19 August 2012

The Hon Tanya Plibersek MP
Minister for Health and Ageing

Parliament House

Canberra

Dear Minister

Registration of formal complaint regarding MSAC 1054.1 decision and processes.

On behalf of the Australian and New Zealand Hyperbaric Medicine Group, the AMA and the AHHA, I wish to register our serious concerns regarding the recent decision to withdraw Medicare funding for Hyperbaric Oxygen Treatment (HBOT) of problem wounds and ulcers in non-diabetic patients (MBS Item number 13015).

The funding for treatment of this vulnerable population ceases on 1st November 2012, unless the decision is reversed. We consider that you have received erroneous advice as a result of the MSAC 1054.1 report, which has led to this result.

This complaint is based on the following grounds:

(1) A flawed clinical pathway was followed in the analysis of outcomes and costs:

a. Hyperbaric Oxygen Treatment was proposed as a second-line treatment in the applicant's submission, yet it was analysed as if it were a first line treatment.

b. This has resulted in a major over-estimate of the overall cost for hyperbaric treatment, because it assumes all patients are treated with hyperbaric oxygen, rather than only those who do not respond to primary measures.

c. Our analysis indicates that HBOT produces a cost saving when implemented as a second line treatment, and its withdrawal will increase health costs for the Government.

d. The results of an Australia-wide wound study were dismissed; hence positive outcome data in the Australian setting has been ignored.

e. The hyperbaric clinical experts appointed to the MSAC 1054.1 review dissented from the report on the basis of the major flaws in methodology relating to analysis of HBOT for non-diabetic problem wounds.

f. There was an erroneous assumption that HBOT is a new technology.

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There has been a denial of natural justice in relation to this withdrawal of Medicare funding:

a. The results of a major study of HBOT for problem wounds (400+ patients over 7 years) have been dismissed by MSAC. This study was specifically requested by MSAC in 2004 after the 1054 report, yet was discarded by MSAC in 2012. It is unjust and inappropriate for MSAC to request clinical data collection then dismiss the data at a later date. It has wasted the time of clinicians and patients Australia-wide, over a 7 year period.

b. The fundamental assumption that HBOT is a new technology was flawed. HBOT has always been funded as a treatment intervention since the CMBS began.

c. The final 1054.1 report had over 70 pages altered when released and panel members were denied the opportunity for further input or consultation.

d. The two experts in hyperbaric medicine on this panel assert that the voting procedures were completed with undue haste, and concerns regarding the report in relation to (c) above were "gagged". The dissent of the clinical experts and the reasons for that dissent is not recorded in the published report.

e. As currently presented, the report reads as if the hyperbaric clinical experts have provided their full approval.

f. MSAC does not have independent scrutiny. When making decisions to withdraw Medicare funding full independent review is essential. This represents a fundamental flaw in Government process, and has potential for flow on to become more generalised.

g. MSAC reviews appeals against its own processes and decisions. There is no independent review. This may be appropriate if applicants are seeking approval of funding for a new technology, but is completely inappropriate when reviewing existing funded treatment. On this occasion our concerns regarding the MSAC 1054.1 report and subsequent decisions were cycled back to the same MSAC committee for review, where they were unsurprisingly rejected.

I have attached more detailed information in relation to the points above.

We request that you consider reversing the decision to withdraw funding from this vulnerable population of patients.

We are also seeking the opportunity to meet with you as a matter of urgency to discuss these issues in detail.

Yours sincerely

Prue Power AM

Chief Executive

Attachment

Background

- The Australian and New Zealand Hyperbaric Medicine Group (ANZHMG) has been working with the AHHA and the AMA to address, in our view, flawed MSAC processes and decisions demonstrated in its reviews and reports (1018-20 and 1054-2004) which recommended withdrawal of funding of HBO treatment for soft-tissue radiation injury and chronic non-diabetic problem wounds. Since 2004, both conditions have been subject to temporary (Ministerial 3C) funding via Item number 13015.

  Concerns regarding MSAC processes span a decade and despite assurances by MSAC that their processes have been reviewed, the same issues have persisted from 2000 to 2012.

MSAC acting outside jurisdiction: processes flawed

- Despite MSAC's brief that it was set up to review new technologies and not existing funded technology (such as HBOT), three reviews have been pursued at considerable cost to the Australian taxpayer.
- In its first report (1018-20), the Committee placed severe restrictions on the medical conditions that could be treated by HBOT, citing "evidence" as their guiding principle. This constituted a withdrawal of funding from the Australian public for an established treatment, and a major shift in the direction of MSAC.
- After MSAC 1018-20, seven conditions remained fully funded by Medicare but ANZHMG made further submissions to MSAC and MBCC to restore full funding of HBOT for *soft-tissue radiation injury and necrosis, and hypoxic non-diabetic problem wounds*. Four ANZHMG members joined the supporting committee to review the evidence. Despite positive conclusions and recommendation of support for funding from this committee (April 2003), the conclusions that were published in the final report (MSAC 1054 - 2004) differed markedly from those agreed to by the committee. It was clear that these conclusions were modified by MSAC, without further consultation, to achieve negative outcome with only short-term funding provided for the two conditions.
- In January 2010, MSAC required that a further submission was made by (ANZHMG, AHHA, the Australian Society of Anaesthetists and the South Pacific Underwater Medicine Society) as evidence for another full review.
- It was pleasing that this resulted in permanent funding for soft tissue radiation injury, however, we dispute the findings in relation to non-diabetic problem wounds.

MSAC fails to consider relevant information: ignores Australasian wound study conducted by ANZHMG

- 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.
- 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.

Mistake of Fact: erroneous calculations re savings in Budget

- In addition, it appears that MSAC made a serious error in its analysis leading to an erroneous calculation of the expected savings from withdrawing funding based on HBOT as the primary treatment rather than the correct 'clinical pathway' where it is applied as a secondary intervention. It is critical to note that it has never been envisaged that HBOT would be the first line of treatment for chronic non-diabetic wounds.
- Therefore, we dispute the expected savings from this measure ($4.9m over 4 years), and emphasise that even using the 1504.1 Report's own flawed costings, the total incremental cost of the item is likely to be less than $800,000 over 4 years. Our own calculations indicate there will be a *cost saving* by using HBOT as a secondary intervention because *HBOT is less expensive* than normal treatment when commenced after three months of failed standard care (see attachment 1). Hence *to withdraw funding from HBOT will actually lead to increased health care costs.*
- Furthermore, HBOT has been funded since the CMBS started in the 1980's, and, until 2001, the use of the treatment was at the discretion of the specialists who work in the field. With self-regulation, the utilisation of HBOT in Australia has been stable for a decade providing a real cost saving for the Federal Government.

Failure to afford natural justice: systemic lack of procedural fairness in MSAC processes

- MSAC spent five months focusing on the incremental cost of soft tissue radiation injury, yet without explanation or proper process reviewed non-diabetic problem wounds, allowing only one month for the full report to be finalised and appeared to ignore specialist advice.
- During this flawed review a planned second face-to-face meeting with the Advisory Panel was cancelled and a teleconference was held instead. This teleconference was convened by a panel which consisted of some new members previously uninvolved with the issues. After a teleconference on 19th August, (which turned out to be the final one), a final report was circulated 8th September, with an expectation that the report must be signed off by members before 16th September, at the insistence of MSAC, making participation or representation from interested parties impossible. Crucial minutes from the 19th August 2011 teleconference were circulated late on 30th September, two weeks after Advisory panel members had been expected to sign off on the 1054.1 report.
- Furthermore, content in 70 out of 200 pages of the report was changed without further opportunity for interested parties to make representations and erroneous assumptions were used in relation to the care pathway. Regrettably, this has required a dissenting report to be published from members of the Panel (Smart and Bennett).
- When the outcome of the MSAC decision was appealed through the DOHA, the appeal was referred back to the same MSAC group. This is a denial of natural justice whereby MSAC does not have independent scrutiny, and no appeals process.
- Independent scrutiny is essential when MSAC has proceeded to act outside its terms of reference and recommend withdrawal of funding from existing funded treatments. The Australian public deserve a high level of scrutiny of Government processes when services are removed. There is a danger that MSAC will continue to expand its activities to a more general process withdrawing funding for treatment without appropriate scrutiny, checks and accountability.

Impact of MSAC decision

- The negative impact on the industry will be considerable. Private hyperbaric facilities in Brisbane, Melbourne, Sydney and Perth are threatened with cessation of operations and there is risk of a significant downgrade of the service provided by Royal Hobart hospital Hyperbaric facility.
- 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.

- Prior to this trial, eight research funding applications over seven years to NHMRC, ARC, CRC and other funding institutions have been unsuccessful.
- The fact that Australasian wound study is not yet complete and the CRC study has now commenced puts into question the 1054.1 MSAC statement in its latest report that 'opportunities to generate any more convincing comparative data was unlikely to be successful'. This incorrect understanding seems to have led to the decision to cease interim funding of refractory non-diabetic problem wounds.

Issues of major concern regarding the MSAC 1054.1 report in relation to HBO treatment for non-diabetic problem wounds:

1. There is a randomized controlled trial underway in the Australian setting to collect further evidence to supplement the Australasian wound study. As part of the craft group's strategy for providing further evidence, RCT has commenced to assess the impact of HBO treatment as a secondary intervention for refractory non-diabetic venous ulcers. The study will provide comparative evidence demonstrating if HBOT is able to influence wound healing in non-diabetic venous ulcers when standard care has failed. The results will be relevant because the entry criteria comply with inclusion criteria that the ANZHMG set in the application for HBOT as a secondary intervention for failed standard care. The study has an end point of wound healing and will also analyse quality of life, costs and cost effectiveness. This is a larger trial with a longer study and follow-up period and therefore a higher probability of generating statistically significant results. The trial also targets a specific sub-group of 'non-diabetic' hypoxic ulcers (i.e. just the venous ulcers), with clinically meaningful outcomes.

   The existence of this study was acknowledged in the MSAC 1054.1 report on page 141: Thistlethwaite, K. (study contact), Wesley Centre for Hyperbaric Medicine, Brisbane, Australia. 'The effectiveness of hyperbaric oxygen therapy (HBOT) for healing chronic venous leg ulcers: A randomised, double blind, placebo-controlled trial.' Anticipated date of participant enrolment is June 2011. See anzctr.org.au for more information, identifier ACTRN12611000505909.

   However, the MSAC 1054.1 report also unfortunately made a judgement that "providing further opportunities to generate any more convincing comparative data was unlikely to be successful"; hence dismissed the value of the Australian RCT.

   This multicentre study is hosted by the Wesley Centre for Hyperbaric Medicine and is detailed in Appendix 1. The Royal Hobart Hospital has also completed ethics approval and is ready to enrol patients in this trial. There is commitment to the trial at Prince of Wales Hospital in Sydney and Fremantle Hospital in Perth.

   The ethics approvals are documented in Appendix 1. To date, 37 patients have been screened, and 15 excluded due to not meeting diagnostic entry criteria. Twenty two (22) have received standard care venous ulcer compression dressings for one month. Five (5) of the 22 have not yet reached one month follow up. Seventeen (17) patients have received one month follow up and nine (9) patients were healing well. These were not entered into the HBOT section of the study. The remaining eight (8) patients did not progress with standard care and have been enrolled to be randomized to receive HBOT or placebo sham treatment. The planned number of enrollments is 64, allowing for 10% dropouts, 58. Patients are not charged for participation in the trial and medical labour is donated.

   The trial is now threatened by the withdrawal of funding for 13015, because although patients are not receiving Medicare benefits, the viability of the Wesley Centre for Hyperbaric Medicine is now seriously threatened.

2. MSAC 1054.1 considered that interim funding of refractory non-diabetic problem wounds was not justified because "providing further opportunities to generate any more convincing comparative data was unlikely to be successful". This is an incorrect assertion, given the RCT in progress described in (1) above, and the fact that the final outcome data for the Australasian wound study is still pending. The craft group is very confident the follow-on RCT will be successfully completed.

3. There have been a number of applications for research grants by groups that have included ANZHMG members, to investigate problem wounds. Very few of these have been successful. It appears that problem wounds are not a priority when research grants are allocated. After 7 years of persistence a successful grant has been allocated to the venous ulcer RCT, which commenced in 2012 .

4. The ANZHMG Australasian wound study prospective data collection, undertaken as a *direct result* of and guided by the recommendations of MSAC 1054 in 2004 has been ignored and dismissed as low level evidence. This is of great concern, given the significant resource allocation that was required to undertake the study, across multiple centres in Australia and New Zealand, by a small group of 12 dedicated professionals. The 1054 report in 2004 specifically called for this study to be undertaken. The current 1054.1 report ignores this. The Australasian wound study provides specific evidence of the performance of HBOT in the Australian setting, and is therefore highly relevant to the application.

   The Australasian wound study took a year of planning and has prospectively collected over six years more than 400 enrollments of patients with problem wounds, treated with HBOT. It is of great concern that MSAC is able to specify requirements regarding data collection and commission studies to be undertaken by craft groups, yet then have no ownership or responsibility for their implementation or outcomes, and then dismiss the data. The Australasian wound study is not yet complete – the final patients have been enrolled and 12 month outcome data will be available after March 2013.

5. The model used in analysis of non-diabetic problem wounds is flawed. Despite outlining a clinical pathway showing HBOT as a secondary intervention on page 6 of the PSD and page 7 of the 1054.1 report, the actual analysis compared HBOT as a primary intervention and compared it head to head against standard care. The Australasian wound study enrolled patients only after three months of failed care. This is a minimum - in fact the median time to referral was 16 months in the early report and more than 19 months in the sixth year report.

   The report and the economic modeling should both make it clear that HBOT is *not* advocated for the *initial treatment* of non-diabetic wounds. Because of the failure to acknowledge this reality, particularly in the economic analysis, MSAC has incorrectly assessed HBOT as a *first line* therapy compared to standard care from the outset. In addition, the effectiveness data used in the economic analysis, for problem wounds not receiving HBOT, came directly from HBO treated patients. This has compounded the flaw in the MSAC assessment and the analysis of the treatment in its correct place in the treatment pathway.

   Even with the flawed cost analysis, the 12 month additional cost for HBOT was $2151 AUD for each patient treated. The cost per ulcer healed was $2524 AUD with 68% healed at 6 months and 80.4% healed at 12 months. Data from a community study of problem wounds (Gordon et al 2006) assessing two models of care indicated that there was a dramatic increase in cost after 3 months of community care, and provided evidence of the need for a secondary intervention such as HBOT. After 3 months of community care where ulcers had failed to heal, the incremental cost per ulcer healed in the leg club was $4970 AUD, and for standard community care was $3203 (total healed with community wound care at 6 months = 44.6%).

   Both of these groups had worse outcomes and are higher than the cost per ulcer healed for patients treated with HBOT ($2524 AUD). Using an appropriate model whereby HBOT is applied as a secondary intervention, there is a cost saving by 6 months compared with community care, of

$7808 per patient. The reason for this cost saving is that HBOT costs do not continue after the treatment stops, and evidence from the Australasian wound study indicates that patient's wounds continue to heal for up to 12 months. If this is indeed the case, to withdraw funding from HBOT will actually increase health care costs, the opposite of the report conclusion.

Because the incorrect clinical pathway was followed in the 1054.1 report, the conclusions regarding costs of HBOT are flawed, and the report misrepresents the costs of HBOT for non-diabetic problem wounds. It is also incongruous to acknowledge a significant local prospective analysis of the treatment of non-diabetic wounds that suggest an 80% success rate at one year, and yet dismiss the support for the use of that treatment in the current 1054.1 report.

6. The final draft of the 1054.1 report was completed with undue haste, during August and early September 2011 preventing any further input from committee members. The analysis of costs of STRI was undertaken over a 4-5 month period with significant consultation to the input data. The non-diabetic problem wound analysis was wrapped up in just over one month. The advice provided by specialist clinicians on the panel was ignored and consequently the non-diabetic problem wound assessment was flawed. The report does not contain any explanation that the specialist advice was provided or why it was dismissed or ignored.

7. Despite the addition of approximately 70 new pages of information and numerous changes since the final teleconference, members of the 1054.1 committee were informed the document required sign off. The minutes of the final teleconference did not arrive until three weeks after the final draft of the report and two weeks after committee members were required to lodge their vote on whether or not to accept the final draft. The precipitous requirement to sign off the report led to flawed analysis and conclusions.

   Committee members were informed that the draft report had received the necessary votes for the panel to officially 'sign off' the document as it is currently written. Members did not receive any information about the numbers in order to confirm that vote, nor were members made aware of who may and may not have voting privileges on the 1054.1 advisory panel. The two experts in hyperbaric medicine on this panel assert that the voting procedures were completed with undue haste, and concerns regarding the report were "gagged". The report has then been published without referencing their dissenting views and the reasons for their dissent. As currently presented, the report presents as if the hyperbaric clinical experts have provided their full approval.

   In 2004, the MSAC 1054 report documented: "*in the absence of effective alternative therapies and in view of the progress of local data collections and an international trial, funding for HBOT should continue for existing MBS listed indications at eligible sites for a further three years.*"

   Since then, there has been very little new evidence generated in support of any treatment for problem wounds with the notable exception of HBOT.

   The small (12 Hyperbaric Specialists) but dedicated professional craft group in Australia has undertaken in good faith to comply with all requirements set by MSAC, and has continued in good faith to collect outcome data and perform high quality research. We request that while this research is continuing, the interim funding for non-diabetic problem wounds continues.