerns raised with the committee regarding the MSAC assessments included the impartiality of experts, whether appropriate consultation occurred, whether there are appropriate review processes, and whether the assessment criteria have changed. These issues are explored in the following sections.

Basis of MSAC decision

2.3 Submitters to the inquiry raised concerns about the MSAC decision in relation to the quality of the evidence used, first line versus second line HBOT application and lack of consideration of a current trial, which may provide further evidence.

Quality of evidence for HBOT assessments

2.4 The quality of evidence has been central to the debate on the MSAC assessment of HBOT for non-diabetic wound patients. Dr John Deeble commented that MSAC had come to its decision because 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. MSAC's Assessment Report included only one small randomised control trial (RCT), the Hammarland and Sundberg study from 1994. The Assessment Report also included five case series reports, three of which come from Australian work requested by MSAC in 2004. Dr Deeble commented that MSAC had dismissed the case series reports as being 'uncontrolled and of too poor a quality to be included, as was the bulk of expert opinion'.[1]

1 Dr John Deeble, *Submission 41*, pp 1–2.

2.5 The dismissal of the Australian and other studies by MSAC was also raised by other submitters.[2] The Australian Healthcare and Hospitals Association (AHHA) provided the committee with correspondence to the Minister for Health and Ageing that stated:

> To investigate HBOT for non-diabetic problem wounds, a large multicentre Australasian wound study had commenced after specifically being requested by MSAC in its 1054 report and reiterated in the 1054.1 report. Entry criteria for the study were strict in that the patients' wounds were refractory to standard care for greater than three months (the median time at entry was 16 months). This study investigated HBOT as a secondary intervention when standard care had failed.
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> Despite results showing that greater than 75% of all wounds referred for HBOT remained healed at 12 months after treatment, MSAC totally rejected this evidence.
>
> We have major concerns that results from this huge national data collection (over 400 cases during a 7+ year period) have been ignored. This untenable situation has resulted in a massive waste of ANZHMG's time and resources and potential loss of valuable patient data.[3]

2.6 The Australian Society of Anaesthetists submitted that:

> MSAC appears to have disregarded the positive results of a major Australian study, involving over 400 patients who were followed up over 7 years, despite the fact that MSAC itself actually requested such a study be performed as part of the assessment process.[4]

2.7 The Wesley Centre for Hyperbaric Medicine also shared its view with the committee:

> In giving its advice, MSAC could only draw on data from a small, 1994 Scandinavian RCT of 16 patients. MSAC declared "…the overall body of evidence is currently insufficient to determine whether clinical management with HBOT is more effective than clinical management without HBOT". (MSAC Assessment Report 1054.1 Nov 2011 page 13). This 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. Indeed MSAC did acknowledge the efficacy of lower level evidence in addition to positive clinical assessment. [5]

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2 Dr Glen Hawkins, *Submission 4*, p. 2; Australian Society of Anaesthetists, *Submission 9*, p. 1; Australian Medical Association, *Submission 10*, p. 2; The Wesley Centre for Hyperbaric Medicine, *Submission 12*, p. 2; Associate Professor David Smart and Associate Professor Mike Bennett, *Submission 18*, p. 5.

3 Australian Health and Hospitals Association, *Submission 13, Attachment 3*, p. 3.

4 Australian Society of Anaesthetists, *Submission 9*, p. 1.

5 The Wesley Centre for Hyperbaric Medicine, *Submission 12*, p. 2.

2.8 The department informed the committee that RCTs are used where possible and that MSAC makes use of the best evidence that is available.[6] Professor Ward, Chair of MSAC, also responded to these concerns, stating that:

> The reason that is very important is that built into a higher level of evidence is the removal of a lot of biases that happen when you do a cohort study. The reason is that, for instance, the enrolment of patients in a wound study is non-consecutive; they do not take every single patient one after another; it is not comparative; you do not compare X with Y; you are just comparing the single group of patients.[7]

2.9 The MSAC 1054.1 assessment indicated that non-comparative studies could not be used to determine an intervention's relative effectiveness within the MSAC process:

> It should be noted that the applicant included in their submission a comprehensive evidence review that incorporated all treatment options for chronic non-diabetic wounds and non-neurological soft tissue radiation injury, and requested that HBOT be assessed within this broader context. However, given the inability for non-comparative studies to be used to determine an intervention's relative effectiveness within the MSAC process, this was deemed outside the remit of the current assessment.[8]

2.10 Professor Ward confirmed that use of HBOT for non-diabetic chronic wounds had failed the clinical effectiveness test in the 1054.1 assessment and stated that:

> Independent of the MSAC consideration, the same conclusion has been reached this year in a systematic review of the available clinical evidence conducted by the internationally acclaimed Cochrane Colloquium and last year by the Australian and New Zealand Clinical Practice Guidelines.[9]

2.11 During the inquiry it was brought to the committee's attention that while MSAC desires RCT as a core piece of evidence, there are often particular difficulties in completing RCT's due to ethics issues and the resulting narrow focus required as Associate Professor Smart explained:

> We would had to have had a narrower focus. Ethically, in a randomised trial I could not treat people who were scheduled for an amputation. That is one of the reasons why the current trial that has been set up at the Wesley has such a narrow focus, to get a group of people who do not stand to be

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6 Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing, *Committee Hansard*, 12 November 2012, p. 42.

7 Professor Robyn Ward, Chair, Medical Services Advisory Committee, *Committee Hansard*, 12 November 2012, p. 42.

8 Medical Services Advisory Committee, *Application No. 1054.1 – Review of Interim Funded Service: Hyperbaric Oxygen Therapy for the Treatment of Chronic Non-Diabetic Wounds and Non-Neurological Soft Tissue Radiation Injuries*, Public Summary Document, 29 November 2011, p. 3.

9 Professor Robyn Ward, Chair, Medical Services Advisory Committee, *Committee Hansard*, 12 November 2012, p. 33.

> severely disadvantaged out of a randomised control trial. To ensure that you have a narrow focus with a group that has very strict, small entry criteria is quite challenging.
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> Indeed, one of the comments made when we appealed that to MSAC was that that trial was not going to answer the question for non-diabetic problem wounds because it is too narrow. The problem with randomised control trials is that they become quite narrow because you have to have very specific entry criteria to them. Let us say that you have an age that stopped at the age of 50—that you had an age 50 to 70 where you accepted people—and you came in with age 48, then the evidence-based medicine purists would not allow you to treat the 48-year-old because they were outside the trial criteria.[10]

2.12 As a consequence, MSAC's review rested on the Hammarlund and Sundberg study. Dr Deeble described this as 'a single study 18 years ago, the small size of which required a considerable difference in outcomes to reach statistical significance'.[11]

The Hammarlund and Sundberg study

2.13 The MSAC assessment indicated that in its view the of the Hammarlund and Sundberg study:

> [S]howed a significant initial decrease in wound area with HBOT compared to placebo, but this benefit was not found at 18 weeks after initiation of treatment. All included case series reports demonstrated beneficial outcomes from use of HBOT in wound healing or pain relief.[12]

2.14 Some witnesses and submitters to the inquiry indicated that in their view the Hammarlund and Sundberg RCT study had been misinterpreted by MSAC.[13] The author of the study also queried the MSAC interpretation of his data:

> I like to stress that the study was designed (by myself) to show significant reduction of wound areas in HBO treated wounds compared with the placebo treated wounds – nothing else.
>
> That's why only 30 treatments were chosen – and thus saving research money.
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> It is not possible to extrapolate to the follow-up results simply because the number of treatments (30) was too few to expect wound healing. That the small wounds healed after 30 treatments is of course interesting –

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10 Associate Professor David Smart, Chairman, Australian and New Zealand Hyperbaric Medicine Group, *Committee Hansard*, 12 November 2012, pp 23–24.

11 Dr John Deeble, *Submission 41*, p. 2.

12 Medical Services Advisory Committee, *Application No. 1054.1 – Review of Interim Funded Service: Hyperbaric Oxygen Therapy for the Treatment of Chronic Non-Diabetic Wounds and Non-Neurological Soft Tissue Radiation Injuries,* Public Summary Document, 29 November 2011, p. 8.

13 The Wesley Centre for Hyperbaric Medicine, *Submission 12*, p. 2; Dr Glen Hawkins, *Submission 4,* p. 3; Mr David Oliver, Executive Director, Wesley Centre for Hyperbaric Medicine, *Committee Hansard*, 12 November 2012, p. 29.

> remembering there had been no tendency to wound healing for at least two years before being treated with HBO.[14]

2.15 The Hammarlund and Sundberg study results for patients given six weeks of HBOT, showed statistically significant wound size reduction:

> The mean decrease in wound area at week…6 in the oxygen group [was] 35.7 per cent (SD +/- 17)…and in the air group…2.7 per cent (SD +/- 11) …The data indicate that hyperbaric oxygen therapy may be used as a valuable adjunct to conventional therapies when nondiabetic wounds do not heal.[15]

2.16 The committee notes that MSAC appears to have placed more weight on the less certain 18 week data than the six week results. The committee observes that at 18 weeks it is more difficult to have confidence due to 5 patients leaving the trial. The Hammarlund and Sundberg study itself actually stated that:

> Although five patients left the study at week 18…the remaining data indicate a continuing effect on wound healing after the hyperbaric treatment had ceased after week 6.[16]

2.17 The committee notes that the National Health and Medical Research Council (NHMRC) provided feedback to the department that MSAC had given appropriate weight to the evidence before it, in its consideration of HBOT for non-diabetic wounds.[17] However, given MSAC's advice that it gives greater weight to the highest quality data,[18] the committee is therefore uncertain as to why MSAC did not place greater weight on the best statistical data from the Hammarlund and Sundberg study, which is the six week data, demonstrating a statistically significant positive outcome for the use of HBOT.

First line versus second line HBOT application

2.18 A further issue raised with the committee about the MSAC HBOT assessment is how HBOT for non-diabetic wound patients was compared to other treatments. Several submitters indicated that in their view MSAC had compared HBOT to first line treatments when that may not be appropriate. It was argued that HBOT is only used as a second line treatment in addition to first line treatments, once first line

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14 Dr Christer Hammarlund, correspondence with Dr Glen Hawkins, *Submission 4*, Attachment 11, p. 1.

15 Hammarlund, C. and Sundberg, T., *Hyperbaric Oxygen Reduced Size of Chronic Leg Ulcers: A Randomized Double-Blind Study*, Plastic and Reconstructive Surgery, 93(4), April 1994, pp 829–833.

16 Hammarlund, C. and Sundberg, T., *Hyperbaric Oxygen Reduced Size of Chronic Leg Ulcers: A Randomized Double-Blind Study*, Plastic and Reconstructive Surgery, 93(4), April 1994, pp 829–833.

17 Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing, *Committee Hansard*, 12 November 2012, p. 34.

18 Professor Robyn Ward, Chair, Medical Services Advisory Committee, *Committee Hansard*, 12 November 2012, p. 42.

treatments had failed.[19] The Wesley Centre for Hyperbaric Medicine informed the committee of its concern:

> While acknowledging HBOT as a second line treatment, MSAC incorrectly costed HBOT as a primary line of treatment that would cost $2151 per patient extra over 6 months of standard wound care (44.6% healed); in reality, when calculated correctly as a second line treatment, after failure of 3 months of standard wound care, there is a cost saving of $5502 per patient (72.8% healed);
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> MSAC costed failed standard care (55.4% failure at 6 months) at $40232 per patient per year, yet ignored this additional cost when advising that withdrawal of HBOT funding will save Government $4.8M over 4 years; the fact is, withdrawing funding for HBOT will add millions to national health costs, not save millions.[20]

2.19 Professor Ward responded by clarifying how MSAC viewed HBOT for non-diabetic wound patients as a second line treatment option:

> MSAC definitely considered this as a second-line treatment. The definition 'chronic' was meant to mean that it had failed standard of treatment. All through the MSAC public summary documents and all through everywhere, 'chronic' means 'having failed standard of treatment'. So we felt that, all through the definitions that were included in the documentation, there was no misunderstanding that we were ever talking about first-line treatment.
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> Every ulcer is labelled as a chronic ulcer, so that means it has failed the 12 weeks of standard care and hence it has entered the phase of treatment where hyperbaric oxygen is one of a number of possible alternatives.
>
> The decision pathways were entirely consistent. Perhaps it is the way the diagrams have been constructed. They did not have the prelude leading into it; they just had 'chronic', meaning that the patients had failed standard of care. So there was no confusion in MSAC's mind or in the minds of the applicants that we were talking about ulcers here that had failed standard of treatment, which was defined as 12 weeks of standard care.[21]

2.20 While the committee recognises that clarity has now been provided on this issue and accepts the MSAC explanation, it is surprised that such a key point had not been clarified between the department, MSAC and the applicants, when it was raised in October 2011.[22] It has taken over a year and a Senate inquiry to achieve such

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19 Dr Glen Hawkins, *Submission 4*, p. 2; Australian Society of Anaesthetists, *Submission 9*, p. 1; Australian Medical Association, *Submission 10*, p. 1; Australian Healthcare and Hospitals Association, *Submission 13*, p. 3; Associate Professor David Smart and Associate Professor Mike Bennett, *Submission 18*, p. 7.

20 The Wesley Centre for Hyperbaric Medicine, *Submission 12*, p. 1.

21 Professor Robyn Ward, Chair, Medical Services Advisory Committee, *Committee Hansard*, 12 November 2012, p. 39.

22 Associate Professor David Smart and Associate Professor Mike Bennett, *Submission 18*, Attachment 3, p. 3.

clarity. The committee considers this to be a further example of the consultation process with the MSAC HBOT assessment not working effectively.

New trial

2.21 A new trial of the effectiveness of HBOT is to commence. However, Dr Hawkins informed the committee that, as a consequence of removing HBOT chronic wound treatment from the MBS, the current RCT being conducted by the Wesley Centre may fail.[23] The applicants will then be unable to conduct the trial to provide the additional evidence required by MSAC. Other evidence received by the committee indicated that it had taken a long time and many applications to get the study started:

> Loss of this revenue will also result in the cessation or downgrading of a multi-centre (Brisbane, Hobart, Perth and Sydney) Cooperative Research Centre randomised double-blind placebo controlled trial, hosted by WCHM. The trial is studying HBOT treatment for refractory non-diabetic venous ulcers for patients with failed first-line treatment.
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> Prior to this trial, eight research funding applications over seven years to NHMRC, ARC, CRC and other funding institutions have been unsuccessful.[24]

2.22 The issue of the agreed research framework and whether that included an RCT appears to the committee to be a key point in the disagreement between MSAC and the HBOT community. In contrast to the statement on the MSAC website about 'an agreed research framework', Professor Ward stated that:

> It is not part of MSAC's terms of reference to provide specific information to applicants about how to collect the data or the nature of their trial design that would best inform future decisions. I think the applicants know their technology better than the MSAC committee would know it, and they need to design a study that they think would provide the best level of evidence for that particular setting.
>
> I would expect it was reasonable that the applicants would understand the sort of evidence that would need to be collected in this context.[25]

2.23 However the committee heard very different evidence from other witnesses. Associate Professor David Smart indicated that as a result of the 2004 MSAC assessment, a different type of evidence collection was done and that they were not informed that it was not appropriate:

> We were set on a path in good faith on the basis of prospectively collecting data not in a randomised manner as a result of the 2004 MSAC inquiry. We duly followed that. I guess we informed the department the three-year

23 Dr Glen Hawkins, Company Medical Director, Hyperbaric Health Pty Ltd, *Committee Hansard,* 12 November 2012, p. 4.

24 Australian Health and Hospitals Association, *Submission 13, Attachment 3,* pp 4–5.

25 Professor Robyn Ward, Chair, Medical Services Advisory Committee, *Committee Hansard,* 12 November 2012, pp 38, 43.

> results of the ANZHMD wound study, which were published in *Diving and Hyperbaric Medicine* journal.
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> Then we find that in 2011 we are asked to make a submission by the department because otherwise the funding would run out, so we duly complied with that submission and we found that the data from the study was rejected because they were not happy with the level of evidence.[26]

2.24 The CHF also commented on this issue, noting that a number of areas regarding an agreed research framework remained unclear even after the committee's public hearing on 12 November 2012:

> [T]he level of clarity of advice to applicants in relation to evidence requirements, and whether or not MSAC had given applicants a belief or expectation that a non-comparative study (such as the extended ANZHMG Wound Care study) would provide sufficient evidence to support public funding for HBOT for chronic non-diabetic wounds; and
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> [W]hether interim funding should have ceased and a decision made about MBS funding for this treatment following the period commencing in 2004 and ending in 2007, given that three years is the conventional timeframe allowed for interim funding.[27]

2.25 Professor Smart also informed the committee that in his view the MSAC report itself contains inconsistent statements regarding the quality of evidence:

> [T]here is a lot of contradiction in the report because in table 53 on page 110 of the MSAC report states that the evidence base is satisfactory and that in fact the generalised ability is good and so is the applicability applicable to the Australian healthcare context with few caveats. That is in the 1054.1 report and in my written submission.
>
> When it comes to the final conclusions the goalposts shifted when they said the evidence was 'low level'. But in the report it records it as being good or satisfactory. So there are a lot of areas of inconsistency: when you read through that report it is supportive of HBO, yet the final analysis said we should not fund it because there is no evidence.[28]

2.26 Dr Deeble also commented on the design of the trial and noted that 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 the primary objective, that is the production of evidence that can be used to support decision making.[29] Dr Deeble further commented that MSAC's recommendations regarding the trial are soundly based but noted further:

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26 Associate Professor David Smart, Chairman, Australian and New Zealand Hyperbaric Medicine Group, *Committee Hansard*, 12 November 2012, pp 26–27.

27 Consumers Health Forum of Australia, *Supplementary Submission 19*, p. 3.

28 Associate Professor David Smart, Chairman, Australian and New Zealand Hyperbaric Medicine Group, *Committee Hansard*, 12 November 2012, p. 27.

29 Dr John Deeble, *Submission 41*, p. 3.

> 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.[30]

Interim funding

2.27 The MSAC Assessment Report commented that there was a potential for interim funding to create 'perverse incentive for applicants to rely on weak rather than strong evidence for the initial MSAC consideration'. Professor Ward explained further:

> If we went on funding, essentially we would be funding a study that we do not have a mechanism for on the MBS to fund a clinical study. Essentially, we would be indicating that their treatment had benefit; whereas, our terms of reference require us to make a determination on that and to provide that advice to the minister. So, within that remit within which we work we do not have a mechanism for funding this study to be done.
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> That is related to previous concerns related to how interim funding in general has failed to deliver any new, useful information to inform their decisions on this. In general, that has been a recurring problem with interim funding. Just as it has in this case, you get down the track and you are no further ahead.[31]

2.28 The committee notes however that the MSAC website indicates that funding to assist in gathering appropriate evidence within an agreed research framework does fit within its process:

> MSAC has the capacity to assemble and review available evidence. In some circumstances, MSAC can recommend interim funding to enable data collection, within an agreed research framework, in order to establish the evidence base. [32]

2.29 In relation to the costs of continuing the use of HBOT for non-diabetic wounds, Dr Deeble noted that patient numbers are small – only about 160 annually. Dr Deeble went on to comment:

> 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

30 Dr John Deeble, *Submission 41*, p. 3.

31 Professor Robyn Ward, Chair, Medical Services Advisory Committee, *Committee Hansard*, 12 November 2012, p. 48.

32 Medical Services Advisory Committee, http://www.msac.gov.au/internet/msac/publishing.nsf/Content/about-us-lp-1, (accessed 5 November 2012).

> 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.[33]

Other issues raised with the process

Consultation, the dissenting report and speed of the process

2.30 During the inquiry, the committee heard conflicting views on whether there had been sufficient and appropriate consultation during the MSAC assessment of HBOT for non-diabetic chronic wounds.

2.31 The Explanatory Statement to the Health Insurance (General Medical Service Table) Amendment Regulation 2012 (No. 4) indicates that for HBOT, 'Consultation in relation to items 1 and 39 involved the Australian Health and Hospitals Association, the Australian Society of Anaesthetists and the South Pacific Underwater Medicine Society'.[34]

2.32 The CHF also advised the committee that they were comfortable with the decision by MSAC, citing their own consultation information:

> Again, let me emphasise that this decision by MSAC is entirely in keeping with CHF's own consumer consultations. Our members have consistently supported removing public funding for those treatments or technologies that are not sufficiently supported by appropriate evidence.[35]

2.33 However, the CHF also acknowledged that they are partly funded by the department that they were aware of the dissenting reports, were not concerned about the MSAC HBOT assessment and had not undertaken consultation specifically on HBOT for non-diabetic chronic wounds.[36]

2.34 The committee was informed by Professor Ward that MSAC has introduced a range of new processes, including those in relation to consultation:

> What is done now is that there is a process whereby there is a protocol designed, and that defines the question for future public subsidy. It is done by a subcommittee of MSAC called the Protocol Advisory Subcommittee. At that committee, which is a standing committee, they have the opportunity to bring in experts and to have a period of public consultation—six weeks—where individual health professionals or the consumers can put in their view as to the place of that particular item in the future MBS schedule. Following that, which is where the place of the new

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33 Dr John Deeble, *Submission 41,* p. 2.

34 Health Insurance (General Medical Service Table) Amendment Regulation 2012 (No. 4), *Explanatory Statement,* p. 1.

35 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard,* 12 November 2012, p. 8.

36 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard,* 12 November 2012, pp 9, 11–12.

> test or whatever is in the MBS is done, the evidence gathering phase occurs. … That document is then critiqued by another subcommittee MSAC, who go through it for technical errors and other errors of fact. Each step of the process has an opportunity for rebuttal by every member, from the applicants to the people who are preparing the submission. Finally, all of that documentation comes to the MSAC committee.[37]

2.35 The department also informed the committee of the steps involved between MSAC finalising its advice and Government decisions for all applications as well as specific interactions regarding HBOT for non-diabetic wound patients:

> All outcomes of the November MSAC process were made public in April. There was no contact between applicants and the department about outcomes until such time as the minister had signed them off in April. This happened with HBOT as with everything else. I had a discussion with Prue Power in early May. At their request, we set up a meeting with them to talk about concerns they had about this, which took place at the end of June. As a result of that, they were asked to document their concerns and these went back to the next MSAC meeting for consideration at the end of July.[38]

> In this case, because it was such a longstanding issue and because of the concerns about it, we effectively tried to come up with a mechanism that allowed some or all of the things that were being said by the applicants to be tested, because we were obviously keen to ensure that there had not been errors made as part of the process.[39]

2.36 In contrast, other witnesses raised strong concerns about consultation during the assessment process. The AHHA informed the committee of its view, including that the new processes had not been applied to HBOT for non-diabetic wound patients:

> We have heard already that MSAC has introduced new systems in 2011–12. It brought in the comprehensive management framework, but this framework does not pertain to this particular study or any of the studies for this HBOT item. In fact, if it had, I understand there would be genuine public consultation around it, it would be systematic, and none of that has happened with these particular reviews. We think there is a dangerous precedent here. There has been no transparency in the HBOT review process whatsoever.[40]

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37 Professor Robyn Ward, Chair, Medical Services Advisory Committee, *Committee Hansard*, 12 November 2012, p. 40.

38 Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing, *Committee Hansard*, 12 November 2012, p. 34.

39 Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing, *Committee Hansard*, 12 November 2012, p. 39.

40 Ms Prue Power AM, Chief Executive Officer, Australian Healthcare and Hospital Association, *Committee Hansard*, 12 November 2012, p. 17.

2.37 The committee notes that in spite of there potentially being years of effective warning as a consequence of the interim listing[41] of HBOT for non-diabetic wounds, other witnesses raised concerns about the conduct of the MSAC assessment, the speed with which it progressed and whether the experts involved were given appropriate access to draft reports by MSAC and its sub committees:

> We believe also that the process of analysis of non-diabetic problem wounds and the data associated with it, including clinical pathways, was rushed and that the whole process to wrap up the report was rushed. We were given very limited time—three weeks, in fact—to look at the issues.
>
> When we were presented with the final MSAC report, it was presented to us initially as a draft document. It had over 70 pages with alterations made to them. When Professor Bennett and I made attempts to indicate that was the case and that there were corrections to be made, we were told, 'Sorry, no, this is a final report for sign-off.' Not long afterwards, we were informed that the necessary quorum had been reached and that the report would be signed off. … As a result of that and the errors that we found in the report, Professor Bennett and I could not sign off on it and dissented from the final report.[42]

2.38 Professor Smart also informed the committee that the dissenting report was not made publically available on the MSAC website until a complaint was lodged with the department.

> Another concern I have is that MSAC did not publish a dissenting report until we actually made a complaint. It was not part of their normal processes to do that. I have submitted data in relation to that; instructions were given to us that it would not be on the website.[43]

2.39 The committee also notes the review of the MSAC HBOT assessment for non-diabetic wound patients by the National Health and Medical Research Council (NHMRC) was not made publicly available. However, following questions from the committee, the department indicated that the NHMRC advice will be publicly released.[44]

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41 Mr Richard Bartlett First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing and Dr Megan Keaney, Acting Assistant Secretary, Medical Specialist Services Branch, Medical Benefits Division, Department of Health and Ageing, *Committee Hansard*, 12 November 2012, pp 36–37.

42 Associate Professor David Smart, Chairman, Australian and New Zealand Hyperbaric Medicine Group, *Committee Hansard*, 12 November 2012, p. 18.

43 Associate Professor David Smart, Chairman, Australian and New Zealand Hyperbaric Medicine Group, *Committee Hansard*, 12 November 2012, p. 18.

44 Answer to Question on Notice 12, 12 November 2012, (received 19 November 2012).

The new MSAC process and new versus existing technologies

2.40 The approach and processes used by MSAC to assess medical technology have changed in recent years. The Government undertook a wide ranging review of Health Technology Assessment in Australia (the HTA Review) that was completed in 2009. The Department of Health and Ageing (the department) submitted that the HTA Review aimed to address regulatory burdens on business arising from HTA processes.

2.41 In response to the HTA review, a comprehensive overhaul of the management and governance processes relating to the Medicare Benefits Schedule (MBS) was undertaken, with reforms to MSAC being introduced in January 2011.

> Key reforms…included new terms of reference for MSAC and the establishment of two sub-committees; the Protocol Advisory Sub-Committee (PASC) and the Evaluation Sub-Committee (ESC) and moving from Advisory Panels to standing subcommittees to better separate the role of advocates for a medical service and sources of expert advice.[45]

2.42 The above changes were supported by the announcement of the Comprehensive Management Framework for the MBS in the 2011 Budget. The department informed the committee that:

> Under the CMFM, MSAC not only provides advice on new medical services involving technologies and procedures, but on all proposed changes to the MBS. The MSAC process ensures that applicants, stakeholders and the general public have ample opportunity to provide input into the assessment.[46]

2.43 A key issue brought to the committee's attention was whether MSAC should be reviewing new or existing technologies. A number of submitters argued that MSAC should only review new technologies. Dr David Wilkinson put his view to the committee:

> Review of existing procedures is not the same as reviewing a new procedure and this is realised by the development of the 2009 framework. Unfortunately, it also means that HBOT has been reviewed by a body who was tasked, at that time, with reviewing new technologies and who did not have the framework to deal with a technology that has been funded for almost 30 years. The result was a corrupted interpretation of the evidence and a lack of procedural fairness that exists to this day.[47]

2.44 Associate Professors Smart and Bennett provided similar views to the committee:

> During the MSAC assessment 1018-1020, the clinical expert advisors (A/Prof Michael Bennett and Dr. Robert Wong) strongly supported the concept of reviewing funding to all conditions where the evidence suggested HBOT to be ineffective, or less effective than alternative

45 Department of Health and Ageing, *Submission 15*, p. 4.

46 Department of Health and Ageing, *Submission 15*, p. 4.

47 Dr David Wilkinson, *Submission 17*, p. 1.

> therapies. Our only major objection at the time was that the MSAC process was not appropriate to this task (vide infra).[48]

2.45 Dr Deeble also commented on the review process and stated nearly all MSAC 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 the information provided was collected and analysed independently and in accordance with the relevant scientific standards. In addition, the onus is on those seeking approval on either commercial or professional grounds to demonstrate its clinical value and cost-effectiveness. However, Dr Deeble went on to note that with HBOT, the review was of an established therapy supported by the MBS for 20 years. Dr Deeble stated that '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'.[49]

2.46 The department confirmed in its submission that assessments of existing technology does fall within MSAC's role:

> The principal role of MSAC is to advise the Australian Minister for Health and Ageing on evidence relating to the safety, effectiveness and cost-effectiveness of new medical technologies and procedures. This advice informs Australian Government decisions about public funding for new, and in some cases existing, medical procedures.[50]

Independent review process

2.47 In addition to the above issues, several witnesses including the Australian Society of Anaesthetists, raised concerns about whether there is an appropriate independent review process for MSAC decisions.[51] Ms Prue Power informed the committee that:

> The fifth and last point is that MSAC lacks independent appeals processes. There is no framework for public consultation. Its appeals process is not transparent; in fact, it undertakes its own appeals process.[52]

2.48 The AHHA also raised similar concerns:

> The MSAC does not have enshrined in its terms of reference or processes any independent appeals process or scrutiny by another body when it has recommended withdrawal of public funding. It is inappropriate when making decisions to withdraw funding from treatments that are already

48 Associate Professor David Smart and Associate Professor Mike Bennett, *Submission 18,* p. 3.

49 Dr John Deeble, *Submission 41,* p. 3.

50 Department of Health and Ageing, *Submission 15*, p 2.

51 Australian Society of Anaesthetists, *Submission 9,* p. 2.

52 Ms Prue Power AM, Chief Executive Officer, Australian Healthcare and Hospital Association, *Committee Hansard*, 12 November 2012, p. 17.

> fully funded as this has an impact on the Australian community and is not accordance with best practice in administrative decision making.[53]
>
> On this occasion, probably due to representations, the Department of Health & Ageing asked the National Health & Medical Research Council to review the MSAC's most recent decision. This extraordinary step was made in haste and within a very narrow brief without consultation from the 1054.1 committee. There was however no structure to the review and no published report from the NH&MRC, confirming this was an ad-hoc process.[54]

2.49 The committee notes that the lack of an independent appeals or review process for MSAC decisions, is in contrast to arrangements that exist for the Pharmaceutical Benefits Advisory Committee (PBAC).

> From 1 January 2005, independent review has been available to any applicant whose submission to the Pharmaceutical Benefits Advisory Committee (PBAC) has not resulted in a recommendation to list the drug on the Pharmaceutical Benefits Scheme (PBS). From the July 2006 meeting, independent review is also available where the PBAC has declined to recommend an extension of the listing of an already listed drug.
>
> The Independent Review (PBS) is managed by a convenor who is responsible for ensuring the efficient conduct of each review, including the selection of a reviewer with appropriate skills and expertise.[55]

2.50 The committee notes that this matter had already been brought to the Government's attention in the Review of Health Technology Assessment:

> Coupled with the inability of the Secretariat to knowledgeably discuss the reasons for rejection, is the absence of a formal appeal procedure, as now exists within the PBAC process. Within the MSAC process there is no avenue other than a resubmission – which is not a suitable option when the applicant believes there to have been a technical error by the evaluation group, or an interpretation error by the MSAC. This is exacerbated by the fact that the usual grounds on which MSAC accepts a re-submission is when new evidence becomes available. This leaves applicants in a difficult position where the onus is put on them to persuade MSAC/ the MSAC Secretariat to accept a re-submission when the reason for that re-submission is an error made by MSAC.[56]

2.51 The Independent Review (PBS) does not overturn a PBAC decision. It is based on information which had already been presented to the PBAC and the review findings are made available to the sponsor and the PBAC. The PBAC will then consider the findings of the review together with the sponsor's comments:

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53 Australian Healthcare and Hospitals Association, *Submission 13*, pp 3–4.

54 Australian Healthcare & Hospitals Association, *Submission 13*, pp 3–4.

55 Independent Review (PBS), http://www.independentreviewpbs.gov.au/, (accessed 16 November 2012).

56 Health Technology Analysts P/L, *Submission to the* Review of Health Technology Assessment.

> The outcome of the PBAC's reconsideration of the submission and the findings of the review will be reported to the Minister for Health and Ageing … Summary recommendations will be placed on the PBS website.[57]

Impartiality of experts

2.52 During the inquiry the committee heard that there can sometimes be vested interests involved with the applications to MSAC and lobbying during assessment processes. The Consumers Health Forum of Australia (CHF) informed the committee that:

> We see that all the time. What we usually see is vested interest lobbying to get their thing funded or to remain a viable industry, or whatever. That is not the intention of the MBS. The intention of the MBS is to provide the most cost-effective, quality treatments to Australian consumers and there does need to be a process that ensures that. It could well be that those experts have particular knowledge but, if they did, why did that process then fall down? That knowledge should have been provided in the form of good evidence to MSAC, which represents a range of views including consumers' views, and assessed on that basis.
>
> The process is intended to provide the checks and balances by having a range of views. You could read it the other way and say: well, you have got two experts who have a vested interest in that particular treatment.[58]

2.53 The Chair of MSAC also raised the issue of experts potentially having conflicts of interest if they were advocates of the technology and involved with advisory groups. The Chair explained how MSAC grappled with these issues under its old process:

> In the past—and this is really a carryover from how things worked in the past—there was an independent advisory group of experts that was set up, and the experts were often heavily conflicted in the sense that they were advocates of the particular technology. They worked with an independent contracted assessment group that the Government contracted. Together they worked on a document. That document is not MSAC's work; it is a document that contains information and data and analyses which are presented to the committee along with other documentation. It includes the opportunity for independent people to raise dissenting remarks, which happened in this case.[59]

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57 Independent Review (PBS), *Pharmaceutical Benefits Scheme Information for Applicants Seeking Independent Review*, http://www.independentreviewpbs.gov.au/internet/independentreviewpbs/publishing.nsf/Content/information-for-applicants-seeking-review, (accessed 16 November 2012).

58 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 12 November 2012, p. 13.

59 Professor Robyn Ward, Chair, Medical Services Advisory Committee, *Committee Hansard*, 12 November 2012, p. 40.

2.54 In defence of the involvement of experts with MSAC HBOT assessments, Associate Professor Smart informed the committee that:

> Dr Bennett and I do come from the public sector and have academic profiles in hyperbaric medicine. Dr Bennett…has a very high profile worldwide in that area.
>
> Patients are referred; they are not sought by us in the community. Other practitioners refer them for hyperbaric treatment because they have failed other care. A typical example would be a patient with mixed arterial and venous disease, because they cannot tolerate compression dressing, because the dressing constricts the arteries and prevents circulation. That is the standard of care for venous ulcers.[60]
>
> These specialists were already exercising considerable self-regulation by adhering to treatment for cases where clinical opinion considered the evidence to be high enough for efficacy. For example, in comprehensive facilities in Australia, treatment was not offered for multiple sclerosis, sports injuries, cerebral palsy, autism, and many other conditions, that lacked supportive clinical evidence. Indeed, members of the ANZHMG have actively campaigned against "off label" use of HBOT.[61]

2.55 The Australia Healthcare and Hospital Association (AHHA) also defended the role played by the experts informing the committee that:

> The AHHA does take offence at the Consumers Health Forum statement that implied that Drs Bennett and Smart had vested interests. Both are committed to the public health care sector. They both work in public hospitals.[62]

2.56 The committee notes that some of these issues have been addressed by the new MSAC process. The committee also observes that expertise in a particular area does not necessarily imply that a particular expert lacks impartiality or has conflicts of interest.

60 Associate Professor David Smart, Australian and New Zealand Hyperbaric Medicine Group, *Committee Hansard*, 12 November 2012, pp 17, 21.

61 Associate Professor David Smart and Associate Professor Mike Bennett, *Submission 18*, p. 3.

62 Ms Prue Power AM, Chief Executive Officer, Australian Healthcare and Hospital Association, *Committee Hansard*, 12 November 2012, p. 17.

Impact of the withdrawal of HBOT for non-diabetic wounds and uclers

Costs to the health system

2.57 After being on the Medicare Benefits Schedule (MBS) since 1984,[63] interim funding of HBOT for non-diabetic wound patients has been provided through Medicare since its first assessment by MSAC in 2001. More than $11 million in Medicare benefits have been paid through the interim item.[64] Dr Smart clarified for the committee that only 44 per cent, of the $11 million, was used for treating non-diabetic wound patients with HBOT over the 2001 to 2012 period:

> That is the total amount for item 13015, extending from 2001 through to 30 June 2012—$10.6 million has been expended. Out of that, the department's own figures sitting in the MSAC report, say that 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. The split was 154 patients treated annually for non-diabetic problem wounds and 189 patients treated annually for soft tissue radiation injury. We are talking a fraction of the $11 million. It is actually 44 per cent of $11 million, or $10.6 million in fact.[65]

2.58 The department informed the committee that the budget papers indicate that the savings over the forward estimates projected from the cut were $4.4 million and that this corresponded to over 800 patients.[66]

2.59 The committee heard evidence on whether the cost savings of removing HBOT treatment for non-diabetic wound patients are greater than the costs incurred by patients requiring other treatments. For example Dr Martin Hodgson provided the committee with one estimate of the costs of using alternative treatments to HBOT:

> MSAC calculated the cost of usual care failure (Table 41) as $40K. If we extrapolate for 5 years after treatment is finished there are huge savings:
>
> Assume of 100 patients only 30 heal with usual care, leaving 70 unhealed. (Remember the patients recruited to the ANZHMG study had their ulcers for an average of 16 months and to say 30% would heal with standard care is generous.)
>
> So 70x40K = $2.8 million/yr = $14million
>
> HBO_2 heals 70, leaving 30 unhealed
>
> 30x40K = $1.2 million/yr = $6million
>
> A SAVING OF $8 MILLION over five years for every 100 patients treated with HBO_2.[67]

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63 Ms Prue Power, Chief Executive Officer, Australian Healthcare and Hospital Association, *Committee Hansard*, 12 November 2012, p. 17.

64 Department of Health and Ageing, *Submission 15*, p. 2.

65 Associate Professor David Smart, Australian and New Zealand Hyperbaric Medicine Group, *Committee Hansard*, 12 November 2012, p. 20.

66 Mr Shane Porter, Assistant Secretary, Medicare Financing and Listing Branch, Department of Health and Ageing, *Committee Hansard*, 12 November 2012, p. 47.

2.60 Associate Professors Smart and Bennett criticised the costing analysis undertaken by MSAC and provided their own estimates on costs savings on a per patient basis:

> [C]ostings have been supplied using the correct pathway that shows HBOT is cheaper that standard care – when used as a second-line intervention. The cost of standard care for six months is $28494 AUD per patient, and the six month cost of HBOT is $22992 AUD per patient. HBOT is on average $5502 AUD ***cheaper*** per patient than standard care when used as a second line intervention because more wounds are healed with this approach, and subsequent ongoing costs are avoided. While there is no comparable evidence on which to base an extrapolation of these data, it is likely that cost savings will continue to accumulate over time.[68]

Accounts of HBOT treatment provided to the committee

2.61 The committee received submissions from individuals who had received HBOT for non-diabetic wounds. These submitters raised concerns about the loss of this treatment for themselves and others. One submitter informed the committee that HBOT have given them new hope for a wound that they thought would never heal, only to have those hopes dashed by the decision to cut HBOT funding for non-diabetic wound patients:

> I have had a serious non-healing painful leg wound that has had various attempted unsuccessful conventional treatments over a period of 6 years plus.
>
> I had given hope on it ever healing and resigned myself to the pain and the possible loss of my foot. I have been on a trial using the hyperbaric oxygen therapy which is showing very good results on this wound after only three weeks of treatment. The Government funding has been withdrawn for non-diabetics which I find appalling as this therapy is clearly working and wonder why the Government has such a short sighted policy on such a successful treatment. I feel confident that given a few more weeks of therapy my wound would finally heal for good.[69]

2.62 Another submitter informed the committee that after eight years of no success with conventional wound treatments, HBOT finally gave them some relief and allowed their wound to be healed:

> I am one of the lucky people who have experienced the benefit of hyperbaric treatment.
>
> I had a chronic wound for over 8 years that would not heal with conventional treatment. I am confined to a wheelchair and have spina bifida so I do not feel my legs and this ulcer, which was on my leg, was due to a surgery that became infected.

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67 Dr Martin Hodgson, *Submission 2*, p. 2.

68 Associate Professor David Smart and Associate Professor Mike Bennett, *Submission 18*, p. 7.

69 Name withheld, *Submission 6*, p. 1.

> I do not have diabetes and if this funding is not available to people like me who's lack of circulation in her legs due to her disability. Causing me to not heal as rapidly as abled bodied people. I would no doubt have this wound for the rest of my life.[70]

2.63 The committee received evidence of some of the challenges faced by patients whose wounds did not heal with standard care, now that HBOT was no longer available for non-diabetic wounds:

> [F]or these patients, all of whose wounds did not respond to standard care, the future is bleak without HBOT; patients will face continuing pain, suffering and reduction in quality of life, while the ever present threat of infection often leads to life threatening sepsis and amputation.[71]

2.64 In another account provided to the committee, a patient had a wound for a year before beginning HBOT treatment, which then led to 90 per cent healing of the wound. However funding HBOT for non-diabetic wound patients was cut, his treatment was therefore cut short:

> Over several months and up until I began Hyperbaric Oxygen Treatment in August 2012, I'd had minimal healing, possibly 10%. After roughly seven treatments I began to a notice considerable reduction in the pain radiating from this area.
>
> In total I received 54 sessions of treatment and had great success – I estimate my wound has healed up to 90%, but due to the funding issues my treatment was cut short.[72]

2.65 In addition to the above accounts, the committee was also informed by the Australian Wound Management Association Inc., that the changes to Medicare funding were already having a negative on waiting periods for other forms of care:

> Due to the recent Medicare item number changes for Practice Nurses in Wound Care, there has now been a blow-out in consultations to Community and District Nurses which has resulted in a minimum 6 weeks waiting period. I cannot imagine what this must mean to someone who has a foul smelling necrotic wound and requires assistance. To be told they have to wait is unacceptable in this society. I know of many patients who have benefitted from HBO therapy when other treatments have failed.[73]

2.66 The AHHA informed that committee that, in their view, the MSAC assessment for HBOT for non-diabetic wound patients did not take into account the impact of HBOT on patients and quoted the relevant section of the MSAC report:

> It is critical to note that the MSAC Assessment Report 1054.1 states: *analysis does not take into account improvements in quality of life following successful treatment or any reduction in quality of life following*

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70 Name withheld, *Submission 8,* p. 1.

71 The Wesley Centre for Hyperbaric Medicine, *Submission 12*, p. 1.

72 Mr Ruben Shearer, *Submission 14*, p. 1.

73 Australian Wound Management Association Inc., *Submission 11,* p. 1.

> *surgery or due to unsuccessful treatment. Evidence suggests that the impact on patient's quality of life may be substantial. Consequently the actual benefit to the patient of providing HBOT is likely to be underestimated.* (MSAC 1054.1 page 95)[74]

Impact on business and health insurance

2.67 The AHHA informed the committee of the current availability of HBOT services in Australia, noting that there is a mixture of both public and private facilities:

> There are nine hyperbaric facilities located Australian public hospitals (most of them provide comprehensive services) as follows: WA – Fremantle and Broome Hospitals; NT – Royal Darwin Hospital; QLD – Townsville and Royal Brisbane Hospitals; NSW - Prince of Wales Hospital; Victoria - The Alfred Hospital; TAS - Royal Hobart Hospital; SA - Royal Adelaide Hospital.
>
> There are an additional four centres operating in the private sector as follows: The Wesley Centre for Hyperbaric Medicine in Brisbane, the Hyperbaric Health facilities at Vaucluse and Berwick in Victoria and the Hyperbaric Health Facility at Mascot in Sydney. The Medical Directors of these facilities constitute the Australian and New Zealand Hyperbaric Medicine Group (ANZHMG).[75]

2.68 The Wesley Centre for Hyperbaric Medicine stated that the removal of HBOT funding for non-diabetic wound patients would have a substantial effect on its business, not only because of the withdrawal of Medicare funding, but also because treatments would no longer be funded by private health insurers:

> Wound care is a core discipline at our facility: 40 of our 115 patients last year were treated for vascular ulcers (compared with the more trauma oriented Royal Brisbane and Womens Hospital facility – 3 of 123); withdrawal of Medicare funding will automatically remove corresponding private Health Fund benefits; our wound care revenue from all sources constitutes approximately 38% of annual revenue which vanishes from 1st November; we will be halving our workforce from that date, jobs will be lost.[76]

2.69 Similarly, Hyperbaric Health commented that over 30 per cent of its business was affected.[77] Mr Tim Snowden explained further:

> From my point of view, it is just astounding that this whole thing has needed to be escalated to a Senate inquiry. I do not see why there were not other avenues available to us before this, or even mentioned to us. This puts the entire company in jeopardy. All the staff who have been with me for

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74 Australian Healthcare and Hospitals Association, *Submission 13*, p. 2.

75 Australian Healthcare and Hospitals Association, *Submission 13*, p. 1.

76 The Wesley Centre for Hyperbaric Medicine, *Submission 12*, p. 2.

77 Dr Glen Hawkins, Company Medical Director, Hyperbaric Health Pty Ltd, *Committee Hansard*, 12 November 2012, pp 3–4.

> about 10 years are fantastic healthcare professionals and are very dedicated, and they are often looking for other jobs right now. God knows what is going to happen to the poor patients. It happened on 1 November. For a long time we have been trying to argue the whole thing through with the department and anyone else who will listen to us.[78]

2.70 The committee also heard that, as well as losing the Medicare Benefits Schedule (MBS) element for in-patients, those who would seek private treatment, patients have also lost access to private health insurance funding as reimbursements are not available for items not on the MBS. Dr Smart indicated that:

> There is a flow-through to any private in-patients who receive the treatment and the private funds will not provide their in-patient costs. They will pay for bed fees or the gap fee associated with the in-patient.[79]

HBOT for other conditions

2.71 The committee sought information on how the evidence base for non-diabetic wound HBOT compared to other treatments. The department informed the committee that HBOT for non-diabetic patients is the only funding that is being cut as a result of the Governments' decision and that other HBOT funding will continue:

2.72 The 1 November MBS book lists the conditions that it is still funded for. Hyperbaric oxygen therapy would still be available for localised non-neurological soft tissue radiation injuries excluding radiation induced soft tissue lymphoedema of the arm after treatment for breast cancer. It is still available for treatment of decompression illness, gas gangrene, air or gas embolism, diabetic wounds including diabetic gangrene and diabetic foot ulcers, necrotising soft tissue infections including necrotising fasciitis or Fournier gangrene, or the prevention and treatment of osteoradionecrosis.

2.73 The committee was also informed by Mr David Oliver, that it was possible that HBOT services for non-diabetic veterans may to continue under funding arrangements by the Department of Veteran Affairs.

2.74 When questioned directly by the committee, the department admitted that HBOT treatment is still funded for decompression illness, the bends, and for gas gangrene and necrotising fasciitis, even though those treatments along with non-diabetic wound treatment do not have unequivocal results from randomised controls tests.

2.75 The committee considers that this situation does not appear to represent a consistent, fair and logical application of the MSAC assessment process across a range of related treatments.

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78 Mr Tim Snowden, Chief Executive Officer, Hyperbaric Health Pty Ltd, *Committee Hansard,* 12 November 2012, pp 6–7.

79 Associate Professor David Smart, Australian and New Zealand Hyperbaric Medicine Group, *Committee Hansard,* 12 November 2012, p. 21.

Conclusions

2.76 The committee acknowledges that MSAC is an independent body providing advice to the Government based on evidence and scientific rigor on the safety, effectiveness and costs effectiveness of medical technologies. However, that does not preclude MSAC from appropriate external scrutiny, such as this very brief inquiry, which has identified some concerns in relation to the assessments of HBOT for non-diabetic wounds.

2.77 The committee believes that interim funding for HBOT for the treatment of non-diabetic wounds should not have been withdrawn. The committee's conclusions is based on the following:

- MSAC's reliance on a very small RCT trial from 1994;
- the rejection of other evidence and expert opinion;
- the rushed nature of the 1054.1 assessment process;
- the poor consultation process;
- the impact on patients; and
- the extremely small savings to be made in the Medicare budget.

2.78 During this inquiry, the committee received evidence which throws some doubt on whether the $4.4 million cost savings indicated in the budget papers would be achieved. The committee has also been informed of the substantial impacts potentially arising for many patients, in that they are faced with a choice of funding their own HBOT treatment, or going without the treatment and living with chronic unhealed wounds that may lead to other complications, or even amputations in some cases. The committee considers that there is some likelihood that the costs to individuals, the health care system and the community from cutting the HBOT treatment option for non-diabetic wound patients, may exceed any savings achieved.

2.79 The committee is also concerned that even if HBOT services were to be re-established in a few years' time, there may be a significant loss of capacity due to loss of specialised staff and facilities in both the public and private sectors. As a result, HBOT services may take some years to return to their current level, further exacerbating the impacts on individuals and the community discussed above.

2.80 While MSAC is an appropriately independent body providing advice to Government, the decisions taken by Government must take into consideration that scientific and cost-effectiveness advice alongside the other factors including the impact of the community, business and that no other effect treatments exist. The committee therefore considers that the decision by the Government to cut funding HBOT for non-diabetic patients is not fair or justifiable. .

2.81 The committee considers that further evidence is required to ensure that clear evidence is available about the effectiveness of HBOT for the treatment of non-diabetic wounds. In order for this to be achieved, the committee supports the continuation of the proposed trial. However, the committee has noted the comments from MSAC concerning problems with the current trial. The committee therefore

considers that clear parameter for the trial must be agreed regarding data quality and procedures, that interim funding only continue for the period of the trial or two years whichever is the less; and that any ethical issues are addressed. The committee also believes that it would be appropriate for an independent body to manage the trial.

Recommendation 1

2.82 The committee recommends that the Government continue Medicare Benefits Schedule interim funding for Hyperbaric Oxygen treatment for non-diabetic wounds until the current randomised control trial is completed and assessed by the Medical Service Advisory Committee.

2.83 The committee also considers that there is a need for an independent review process to be established for MSAC decisions, using a similar approach to the independent review of the PBAC.

Recommendation 2

2.84 The committee recommends that an independent review process be established for decisions by the Medical Service Advisory Committee using a similar approach to the independent review of the Pharmaceutical Benefits Advisory Committee.

Senator Scott Ryan

(Chair)