Review of MSAC 1054.1

MSAC 1054.1 RESPONSE

AUTHOR:

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INTRODUCTION:

The Medical Services Advisory Committee (MSAC) is set up to evaluate ***new*** technologies and treatment modalities under three criteria:

1) Safety

2) Efficacy

3) Cost effectiveness

Assessment 1054.1 is the third attempt to assess the role of Hyperbaric Oxygen Therapy (HBOT) in the treatment of non-diabetic chronic non-healing wounds and non-neurological soft tissue radiation injury (STRI). MSAC assessment 1054.1 has approved the public funding of non-neurological STRI and we accept that assessment. Our concern is with the withdrawal of approval for public funding for non-diabetic chronic non-healing wounds and the methodology that was used in that assessment.

HISTORY OF PROCESS:

HBOT for non-diabetic non-healing chronic wounds is not a new treatment. The MSAC terms of reference and membership (as stated in Appendix A of the MSAC 1054.1 Report Page 119) state that:

> *"It advises the Minister for Health and Aging on whether a* ***new*** (my emphasis) *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*** (my emphasis)*"*

Prior to 2001 non-diabetic, chronic hypoxic wounds were fully funded by Medicare. In 2001 an assessment process was started to look at the funding of other indications and the funding of non-diabetic hypoxic wounds was reassessed. This was MSAC assessment 1018-1020. The assessment concluded that there was ***insufficient evidence*** to support public funding and recommended that public funding should be withdrawn for this indication. This was not proceeded with as it was not the core issue being requested.

In 2004 MSAC review 1054 was performed. Further evidence of efficacy was presented in small studies and positive benefits were indicated, but still there was limited evidence. MSAC agreed to allow the development of a local prospective cohort collection of information that would prospectively look at the benefits of HBOT out to a year in individual patients with chronic wounds. The study was designed to follow each person out to 1 year at

different stages, to see if HBOT improved healing rates in chronic non-healing wounds after three months of standard wound care. This design was deemed acceptable by MSAC and was extended in 2007 as the numbers of patients reaching a full years follow up were not sufficient to make an interpretation.

Due to evidence of benefit, the MSAC review committee stated

> *"…in the **absence of an effective alternative therapies** (my emphasis) and in view of local data collections and international trial, funding for HBOT should continue for existing MBS listed indications at eligible sites for a further three years."*

The current assessment (1054.1) is a continuation of this assessment with additional evidence from the MSAC approved study being available.

There is some concern expressed by the clinical experts that the current MSAC review process may not be applicable for HBOT as:

> *"Clinical expert opinion indicates that the current MSAC assessment process may not be appropriate for an established therapeutic intervention such as HBOT. The current assessment should determine the relative merits of the treatment options available rather than simply examining a single, existing treatment option in isolation. Clinical expert opinion is that a patient-centred approach, where all options for the treatment of the nominated conditions are examined, would be optimal." (MSAC 1054.1 Pg 17)*

The primary problem being that HBOT is a ***secondary*** treatment modality only used after three months of the primary treatment of 'usual care' has failed. It therefore limits options as well as restricting a clinical option that has been shown to enhance healing and terminating the long-term requirement for care.

POINTS:

•HBOT for non-diabetic non-healing wounds is **not a new technology** and should not be assessed under new treatment/technology guidelines as it was fully funded prior to 2001

•There is some concern that the MSAC assessment process is actually applicable to this therapy (as it is a secondary treatment modality when the primary treatment modality has failed already)

• MSACs prior reviews have recommended continuation of funding while studies were done and positive outcomes of those studies allowed further continuation of funding

• Due to the cost of developing and running a Randomised Controlled Trial (RCT) and the ethical dilemma of withholding treatment for at least a year, a prospective cohort study that was suggested and approved is the current best available evidence for HBOT

• The ANZHMG Woundcare study was accepted by MSAC as a study that would allow assessment of efficacy of the treatment and funding was extended based on the preliminary positive outcomes of this study

• The ANZHMG Woundcare study does not assess the rate of healing or failure of treatment in 'usual care' cases and therefore cannot be used to determine healing rates in patients that have not had HBOT

APPENDIX 1: PRIMARY ASSESSMENT REPORT OF MSAC 1054.1

THE ASSESSMENT PROCESS:

The use of HBOT is listed as having 15,579 Medicare Services for the 2010-2011 financial year for all MBS numbers of which 8,910 Services were related to either non-diabetic chronic non healing wounds or STRI (the item number 13015 does not distinguish between the two).

HBOT was seen as a uniquely placed clinical modality in that it is used

> *"after primary interventions and conventional therapies have failed to promote wound or radiation injury healing." (MSAC 1054.1 Page 6).*

Therefore by definition, the treatment modality is a secondary intervention only introduced *after* conventional treatment has failed.

SAFETY ASSESSMENT:

In all three reviews (2001, 2004 and 2010) have found that

> *"Adverse events related to treatment with HBOT are generally minor and self-limiting, rarely lead to discontinuation of treatment, and where present usually resolve shortly after cessation of treatment" (MSAC 1504.1 Pg 113)*

In summary the MSAC committee found

> *"…based on absolute data HBOT can be considered to be a safe and well-tolerated intervention for which serious, life threatening adverse effects and fatalities are rare." (MSAC 1504.1 Pg 113).*

Therefore HBOT is considered to be a relatively safe and well-tolerated treatment in all three reviews.

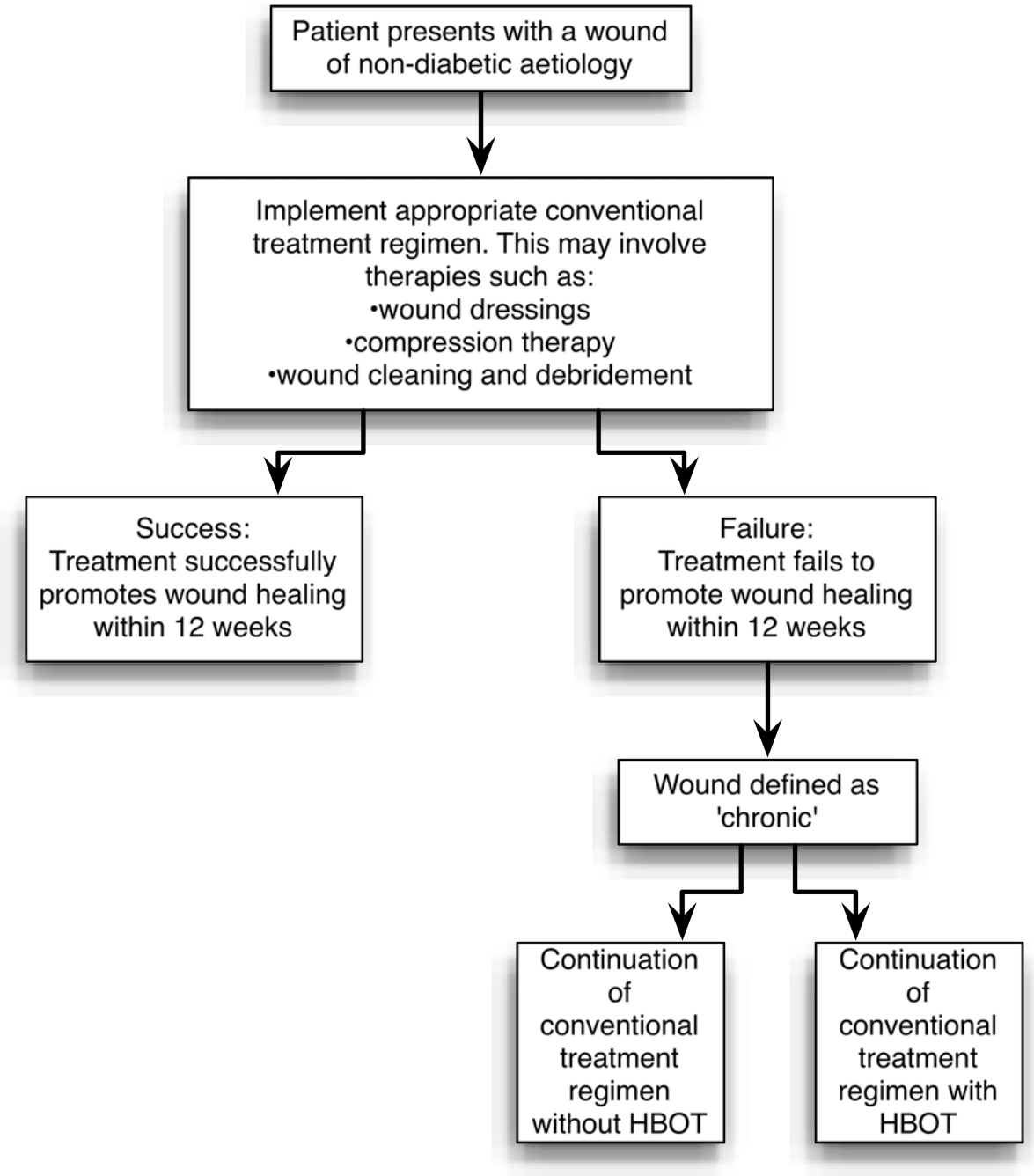
EFFECTIVENESS:

There is very little high level evidence regarding the effectiveness of HBOT vs conventional care in non-diabetic chronic wounds. This is for several reasons:

1) Diabetic wounds make up the bulk of most community based problem wounds that progress rapidly to major surgical interventions. Therefore most studies have been performed on them showing significant improvement with HBOT in several RCTs (and has current public funding under MBS item number 13020). Other wounds have different causes but they all have similar issues with wound hypoxia (low oxygen in the tissues) but because they are divided into smaller 'aetiological groups' no one causative group develops enough numbers to attract funding for an RCT of sufficient power.

2) The end point problem in most of these conditions is the same, hypoxic skin tissue (as is required to be demonstrated for funding) and HBOT has a demonstrable effect on this (as per an oxygen challenge) so there is reasonable circumstantial evidence that the effect is a class effect with virtually all wounds regardless of aetiology.

3) The ANZHMG wound care study has shown that for *ALL* aetiological groups, there is improvement >50% out to a year. This has the starting point of the patient having to have had the wound for *at least 3 months* and the ***average*** time to entry into the study was a wound of greater than 16 months. This is not taken into consideration by the MSAC interpretation as a failure of 'usual treatment' although it is stated on Page 21 of MSAC 1054.1 and is quoted directly in the clinical pathway diagram below.



From MSAC Report 1054.1 Page 7

4) Quality of life assessments are also discounted because there is difficulty in assessing quality of life in a group that has limited lifespans (due to the age group in which these wounds occur). The one study quoted (from data in the ANZHMG wound study) looks specifically at the reduction in pain which greatly enhances quality of life but the economic and lifestyle benefit are not attributed.

5) The ongoing cost of failure of the treatment is also very significant beyond the one year mark. For a lot of patients the end point of the disease is an amputation which has a significant impact both socially and in terms of health economics, that extends well beyond the single year.

COST EFFECTIVENESS:

The biggest issue is that when the cost effectiveness study is performed, there is an assumption that there is no difference in healing between the HBOT group and conventional treatment. A simple comparison between the Gordon et al (2006) paper which looks at two different models of conventional wound care and the Hawkins and Bennett (n.d.) paper both show healing rates at 6 months. This is used in the current MSAC 1054.1 assessment as the source for cost of funding and therefore out to 6 months gives an indication of comparative independent record of healing rates. The MSAC 1054.1 review states healing rates from the Gordon *et al* (2006) paper, with two different care models, of 5/36 patients in both groups (13.9%). On review of the original paper there is no record of the number of patients healed actually contained within the paper itself. Also the total number of patients was 56 (28 in each group randomised). This leads to some concern as to the source and validity of the data.

Personal communications with Dr Gordon actually had the healing rate at 3 months as 20/56 (35.7%) for both groups and 25/50 (50%) at 6 months as points of effectiveness for standard, high level wound care. As the ANZHMG has only the 6-month point of assessment in common, cost calculations can be performed at this point and compared between HBOT and ‘usual care’ under cost modelling.

Therefore it would be more correct to use this as a cost comparator rather than assuming that the two treatments are equally efficacious.

Using the data from the MSAC review we can do a cost effectiveness study using the real data at 6 months and it generates a table shown below.

APPENDIX 1: PRIMARY ASSESSMENT REPORT OF MSAC 1054.1

Table 1: Cost comparison between "usual care" and HBOT and "usual care" to heal a wound at six months.

ITEM	HBOT+ USUAL CARE		USUAL CARE ONLY		COMMENTS
HBOT Costs	$4,245.65		$0.00		*From MSAC 1054.1 Table 37 Pg 91*
Surgical Costs*	$9,653.00		$9,653.00		*From MSAC 1054.1 Table 39 Pg 93*
Usual Care Costs	$4,610.00		$5,448.39		*From MSAC 1054.1 Table 38 Pg 92*
TOTAL COSTS (Per wound healed at 6 months)		**$18,508.83**		**$15,101.39**	
Documented healing rate	0.689		0.5		*From Hawkins & Bennett (n.d.) and Gordon et al (2006): exact numbers from personal communication with Louisa Gordon*
Failure of treatment cost at 12 months	$42,383.00		$40,232.00		*From MSAC 1054.1 Table 37 Pg 91*
Annual Costs per person per wound healed**		**$25,933.70**		**$27,666.70**	
Annual total costs per annum for service***		**$3,993,789.32**		**$4,260,671.03**	
COST DIFFERENCE (HBOT cost vs Usual Care Cost)	Per person per wound healed	**-$1,733.00**	Per annum cost for all wounds healed	**-$266,881.71**	*Negative number favours HBOT costing less per wound healed than "Usual Care"*

*Calculation from MSAC 1054.1 Table 39, Pg 93 is used as cost calculations in the original paper use the complication cost number in error.

**Annual costs per person per wound healed is: (6 month cost x healing rate) + ((1-healing rate) x failure of treatment cost)

*** Annual total costs per annum for service = Annual costs per person per wound healed x 154 services *(from MSAC 1054.1 Table 42, Pg 96)*

Assumption is made that the wounds that are not healed at 6 months go on to be failure of treatment in both groups at 12 months

The above table using data calculated form the MSAC 1054.1 review shows that in fact, the addition of HBOT after 3 months of standard care saves Medicare **$1733.00** per person per wound healed and **$266,881.71** per annum in total cost savings as compared to usual care. This is a conservative number as we know that the healing rate at 12 months is 85.2% (0.852)

from Hawkins and Bennett (n.d.), the difference in cost could be expected to increase in favour of HBOT. This is at odds with the outcome cost of **$331,256.00** per annum in favour of 'usual care' in Table 42 Pg 96 but as noted before this is the accumulating the costs of adding the of HBOT without giving effect credit to the intervention.

The use of the Gordon *et al* (2006) paper as a comparator is valid based on the fact that: 1) both papers looked at rates of healing and provision of costs of service 2) Gordon *et al* (2006) is a standard example of the mixed outpatient/in home care model in Australia and represents the standard of high level wound care available to Australians 3) there are defined outcomes at the same point of treatment (six months) that are directly comparable between the two studies. It is also helpful that the Gordon et al study is independent of the wound care study as it cannot be criticised for potential bias towards HBOT.

The cost effectiveness calculation was done by the Incremental Cost-Effectiveness Ratio (ICER) model, which allows comparative costs to be assessed between different technologies.

DISCUSSION:

MSAC Review 1054.1 did this assessment based on a mixture of hard data (ANZHMG Wound care study) and several assumptions that are not logical and are not supported by the data available. The primary concern is that the outcome was pre-determined as part of the assessment and then the technologies were assessed against this outcome (MSAC 1054.1 Pg 87).

The assumption made is:

> *"However since there is no common comparator it is not possible to undertake a direct comparison of the data from Hawkins and Bennett (n.d) and Gordon et al (2006).* ***As a result the data from Hawkins and Bennett (n.d) formed the basis of the effectiveness of HBOT and usual care for the economic analysis.***(my emphasis)*"*

This is incorrect as the Hawkins and Bennett paper did not look at the effectiveness of non-hyperbaric wound care and no assumption of efficacy should be made from this paper regarding non-hyperbaric wound care outcomes.

Given that there is an artificial (and incorrect) assumption of equal outcome and both have the same standard care with one having an additional care resource allocated to it, then by definition, it will never be cost effective no matter what the intervention is.

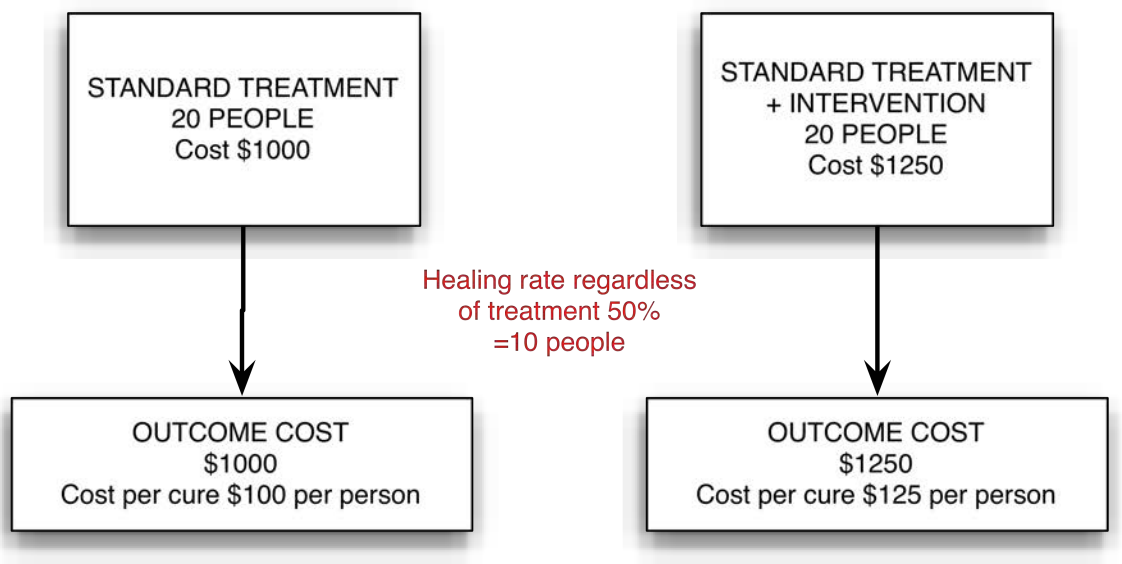
It is stated in the "Objective" under Economic Considerations in MSAC 1054.1 (Pg 84):

> *"For chronic non-diabetic wounds the most appropriate comparator is usual care."*

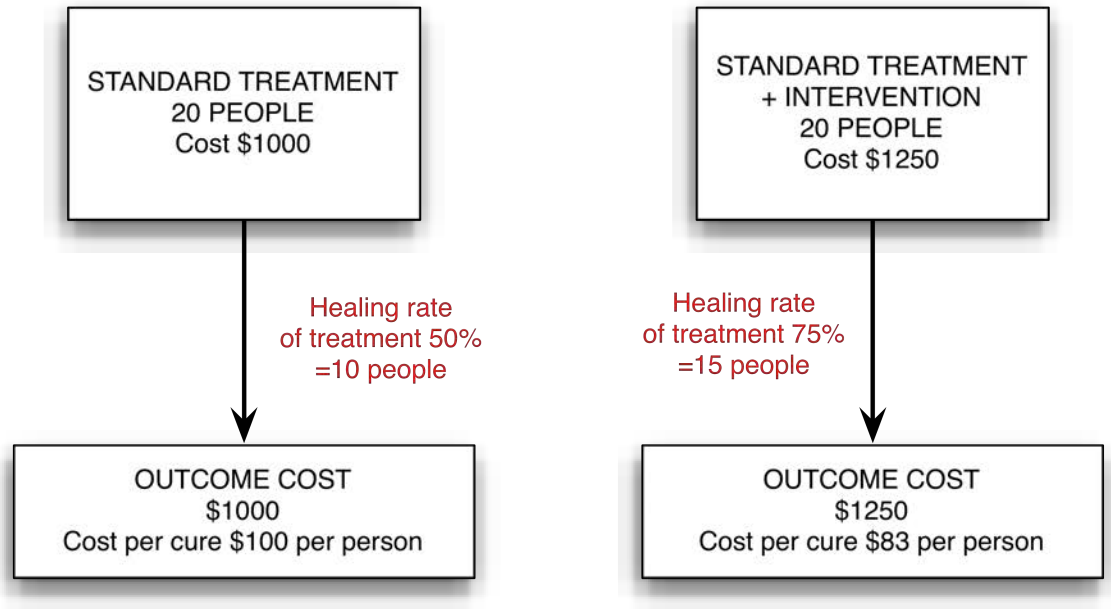
As the Gordon et al (2006) paper is a study of two models of usual care to look at costs effectiveness, the statement on page 87 of the MSAC 1054.1 review that:-

> *"However since there is no common comparator it is not possible to undertake an indirect comparison of the data from Hawkins and Bennett (n.d.) and Gordon et al (2006)"*

-seems illogical as the aetiologies and the reporting dates are identical and they are clearly looking at the two modalities of treatment that we are interested in. It is therefore more appropriate to compare the two papers as benchmarks of best evidence than to make an assumption on a paper that does not cover the results that are used. The model of what has been done and what should have been done is shown in Figure 2.



Predetermined outcome with two treatment modalities



Outcome determined by actual intervention rates

The cost reduction effect is critically dependant on the number of people 'cured' so that the artificial equalisation of the outcomes makes the costs effective exercise pointless. The whole basis of the intervention is to reduce either the duration or severity of care and hence saving money it total. In MSAC 1054.1 the cost effectiveness assessment has managed to get the result that is opposite to clinical reality, and in fact will cost the government an incremental differential increase (cost of using more expensive treatments minus loss of cost benefit savings) in costs in excess of $500,000.00 per annum because of this.

CONCLUSION:

So the end conclusion of the MSAC review is incorrect as public funding for this modality of treatment would provide a cost benefit to the public over 'usual treatment' alone.

POINTS:

• HBOT is a safe treatment modality and is well tolerated by patients

• it is introduced AFTER conventional wound care has **not** had a significant result for three months and the wound has become "chronic"

• the MSAC requested ANZHMG wound care study shows that patients come to HBOT centres after having a wound for an average of 16 months and of those that are non-diabetic venous ulcers (comparable to Gordon *et al* 2004) at six months 68.9% have healed

• a comparator study of wound care alone in a similar group shows that at six months only 50% have healed

• randomised controlled trials are difficult to perform in this setting because of a) the cost and b) ethical considerations of not treating patients in the control group but current best available data shows a probable benefit in the HBOT group

• a properly funded randomised controlled trial (RCT) to determine wound care cost burden vs potential saving should be performed prior to removing funding for potentially a significant cost saving treatment modality.

OTHER ISSUES OF THE REPORT:

1) The initial sentence in page one is not correct: the application was to retain the MBS number for STRI and HBOT for chronic non-diabetic non-healing wounds. At no stage was this a new treatment and new number. The assessment was aimed at determining whether a 'temporary' number imposed after the 2001 assessment was to be made permanent or not. This is outside the scope of the MSAC system as it was then run (there is now a different system in place).

2) Verbal communications from two expert members of the committee stated that they have dissented from the findings reported based on some of the issues outlined here. This fact is not clear, nor their reasons for dissent. This should have been made clear to the Minister of Health prior to the decision to remove funding.

3) There has been no time for external discussion of the document prior to it being listed as a removal of MBS item number in the May 2012 budget. There was no scrutiny of the decision and the report itself was not available until mid April 2012 prior to a May 8th budget release. In fact the Minister of of Health did not even review the MSAC 1054.1 report until 30th April 2012, eight days before the budget.

4) A number of factual errors are present in the report:

> -there are only three monoplace chambers available on the ARTG at the time of the report. The fourth chamber is a large multiplace chamber (Pg 4)
>
> -the costing of routine treatments surgical component uses the costing of complications (Table 40 Pg 94) not the costing of surgery (Table 39, Pg 93) but as it is incorrect for both sides, only the total number is elevated not the differential.

5) This is the third full review all showing increased evidence that the addition of HBOT to a wound care regimen after 3 months of standard care in all likelihood facilitates

i) a cheaper option than ongoing, 'usual wound care' with treatment already extending beyond a year

ii) the costs of the assessments has probably exceeded any saving that would have been gained in the use of HBOT for wounds

iii) other factors of patient satisfaction and lifestyle are also improved by more rapid healing of the wounds and this component is not factored into the MSAC assessment for wound care unlike it was for STRI.

REFERENCES:

Gordon, L., Edwards, H., et al, 2006. 'A cost-effectiveness analysis of two community models of care for patients with venous leg ulcers', *Journal of Wound Care,* 15 (8), 348–353.

Hawkins, G. C. and Bennett, M. n.d.. 'The outcome of chronic wounds following hyperbaric oxygen therapy: a prospective cohort study – the sixth year report.'

Hawkins, G. C., Bennett, M. H., et al, 2006. 'The outcome of chronic wounds following hyperbaric oxygen therapy: a prospective cohort study - the first year interim report', *Diving and Hyperbaric Medicine,* 36 (2), 94–98.