Associate Professor David Smart and Associate Professor Mike Bennett
Submission to

Standing Committee on Finance and Public Administration References Committee
Inquiry into Medicare funding for Hyperbaric Oxygen Treatment

1. Terms of Reference

On 1 November 2012, the Senate referred the following matters to the Finance and Public Administration References Committee for inquiry and report by the first sitting day of 2013:

(a) the withdrawal of Medicare funding for Hyperbaric Oxygen Treatment (HBOT) of problem wounds and ulcers in non-diabetics (MBS Item number 13015), which will commence on 1 November 2012;

(b) the Medical Services Advisory Committee (MSAC) process regarding this withdrawal, and other changes to the Medicare Benefits Schedule;

(c) the costs/benefits of this withdrawal in relation to associated treatments for these medical conditions; and

(d) any related matters.

Information regarding the authors

Associate Professor David Smart,
BMedSci, MBBS(Hons), MD(UTas), FACEM, FIFEM, FACTM, FAICD, DipDHM, CertDHM ANZCA

Associate Professor David Smart is a specialist in Emergency Medicine, Diving and Hyperbaric Medicine. He has worked in the field of Diving and Hyperbaric Medicine for 28 years. He has over 100 publications and abstracts in the field of Diving and Hyperbaric Medicine including his MD Thesis completed in 2005 with the University of Tasmania in 2005. He is senior visiting specialist and Medical Co-director, Department of Diving and Hyperbaric Medicine, Royal Hobart Hospital and Associate Professor, School of Medicine, Faculty of Health Sciences, University of Tasmania. He is Chairman of the Australian and New Zealand Hyperbaric Medicine Group, Education Officer and Censor, South Pacific Underwater Medicine Society (SPUMS), Medical advisor to CSIRO and the professional diving industry in Tasmania, and SPUMS representative on Australian Standards. In addition he provides medical teaching and consultancy advice to the Royal Australian Navy and is a faculty member of the Introductory Course in Diving and Hyperbaric Medicine run by the Australian and New Zealand Hyperbaric Medicine Group.

Associate Professor Mike Bennett
MB BS, MD, MM(Clin Epi), FFARCSI, FANZCA, DA, DipDHM, ANZCACertDHM

Associate Professor Michael Bennett is a specialist in Anaesthesia and Diving and Hyperbaric Medicine. He has worked in hyperbaric medicine since 1993 and is widely published in the field. His MD was a thorough investigation of the evidence-basis of diving and hyperbaric medicine and included primary authorship on 12 Cochrane reviews in the area. He is currently President of the South Pacific Underwater Medicine Society, is a past Chair of the ANZHMG and has served

twice as the Vice-President of the world peak body in the field – the Undersea and Hyperbaric Medical Society. He has been the course directory of the ANZHMG 'Introductory Course in Diving and Hyperbaric Medicine since establishing the course in 2001.

The Australian and New Zealand Hyperbaric Medicine Group

The Australian and New Zealand Hyperbaric Medicine Group is a subcommittee of the South Pacific Underwater Medicine Society. Its membership consists of the clinical directors and senior specialists from all comprehensive hyperbaric facilities in Australia and New Zealand. The group provides input and representation on issues regarding safety, standards and clinical operation of Hyperbaric facilities in Australia and New Zealand. This includes input to Government reviews. All members are voluntary and unfunded. The ANZHMG also promotes education in the field of Diving and Hyperbaric Medicine through its annual introductory course in Diving and Hyperbaric Medicine held at Prince of Wales Hospital, and coordination of clinical trials via its multicentre trials group.

INTRODUCTION

We appreciate the opportunity to make this submission. Both of us have been involved with and have observed the MSAC process relating to Hyperbaric Oxygen Treatment since it commenced in 1999. It is of great concern to us that funding for an effective second line treatment for non-diabetic problem wounds and ulcers is threatened as a result of MSAC processes that are flawed.

This document will address the terms of reference:

(1) Fundamental flaws of natural justice that have taken place in the multiple reviews of HBOT over the last 13 years, that has resulted in withdrawal of funding for HBOT for non-diabetic problem wounds and ulcers

(2) Flaws in process in the most recent MSAC 1054.1 review that led to Associate Professors David Smart and Mike Bennett dissenting from the report.

(3) Detail regarding the flawed costing model for HBOT

(4) Attachments supporting (1-3 above)

TERM OF REFERENCE (A)

There are a number of fundamental flaws in the MSAC process that have never been addressed, and have led to flaws of natural justice for patients receiving Hyperbaric Oxygen Treatment. Despite receiving appeal documents regarding MSAC 1054.1, DOHA and MSACV have not addressed some fundamental issues of natural justice:

(1) HBOT should NEVER have been reviewed by MSAC in the first place.

MSAC 1054.1 Documented this page 81:
"Clinical expert opinion is that HBOT is not a new technology, but an established therapeutic modality for a range of health conditions. It is approved for 13 indications by the UHMS, while in 1998 the ANZHMG developed a heavily restricted list of conditions for which there is an adequate base of clinical evidence to support routine clinical use. Both of these lists include chronic non-diabetic wounds and soft tissue radiation injuries. The members of the ANZHMG and the Australian and New Zealand College of Anaesthetists do not support the use of HBOT as a routine treatment outside this list of conditions. Prior to MSAC assessment 1018-1020, the use of HBOT for the treatment of these indications had received full funding on the MBS (previously under MBS Items 13012 and 13020)."

HBOT has been funded since the Commonwealth Medicare Benefits Schedule 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. 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. (REFERENCE: Attachment 1 – SPUMS statement minimal HBOT). 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 therapies. Our only major objection at the time was that the MSAC process was not appropriate to this task (vide infra).

In 1999, a manufacturer of monoplace (single person) hyperbaric chambers applied to MSAC to have a separate Medicare item number added to the CMBS. MSAC commenced review 1018-20 as a result of this inadequate and non-complying application, which then led to recommendations that funding should be withdrawn for Hyperbaric Oxygen Treatment of non-diabetic problem wounds and ulcers and soft tissue radiation injury.

This recommendation was contrary to MSAC's terms of reference because it was set up to review NEW technologies NOT existing *funded* technology. These terms of reference have subsequently been confirmed by the Minister again in 2010:

The Medical Services Advisory Committee (MSAC) is an independent scientific committee comprising individuals with expertise in clinical medicine, health economics and consumer matters. It advises the Minister for Health and Ageing on whether ***a new medical service*** *should be publicly funded based on an assessment of its comparative safety, effectiveness, cost-effectiveness and total cost, using the best available evidence.*

In providing this advice, MSAC may also take other relevant factors into account. This process ensures that Australians have access to medical services that have been shown to be safe and clinically effective, as well as representing value for money for the Australian health care system.

In its first report 1018-20 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 (outside its terms of reference).

Following its 1018-20 review, MSAC has recommended withdrawal of public funding from funded treatment but provided no evidence that alternative treatments (which continue to be funded), were effective.

There is a fundamental difference between the processes required for assessment of new technology to see if new funding will be allowed and that for assessing existing funded treatments.

For new treatments, it must be proved that the new treatment is better, cheaper and at least as safe as the treatment it will replace. MSAC *has* been constituted to undertake this process effectively.

For existing funded treatments, the MSAC methodology is fundamentally flawed, because it focuses on only one possible treatment for a clinical disease process.

The first basic flaw was that **MSAC has never reviewed the evidence for other funded treatments of non-diabetic problem wounds and ulcers**, hence funding was maintained for treatments that have no better, or even less evidence that HBOT. It has always been the position of the ANZHMG that a process using a 'patient focussed' approach was required to assess all funded therapies for a particular condition. This is the only rational way to ensure support of the best treatment strategies.

Because MSAC stepped outside its terms of reference in the review of HBOT, it has denied natural justice in the decision to unilaterally axe funding for HBOT. In addition, MSAC has no legislated or documented independent appeals process or scrutiny by another body when it has recommended withdrawal of public funding.

MSAC recorded the concern regarding the lack of evidence for other funded treatments of non-diabetic problem wounds and ulcers, but then ignored and dismissed these concerns as being outside its scope – a clear indication that it was stepping outside its own terms of reference:

From MSAC 1054.1 Page 81:

"While outside the scope of the current assessment, clinical expert opinion is that the overall evidence base for other treatment options for both indications of interest is relatively poor, including some treatments which currently receive MBS funding. Clinical expert opinion is that

the evidence in support of the use of HBOT is at least as good as that available for alternative treatments and therapies.

• The determination of the relative clinical and economic effectiveness of HBOT is confounded by a number of issues: − HBOT is an adjunctive treatment option that is generally added to a regime after the failure of conventional treatment to provide healing, and does not have a clear and direct comparator intervention.

- There are no definitive 'gold standard' treatments available for the two indications covered in the current assessment when conventional care is shown to be ineffectual.
- In many cases, patients have exhausted all available conventional treatment options.
- Ethical issues related to therapeutic beneficence and the offering of optimal medical care render it difficult to randomise patients to a placebo arm in a methodologically rigorous study, due to potential exposure of patients to risks associated with denial of treatment. This is especially significant due to the limited treatment options available for the indications of interest.
- The established nature of HBOT as a therapeutic modality means there has been little impetus to conduct further large clinical trials.

Clinical expert opinion is that the current assessment process may not be appropriate for an existing and widely-used therapeutic intervention such as HBOT. Instead, a patient-centred approach where all options for the treatment of the nominated conditions are examined would be optimal. Clinical expert opinion is that the current assessment should determine the relative merits of the treatment options available, rather than simply examining a single, existing treatment option in isolation. The application included 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, this was deemed to be outside the remit of the current assessment."

MSAC also ignored the detail submitted by the applicants for the 1054.1 review regarding relative strength of evidence of other treatments for non-diabetic problem wounds and ulcers.

(2) MSAC made recommendations for data collection in 2003/4 to be undertaken by the profession, then ignored the the data when it was presented to the MSAC 1054.1 review

As a result of their 1054 (2004) report, *MSAC requested that the profession develop guidelines and collect data regarding the outcomes of patients with non diabetic problem wounds treated with HBOT*. The document associated with these recommendations is attached as Attachment 2 (REFERENCE MONASH 2003 MSAC). Both Associate Professors David Smart and Mike Bennett were on the MSAC 10654 committee at the time the recommendations were made.

This request led to setting up the ANZHMG wound study – a nation-wide study of patients receiving HBOT AFTER 3 months failed usual wound care, then followed up to 12 months. The data from this study was submitted to the 1054.1 review, and involved over 400 patients in a seven year period, with ethics approvals in all states.

The requests for this data collection have been reaffirmed and documented multiple times in the 1054.1 Report:

Pages 9 and 10

"Three of these reports were derived from the ANZHMG Wound Care study, a multi-centre Australian prospective cohort study initiated following recommendations arising from MSAC assessment 1054. Although uncontrolled, this study represents a sizeable body of collective clinical data from Australian hyperbaric facilities, which measures the response of chronic problem wounds (those that have failed three months of standard treatment) to HBOT."

Page 17

"Data on the impact of HBOT on chronic non-diabetic wounds in the Australian healthcare context continues to be collected from the ongoing ANZHMG Wound Care study, a multi-centre prospective cohort study initiated following recommendations arising from MSAC assessment 1054."

Page 64
"The case series by Hawkins et al (2006) reported the first-year results from the ANZHMG Wound Care study, an ongoing prospective cohort study of patients presenting to hyperbaric facilities across Australia with chronic wounds (>3 months duration), initiated in June 2004 as a recommendation of the previous MSAC assessment (MSAC 2004)."

Page 113
"Three of these reports were derived from the ongoing ANZHMG Wound Care study, a multi-centre Australian prospective cohort study initiated following recommendations arising from MSAC assessment 1054. Although uncontrolled, this study represents a sizeable body of collective clinical data from Australian hyperbaric facilities measuring the response to HBOT of chronic problem wounds that have failed three months of standard treatment."

Despite recommending that the profession collect this data, MSAC rejected the data that they had requested. If previous MSAC committees have made recommendations, regardless of any subsequent changes in membership or processes, then MSAC needs to be accountable and fully accept the data collected as a result of their recommendations.

(3) MSAC costed HBOT as a first line treatment compared head to head with standard care. This resulted in flawed cost analysis, and a flawed conclusion that HBOT is more expensive than standard care.

The critique of this analysis is presented below, and costings 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.

(4) MSAC did not publish the dissenting report by Associate Professors Smart and Bennett until they were forced to do so after a complaint was made. This dissenting report is now available on the MSAC website, however it has not been included in the 1054.1 report document, nor with the public summary document. As such it will not be apparent to anyone downloading these two documents that the clinical experts dissented from the report .

TERM OF REFERENCE (B)

Flaws in the MSAC 1054.1 Committee processes

Associate Professors David Smart and Mike Bennett were the clinical experts on the MSAC 1054.1 Committee. A number of flaws in process occurred

(1) A second scheduled face to face meeting in March 2011 to discuss the detail of the clinical pathway was cancelled and instead was run as a teleconference May 3rd2011. Before the teleconference, there were significant changes made to the committee structure including change of the chairperson. The change to a teleconference prevented detailed face-to-face discussion regarding the clinical pathways and also prevented effective tabling of documents.

(2) Failure to provide appropriate time for working through the clinical pathway and costing for non-diabetic problem wounds and ulcers

The MSAC 1054.1 committee spent five months working on the cost model for soft tissue radiation injury, yet without explanation or proper process reviewed non-diabetic problem wounds, in less than one month before the full report was be finalised and appeared to ignore specialist advice.

Discussion regarding the costs started on 19th July 2011and a first full draft report was circulated on 5th August 2011 by Ben Hoggan of ASERNIP-S. The clinical experts advised that the clinical pathway used in cost analysis of problem wounds was incorrect, and this advice was ignored during this very rapid assessment. This gave the impression that there was external pressure to meet a deadline.

(3) Unsatisfactory delays in releasing minutes of a critical final teleconference from 19th August 2011. The minutes were released on 30th September 2011.
A teleconference was held on 19th August 2011 to discuss the first draft report. The second draft report was circulated by Ben Hoggan on 8th September 2011, with expected sign off on 16th September. Associate Professors Mike Bennett and David Smart noted that over 70 pages of the first draft report had been changed. They indicated that there were significant errors that required attention, and that many of the altered 70 pages required further modification to appropriately represent the facts.

(4) Expectation that committee members sign off on the second draft report that had 70 out of 200 pages changed, with no further discussion allowed.

Both Associate Professors Smart and Bennett had multiple comments regarding the

report, including statements regarding inaccuracies in the report. They were informed by Ben Hoggan that the "draft report" was actually a final version to be signed off by 16th September.

This gagged and closed all further input from the Australian clinical experts. The report was expected to be signed off **before any minutes were released** from the meeting of 19th August 2011 making any real participation or representation from interested parties impossible. This locked in the **altered content** of 70 out of 200 pages of the report that had been changed, without further consultation.

(5)

(6) Voting processes for the report were not transparent.

MSAC 1054.1 members Smart and Bennett were informed on 29th September 2011 by Lyndall Thomas-Sibraa of the MSAC secretariat that the report had been approved by a "quorum of members". The clinical experts were unaware that a voting process had been initiated, what constituted a quorum, and were never informed of who had voted or what the numbers were in favour or against finalising the report. This process completely lacked transparency or any shred of fairness or due process.

The clandestine voting process also prohibited further opportunity for the clinical experts to make representations regarding the erroneous assumptions that were used in the clinical pathway for problem wounds.

Regrettably, this has required a dissenting report to be published from the Hyperbaric Clinical expert members of the Panel (Smart and Bennett).

Despite this it appeared that there were attempts to silence our dissent. We were clearly informed by Lyndall Thomas-Sibraa of MSAC secretariat that our dissenting report would not be published on the MSAC website, on 5th October.

"Thank you for forwarding your dissenting report. The Department has no formal template for such a document and as we do not want to restrict panel members in putting forward their views, leave it to your discretion.

Please note that your dissenting report is only considered by ESC and MSAC and will not be published on the MSAC website. Only the fact of your dissent to the assessment report will published on the MSAC website."

Prior to our complaint, the only reference to dissent on the website was in the public disclosure document:

"MSAC noted:

☐ the two dissenting views from the hyperbaric oxygen clinicians on the advisory panel;"

The reason for dissent was not recorded. After a complaint was lodged with DOHA, the dissenting report is now on the website.

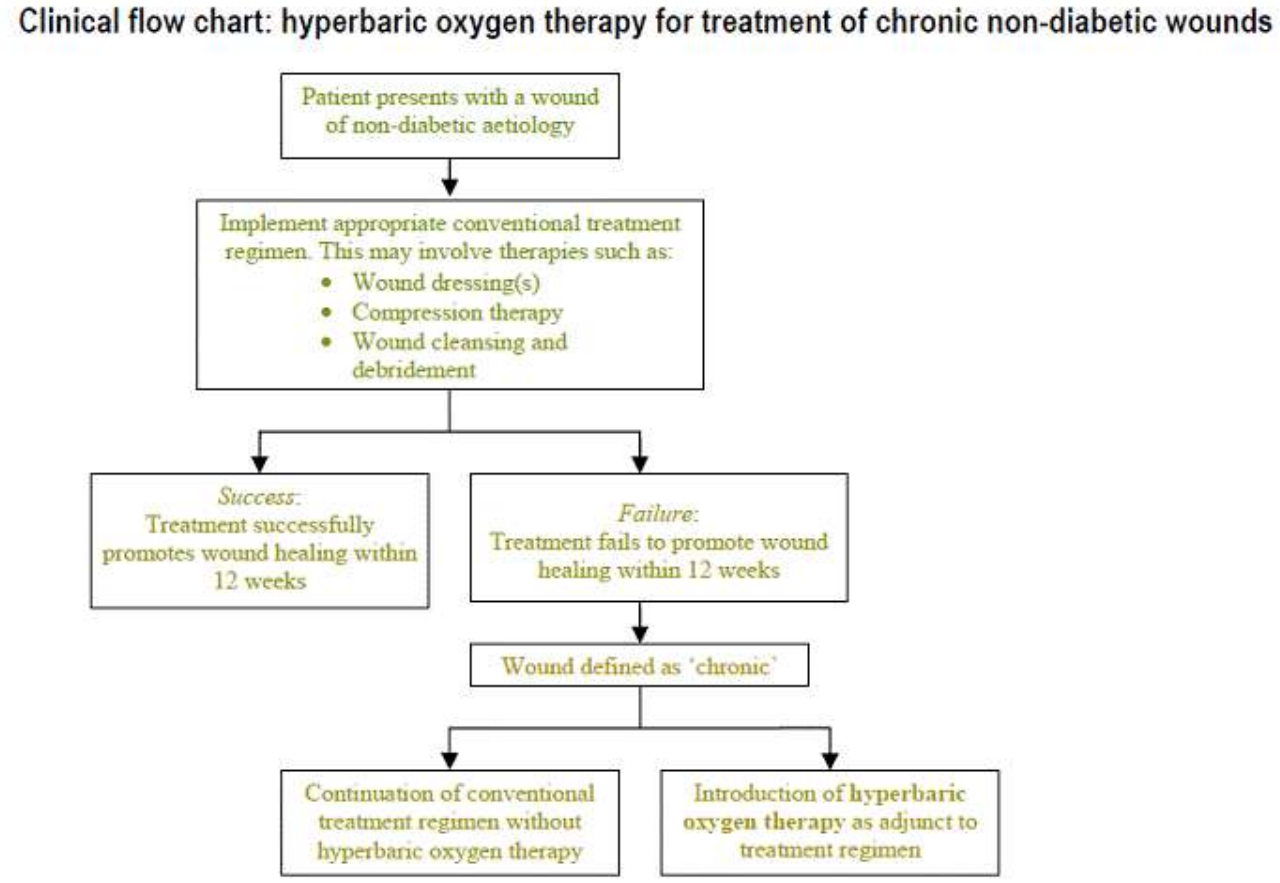
The dissenting report is attached as Attachment 3.

TERM OF REFERENCE (C)

CLINICAL COSTING DATA OF HBOT FOR NON DIABETIC PROBLEM WOUNDS USING APPROPRIATE PATHWAYS.

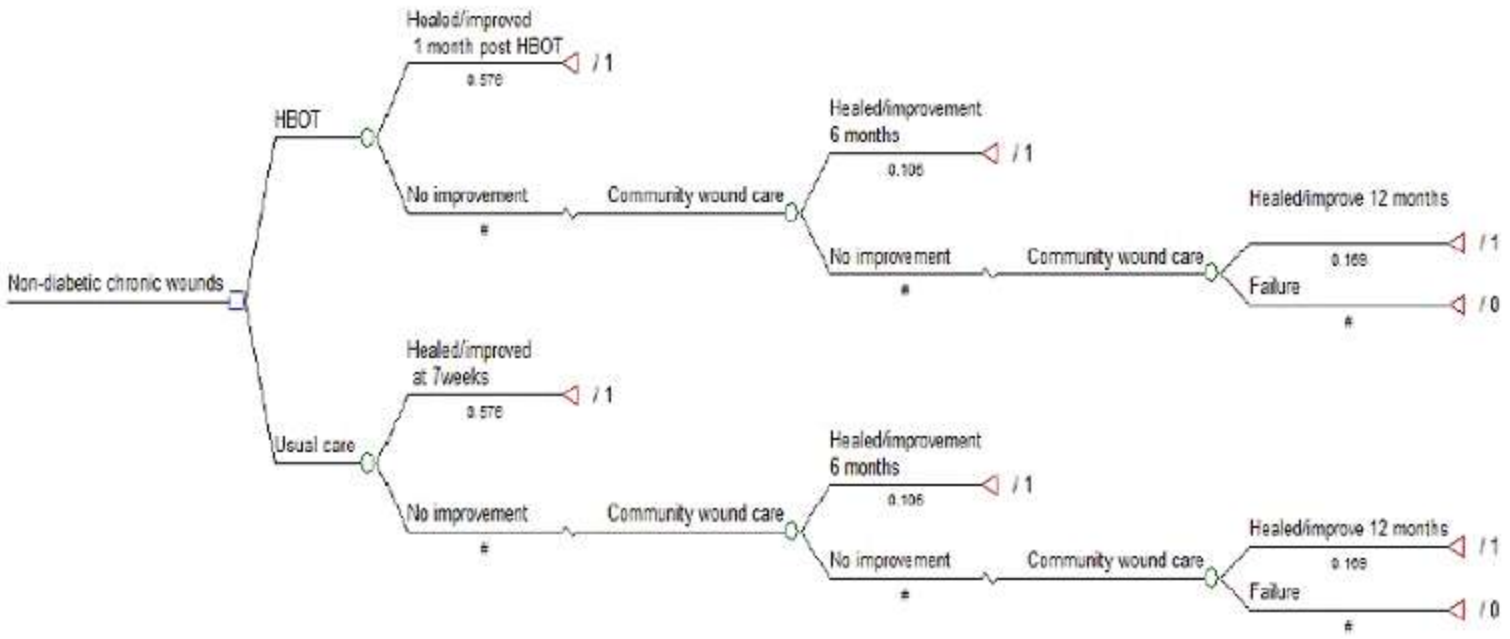
The clinical pathway presented by MSAC in the 1054.1 report is correct – on the surface it appears the analysis will compare HBOT as an intervention only after 3 months of usual wound care:

On the surface, it would be assumed that all analysis after that point used this clinical pathway (Ref Pages 7, 33 MSAC 1054.1 report, and page 6 PSD)



However – the above pathway completely misrepresents how MSAC undertook the cost analysis, which compared HBOT head to head with standard care, assuming HBOT was a first line treatment (see below):

Decision tree: Chronic wounds



(Reference Pages 11, 89 MSAC 1054.1 and Page 10 PSD)

In addition, <u>MSAC used the outcome data from the ANZHMG wound study</u> and assumed the outcomes would be the same for community care. There are no outcomes available for community care after 6 months.

In the diagram above, the outcome after 3 months of community "usual" care shows 57.6% of wounds healed. (This is exactly the outcome that was determined when HBOT was added after 3 months of failed care.

Data from Gordon et al 2006 shows that only 8.9% of problem wounds heal with community care in the 3 to 6 month period.

<u>This data was available to MSAC but they declined to use it.</u>
MSAC kept demanding randomised trial data, and rejected the data from the study that was set up following MSAC's own recommendations in 2003/4 (Attached sheet).

From the above cost analysis, MSAC 1054.1 calculated HBOT as first line treatment was $2151 per patient more expensive than usual care

The data presented in Table 2, page 11 of the MSAC report is highly relevant and indicates a fundamental reason to continue to fund HBOT:

Table 2 Costs of clinical pathways: chronic non-diabetic wounds

Description	Treatment	Cost
HBOT success (1 month)	1 year	$13,898
HBOT success (6 months)	1 year	$17,670
HBOT success (12 months)	1 year	$23,119
Usual care success (1 month)	1 year	$11,747
Usual care success (6 months)	1 year	$15,519
Usual care success (12 months)	1 year	$20,968
HBOT failure	1 year	$42,383
Usual care failure	1 year	$40,232

HBOT: hyperbaric oxygen therapy.

They have calculated that the cost of usual wound care FAILURE is $40,232 per annum.

The success rate for usual care in the Australian setting (Gordon et al, 2006) is only 44.6%. Hence there is a huge cohort of patients continuing to access Medicare funded treatments with poor success and at high cost.

HOWEVER
Applying HBOT as a second line treatment, (after 3 months failed community care), AND using all of the data that MSAC provided produces a completely different outcome for cost:

AVERAGE COST ALL PATIENTS COMMUNITY WOUND CARE TO 6 MONTHS = $28494 PER PATIENT
PERCENTAGE HEALED = 44.6%

AVERAGE COST ALL PATIENTS 3 MONTHS COMMUNITY CARE THEN HBOT COURSE = $22992 PER PATIENT
PERCENTAGE HEALED = 72.8%

Hence HBOT is a lower cost treatment by $5502 per patient, with better outcomes when applied after usual care has failed

Despite recommending withdrawing funding for HBOT, at no stage has MSAC ever been able to demonstrate that outcomes are worse with HBOT. All evidence points to the opposite, and is acknowledged in the MSAC report:

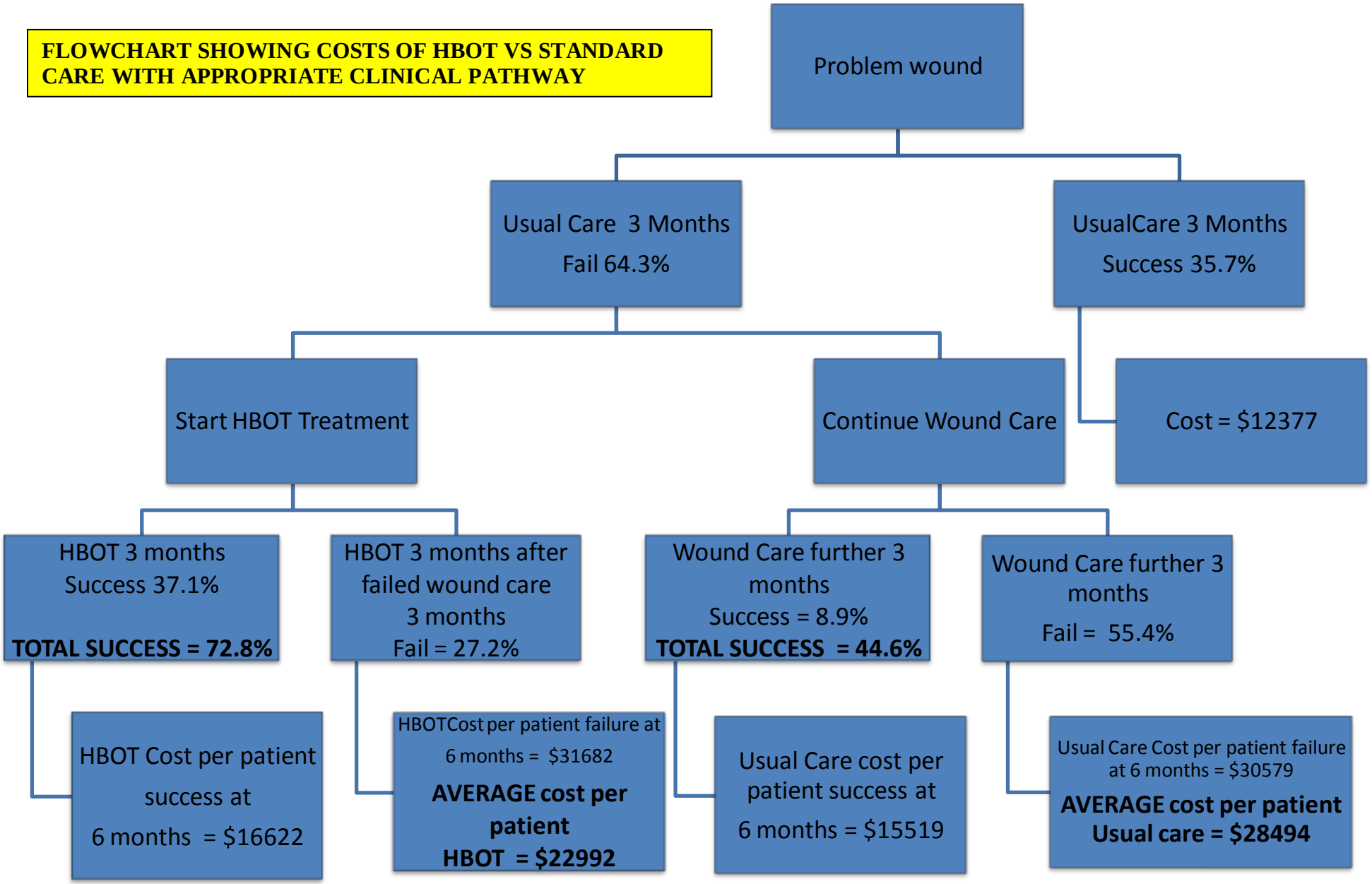
"HBOT offers a viable, safe and non-invasive treatment to promote healing in patients where conventional treatment therapies have been found to be ineffective. Indeed there may be a good argument to introduce HBOT earlier in the treatment pathway to potentially significantly improve patients' clinical outcomes and quality of life, and avoid the more radical and invasive treatment strategies otherwise used for these conditions."

THE APPROPRIATE PATHWAY AND COST CALCULATION IS SHOWN IN THE FLOWCHART BELOW:

THIS DEMONSTRATES THAT BY KEEPING HBOT, THERE IS A COST SAVING OF $5502 PER PATIENT (ON AVERAGE).

HENCE THE DECISION TO AXE HBOT FUNDING WILL ACTUALLY COST THE TAXPAYER MONEY.

FLOWCHART SHOWING COSTS OF HBOT VS STANDARD CARE WITH APPROPRIATE CLINICAL PATHWAY



TERM OF REFERENCE D

OTHER RELATED MATTERS

In 2004, MSAC concluded in the 1054 report:

The clinical evidence was inadequate to substantiate claims that hyperbaric oxygen therapy (HBOT) was cost-effective in the treatment of refractory soft tissue radiation injuries or non-diabetic refractory wounds. However, **MSAC recommended that, as there are no effective alternative therapies and in view of the progress of local data collections and an international trial,** funding for HBOT continue for MBS listed indications at currently eligible sites, for a further three years.

The Minister for Health and Ageing accepted this recommendation on 31 August 2004.

Since 2004, the evidence base for HBOT has improved, and there has been very little additional evidence for other funded treatments of non-diabetic problem wounds.

In 2012, MSAC 1054.1 concluded:

"While low-level evidence was found within the Australian healthcare context indicating a healing benefit for the use of HBOT, the overall body of published evidence is currently insufficient to determine the relative clinical effectiveness of HBOT as an adjunct to conventional treatment for chronic non-diabetic wounds, compared to conventional treatment without HBOT."

The reason for this statement is that HBOT has not been compared head to head against standard care. It has always been applied as a second line treatment for a minority of patients who fail standard care after 3 months. It does not indicate that HBOT is ineffective as a treatment. In fact the MSAC report records support for HBOT on page 13:

"*HBOT offers a viable, safe and non-invasive treatment to promote healing in patients where conventional treatment therapies have been found to be ineffective. Indeed there may be a good argument to introduce HBOT earlier in the treatment pathway to potentially significantly improve patients' clinical outcomes and quality of life, and avoid the more radical and invasive treatment strategies otherwise used for these conditions*''

It also recognises the poor level of evidence for other treatments page 81

"*the overall evidence base for other treatment options for both indications of interest is relatively poor, including some treatments which currently receive MBS funding. Clinical expert opinion is that the evidence in support of the use of HBOT is at least as good as that available for alternative treatments and therapies*".

On page 110 (table 53) the MSAC 1054.1 report assesses the evidence for HBOT as "satisfactory" and the applicability and generalisability of the evidence as "good".

Table 53 Body of evidence assessment matrix for HBOT: chronic non-diabetic wounds

Component	A Excellent	B Good	C Satisfactory	D Poor
Evidence base[a]			Level III studies with a low risk of bias, or level I or II studies with a moderate risk of bias	
Consistency			Some inconsistency reflecting genuine uncertainty around clinical question	
Clinical impact			Moderate	
Generalisability		Population/s studied in the body of evidence are similar to the target population		
Applicability		Applicable to Australian healthcare context with few caveats		

a Level of evidence determined from the NHMRC evidence hierarchy (Table 12).
HBOT: hyperbaric oxygen therapy

Despite the above MSAC has recommended withdrawal of funding from the existing funded treatment (HBOT) – when it has not recommended withdrawal of funding from the alternative "standard" treatment that it recognises as having poor evidence of efficacy.

On that basis MSAC is acting contrary to the fundamental principles of Medicare.

Few other **funded** treatments on the CMBS would have better evidence than that assessed for HBOT for non-diabetic problem wounds and ulcers.

Attachment 1
SPUMS Statement on Minimal Hyperbaric Oxygen Treatment

Attachment 2
Recommendations from 1054 Committee regarding conclusions and setting up data collection

Attachment 3
Dissenting Report by Associate Professors David Smart and Mike Bennett