Dissenting Report

Australian Labor Party

1.1 The Government decision to amend the Medicare Benefits Schedule (MBS) so that it no longer covers Hyperbaric Oxygen Treatment (HBOT) for non-diabetic wounds was not taken lightly. The decision is based on advice from the Medical Services Advisory Committee (MSAC) following a rigorous assessment of the evidence for the effectiveness of HBOT for non-diabetic wounds. MSAC stated to the committee that the available evidence indicates that HBOT for non-diabetic wounds has failed the 'effectiveness test', that it failed to provide sufficient evidence that this was effective treatment.[1] As Professor Robyn Ward, Chair, MSAC, informed the committee that in the only available Randomised Controlled Test (RCT) of HBOT for the treatment of non-diabetic wounds published in 1994:

> …data shows you there is no statistical difference in the proportion of patients who achieve resolution of their wounds, or in the wound size, at 18 weeks.[2]

1.2 The MSAC assessment of 2011 of HBOT for non-diabetic wounds, follows earlier assessments in 2001 and 2004 in which the same 1994 RCT data was assessed. It was the only RCT available at the time of all three assessments. Following the 2001 and 2004 assessments, interim funding was provided for HBOT for non-diabetic wounds, thereby allowing the applicants more time to gather further evidence, including a significant extension to the three year timeframe set after the 2004 assessment.[3] The Department of Health and Ageing (the department) noted that the applicants were now seeking 'a continuation of interim funding, to more than fifteen years, on the basis of evidence which was insufficient at MSAC's first consideration in 2001'. The department stated that throughout the consideration by MSAC, the HBOT industry had many opportunities to provide additional information. The HBOT industry also had over a decade of interim MBS funding to conduct an RCT to demonstrate the long-term effectiveness of HBOT 'but have not done so'.[4] The department concluded:

> If the HBOT industry believes it has new or additional evidence another application can be submitted to MSAC at any time.[5]

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1 Professor Robyn Ward, Chair, Medical Services Advisory Committee, *Committee Hansard,* 12 November 2012, p. 35.

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

3 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.

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

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

1.3 The department also noted that in October 2012, in response to further issues raised by the applicants in discussions with the department following the release of the MSAC assessment, the Government commissioned a further review from the National Health and Medical Research Council (NHMRC) of MSAC's assessment.

> Following the outcome of the August consideration by MSAC, the applicants were offered the opportunity to highlight any errors of fact that they believed were present in the MSAC analysis.
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> Meetings were held with Hyperbaric Health and other interested parties on 5, 10 and 13 September. Dr Hawkins of Hyperbaric Health made a submission on 17 September which outlined the concerns of the affected parties. These continued to focus on the Assessment Report, rather than the MSAC documents. The material, together with the various MSAC documents was forwarded to NHMRC with a request to review the material and provide advice about the approach and the issues raised.[6]

1.4 The NHMRC endorsed the approach taken by the MSAC.[7] Mr Richard Bartlett, Department of Health and Ageing, explained the reasons for the NHMRC review:

> …I said that if there were any errors of fact that [the applicants] could identify in what MSAC had done that we would get them independently reviewed. Dr Hawkins subsequently provided a document which did not identify errors of fact; it identified differences in interpretation. I asked NHMRC to go through that, and to have a look at the MSAC documents, and to comment on the process that was followed. The NHMRC feedback was that MSAC had given appropriate weight to the evidence before it. [8]

1.5 The department also clarified for the committee that in addition to special consideration given to HBOT for non-diabetic wounds by the NHMRC, the department taken every step to have the concerns of the applicants addressed:

> Since then, there has been some ongoing discussion with the applicants…Since the public summary document was made available, we have taken extensive steps to ensure that the applicants were given every opportunity to raise concerns that they had with the process and to have these explored.[9]

1.6 Labor Senators also note that the department also informed the committee that the MSAC processes have recently been enhanced, following the 2009 Health Technology Assessment Review (HTA Review) which 'aimed to address the regulatory burden on businesses that results from HTA processes, to ensure that those

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6 Department of Health and Ageing, *Submission 15*, p. 7.

7 Department of Health and Ageing, *Submission 15*, pp 2–3.

8 Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing, *Committee Hansard*, 12 November 2012, pp 34–35.

9 Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing, *Committee Hansard*, 12 November 2012, pp 34–35.

processes are efficient, measured and proportionate.[10] The submission further indicated that:

> The importance of MSAC's assessment of evidence was reinforced in the 2011 Budget through the announcement of the Comprehensive Management Framework for the MBS (CMFM). 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.[11]

1.7 Professor Ward, Chair of MSAC, set out for the committee how MSAC conducts its work and prepares advice to the Minister, in a rigorous, systematic and transparent way:

> When preparing its advice to the minister, MSAC's terms of reference require the committee to appraise the strength of the evidence on safety, effectiveness and cost-effectiveness of a medical service compared to its likely alternatives. To do this, MSAC's deliberations rely on a series of sources, including a large assessment report prepared by external contractors and the inputs from its subcommittees, as well as dissenting reports from applicants. MSAC publishes the rationale for its advice in the form of a public summary document. In all its work, MSAC uses processes which provide transparency and accountability, procedural fairness, to affect its stakeholders, which minimise conflicts of interest by separating advocacy from advice.[12]

1.8 While there were concerns raised about the handling of the dissenting report by David Smart and Mike Bennett, the department clarified for the committee that Dr Smart was a member of an assessment panel providing information to MSAC and was not a member of MSAC itself.[13]

1.9 Labor Senators also note that the Consumers Health Forum (CHF) of Australia was supportive of the independent process for assessing whether treatments are publicly funded, so that the decisions are not driven by media profile or political know-how:

> In all our consultations with health consumers there is very strong support for basing health decisions on independent, validated evidence about what is effective … This approach has constantly been reinforced in all of CHF's consumer consultations over the years.
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> CHF's view is that MSAC's role as an impartial adviser is fundamental in ensuring consumers receive the best possible care. If there were no

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

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

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

13 Mr Richard Bartlett, First Assistant Secretary, Medical Benefits Division, Department of Health and Ageing, *Committee Hansard*, 12 November 2012, p. 40.

> independent, evidence based process it would mean that those with the loudest voice, the highest media profile or the political know-how would be able to influence whether to spend public funds, and that is not a situation that would serve health consumers well. It is not a system that the public could have confidence in.[14]

1.10 An issue that received a lot of attention during the inquiry was the suggestion by some witnesses that MSAC had not treated HBOT as a second line treatment in its calculations and that by doing so the cost-effectiveness estimates were flawed.[15] MSAC clarified that HBOT for non-diabetic wounds had failed the effectiveness test and that it had examined HBOT as a second line treatment.[16]

1.11 A further issue raised by some witnesses to the inquiry was the nature of the evidence required by MSAC and whether or not MSAC had made it sufficiently clear, what was required.[17] The Chair of MSAC, Professor Ward, explained that required level of evidence from a RCT should have been well known:

> Medical practitioners and scientists nowadays are skilled and trained in the sorts of evidence that they need to collect which is most influential in informing their own practice and is obviously now of use in health technology assessments like this. It is true to say that the practice of evidence based medicine has been going for about 20 years. Probably in more recent times the medical profession has actually understood what it means and the sort of data they needed to collect in order to comply with evidence based practice. The short answer to your question is, yes, I would expect it was reasonable that the applicants would understand the sort of evidence that would need to be collected in this context. I am pleased to see that they are doing that now.[18]

1.12 The committee was also informed that an RCT is currently being conducted by the Wesley Centre for Hyperbaric Medicine.[19] Following the completion of that trial a new application may be made to MSAC if the study provides new evidence in favour of HBOT for non-diabetic wounds. Professor Ward, Chair of MSAC, noted that:

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

15 See for example, Dr Glen Hawkins, Company Medical Director, Hyperbaric Health Pty Ltd *Committee Hansard,* 12 November 2012, p. 2, Mr David Oliver, Executive Director, Wesley Centre for Hyperbaric Medicine, *Committee Hansard,* 12 November 2012, p. 32.

16 Professor Robyn Ward, Chair, Chair, Medical Services Advisory Committee, *Committee Hansard,* 12 November 2012, pp 35, 39.

17 Associate Professor David Smart, Chairman, Australian and New Zealand Hyperbaric Medicine Group, *Committee Hansard,* 12 November 2012, pp 17–18.

18 Professor Robyn Ward, Chair, Chair, Medical Services Advisory Committee, *Committee Hansard,* 12 November 2012, p. 43.

19 Mr David Oliver, Executive Director, Wesley Centre for Hyperbaric Medicine, *Committee Hansard,* 12 November 2012, p. 29.

> MSAC very much look forward to receiving the randomised control study when it is completed. We hope that the applicants take onboard some of our suggestions—they are not obliged to—around that study, particularly issues related to the endpoint of that study, so that we are in a good place to make a decision or recommendations about HBOT down the track.[20]

Conclusion

1.13 The applicants for HBOT services for non-diabetic wounds have now been given opportunities, spread over a decade, to meet the criteria for ongoing Medicare funding and have been unsuccessful on all three occasions. It was identified over a decade ago that a more substantial Randomised Control Trial was needed, but such a trial has not been provided to MSAC to date. When the current trial is completed a new application to MSAC can be made. The 2011 MSAC assessment of HBOT for non-diabetic wounds has also been scrutinised by the National Health and Medical Research Council and this inquiry.

1.14 Government Senators support the decision to withdraw Medicare funding for HBOT for non-diabetic wounds as:

- the decision is consistent with its commitment to evidence based decision making;
- the department has gone out its way to assist the applicants, including the special review by the NHMRC and other follow-up activities;
- interim funding has been provided for around a decade to enable new evidence to be obtained to determine if HBOT for non-diabetic wounds can meet the effectiveness test, but such evidence still has not been produced; and
- even though a new trial is underway, it does not appear to provide a reasonable prospect of better evidence for some years.[21]

1.15 As indicated in the Department of Health and Ageing submission,[22] it is important to note that funding under the MBS is continuing for HBOT services for a range of other indications including diabetic gangrene and diabetic foot ulcers, soft tissue radionecrosis, osteoradionecrosis, necrotising soft tissue infections including necrotising fasciitis or Fournier's gangrene, air or gas embolism, gas gangrene, and decompression illness.

Senator Helen Polley
Senator for Tasmania

Senator Anne McEwen
Senator for South Australia

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20 Professor Robyn Ward, Chair, Chair, Medical Services Advisory Committee, *Committee Hansard*, 12 November 2012, p. 45.

21 Department of Health and Ageing, *Submission 15*, p. 8.

22 Department of Health and Ageing, *Submission 15*, p. 8.