



MINUTES

32nd MEETING 16 November 2005 Canberra

Members Present

Dr Stephen Blamey (Chair)
Professor Brendon Kearney
Professor Syd Bell
Dr Michael Cleary
Dr Paul Craft
Dr Kwun Fong
Dr David Gillespie
Dr David Wood
Dr Debra Graves
Dr Terri Jackson
Dr Ray Kirk
Associate Professor Don Perry-Keene
Dr Ewa Piejko
Professor Ken Thomson
Dr Doug Travis
Dr Mary Turner
Mrs Sheila Rimmer
Ms Samantha Robertson

Apologies

Associate Professor John Atherton
Professor Jane Hall
Associate Professor Frederick Khafagi
Professor John Horvath
Professor Alan Lopez

MSAC Secretariat

Ms Eliza Hazlett
Ms Robyn Bilston
Dr Jane Cook
Ms Brenda Campe
Ms Helen P Brown

1. OPENING OF MEETING

1.1 Welcome and Apologies

The Chair opened the meeting at 8.35am and welcomed everyone.

Apologies were received from Associate Professor John Atherton, Professor Jane Hall, Associate Professor Frederick Khafagi and Professor John Horvath.

The Chair announced the members who have left MSAC since the last meeting;

Dr Michael Kitchener
Professor Jeffrey Robinson
Professor Michael Solomon
Dr Gerry FitzGerald
Professor Alan Lopez – Since his re-appointment Professor Lopez has sent a letter of resignation. A formal letter accepting his resignation will be forwarded to Professor Lopez.

The chair welcomed the new members:

Dr David Gillespie - Gastroenterologist;
Dr David Wood - Orthopaedic Surgeon;

Professor Frederick Khafagi - Nuclear Medicine Physician; and
Dr Mary Turner - AHMAC representative.

1.2 Conflict of interest and Confidentiality

The Chair reminded members of the conflict of interest and confidentiality agreements.

With regard to confidentiality the Chair pointed out that recommendations made at Committee meetings cannot be divulged to members of the public until the Minister has signed off on the recommendations. The Chair advised members that Confidentiality did not mean that members could not seek advice from colleagues in relation to an assessment that they were part of.

The following conflicts or potential conflicts of interest were declared:

- Professor Kearney advised of his potential conflict of interest as Director at the Institute of Medical and Veterinary Science (a provider of pathology services);
- Professor Thomson stated that he would have a potential pecuniary interest and contributed to the application for Uterine Artery Embolisation (Application 1081) and would excuse himself during the committee's discussion;
- Dr Travis advised of his possible conflict of interest as the Vice President of the Victorian Australian Medical Association and mentioned a standing conflict regarding prostate treatment;
- Dr Wood stated that he had previously received a research grant of \$10,000 from a prosthetic knee company, a research grant of \$5,000 five years ago and had also received a grant for MRI tunnel widening – ACL reconstruction;
- Dr Cleary advised that he had a general conflict as he was finalizing a state tender in relation to cardiac stents;
- Dr Blamey advised that he had minimal conflict of interest but is a practicing surgeon; and
- Dr Turner advised that being the AHMAC representative she would be looking at decisions from a public sector perspective, but will take advice as her membership progresses as to whether this is a conflict.

Members were advised the Minutes are made public on the MSAC website.

2. DRAFT REPORT OF THE THIRTY FIRST MSAC MEETING HELD 24 AUGUST 2005

The Minutes from 24 August 2005 were accepted with minor amendments by the Committee.

2.1 Matters arising

- Transurethral Microwave therapy (HE-TUMT) for benign prostatic hypertrophy – the MSAC feedback was provided to the evaluators, the evaluators revisited the economic analysis and provided the revised report to the Secretariat for consideration by the Executive. The Executive considered the revised report at its meeting of the 7 October 2005. The rework resulted in no significant change to the outcomes of the report. The Executive agreed to forward the MSAC recommendation to the Minister for Health and Ageing.
- Application 1080 - Coronary Pressure Wire was presented at the August MSAC meeting,

however discussion was not complete and the application will be re-presented (see Agenda Item 3.1).

- Application 1084 - UAE will be brought back to this meeting after the reworking of the Economic Section of the report (see Agenda Item 3.4).

3. FINAL REPORTS FOR MSAC ENDORSEMENT

3.1 Application 1080 – Coronary Pressure Wire

Professor Thomson a member of the Advisory Panel presented this Application, in the absence of Associate Professor Atherton, the Advisory Panel Chair:

- There is an issue regarding when and how often this procedure will be used. Some patients will be investigated one day and return another day for stenting while others will be investigated and receive treatment on the same day. This will depend on the experience of the surgeon and individual hospital practice;
- Intermediate lesions are not necessarily picked up on stress tests; and
- The best results using Coronary Pressure Wire would be obtained in someone with a single coronary artery lesion in a big vessel with everything else normal.

Dr Fong critiqued this report as follows:

- Some editorial changes were suggested - grammatical and tabulation;
- The heterogenous nature of the studies included in the report should be stated;
- The report indicated that there was no evidence related to the use of Coronary Pressure Wire after stenting;
- There is evidence to support that it is a reasonable test for a particular patient group, but how it changes current practice and future practice is debatable; and
- There are some errors in the economic analysis that require rework.

There was general discussion by the MSAC members and it was agreed that:

- There was no evidence to support that this test would decide if a stent was properly placed or not;
- That the labour costs for coronary pressure wire should be stated as a range from \$100 - \$250. As the economic analysis was based on \$250 there is some rework required to reflect a range from \$100 - \$250;

After consideration the Committee's recommendation was:

1st indication

“On the strength of evidence relating to safety, effectiveness and cost-effectiveness, the MSAC recommends that public funding be supported for the use of coronary pressure wires to determine whether revascularisation should be performed on intermediate lesions identified on coronary angiography, where previous stress testing has either not been performed or the results are inconclusive.”

2nd indication

“On the basis of the limited evidence relating to effectiveness and cost-effectiveness, the MSAC recommends that public funding not be supported for the use of coronary pressure wires to assess the effectiveness of percutaneous coronary interventions.”

If the reworked economic analysis makes a substantial difference to the conclusions of the report then the report will come back to this Committee to be reconsidered. If they don't make a lot of difference the Executive will sign off on the recommendation as it stands.

Action:

- **Points raised by Dr Fong (critiquer) to be forwarded to the evaluators for incorporation in the report;**
- **Rework the economics/sensitivity analysis to reflect a range of labour costs between \$100 to \$250; and**
- **Forward the above recommendations to the Minister for Health and Ageing if reworking of the economic analysis does not impact on the cost-effectiveness.**

3.2 Application 1090 – Artificial Intervertebral Disc Replacement

Professor Thomson, Advisory Panel Chair, opened the discussion on this assessment:

- The artificial disc is designed to alleviate pain associated with disc problems. This procedure replaces the disc. The alternatives are (a) do nothing at all or, (b) fuse the disc space, this fuses two vertebral bodies together;
- Fusing the back at one level creates mechanical stress on the levels above and below the fusion; this may lead to accelerated degeneration at these levels
- The artificial disc is designed to provide a better (than fusion) or normal range of motion at the level of placement and so reduce the adjacent associated disc degeneration above or below it. It is also designed to reconstitute the disc height to that of a normal disc and to optimise spinal alignment;
- The artificial disc is that they are implanted from the front of the patient. This is not a problem in the neck region, but for the lumbar spine region access for the operation is more difficult;
- The assessment was based on 2 randomised control trial's (RCT). One of the RCTs (Charite) was based on 304 patients over 14 centres with 24 months follow up. 99 patients in the control group had a fusion and this was compared with 205 who had an artificial disc. Most of the data in the assessment in terms of efficacy, safety and long term follow up is from this study. The final Charite paper was not available for this report however the data obtained from study report abstracts has been included. This was. The long term data from the final paper is the only data not presented in the report and this is indicated in the report;
- The procedure is relatively safe when performed by well trained people;
- In the short term it appears to be as effective as spinal fusion in reducing pain;
- The Applicant disagreed with the costing analysis, claiming that patients that have a fusion also have bone mineral protein (BMP), a material injected into the site around a bony fusion to increase effectiveness of the fusion. Including the cost of BMP could make a significant difference in the costing analysis;

- The Advisory Panel considered that BMP is not yet generally used in spinal fusion for the indications being considered and hence it was not included in the cost analysis. The Advisory Panel held another teleconference to discuss issues raised by the applicant. Surgeons on the panel advised that it was not their experience or practice to use BMP; and
- The Advisory Panel considered that the infection rates for AIDR were under reported.

A brief history was provided on the claiming of this procedure under current MBS items. It was noted that MBS fusion and internal fixation items had been used to claim for this procedure as a result of incorrect advice was provided from the HIC in 1999. The Department, as an interim measure because written advice had been provided, had advised professional bodies and craft groups that currently trained practitioners could use four Medical Benefits Schedule items while the technology was being assessed by MSAC.

The Committee noted that:

- If BMP was used only in 25% of fusion cases that there would be a significant change to the economic analysis. It was suggested that further opinion be sought from the Spine Society;
- The Advisory Panel suggested that the economic analysis would be correct because the report did not look at people with osteoporosis with multi level disease where BMP is mainly used, but rather at younger people with single level disease;
- The evidence seemed to suggest that BMP usage was uncommon. It was noted that if the evaluation was to be redone to look at spinal fusion with or without BMP then the literature search would also be redone. The comparator would change to fusion with BMP rather than fusion alone;
- In the lumbar spine, on the basis of the data, there was no statistically significant difference between fusion and the artificial disc in terms of safety or effectiveness; and in a patient who had a single level lesion there may be less chance of associated segment disease;
- In the cervical spine there is insufficient data to demonstrate superior effectiveness or even the same effectiveness; and
- Based on the selection criteria for the studies – being for single level lumbar disease, where disc disease was the predominant cause of the symptoms and there was clear evidence that disc disease was the major cause of the symptoms the Committee suggested that the recommendation should be along the lines of the Blumenthal study- for patients with single level disease where there would be an expectation that the patient could return to normal activity. An age cut off may also be required.

Dr Craft critiqued this report and further to the Committee's comments provided the following:

- The effectiveness section of the Executive Summary requires rework; and
- Consideration should be given to deleting reference to the second comparator – non-operative treatment. No data are presented on this question as no data could be found. The procedure or strategy most likely to be replaced by the new technology is spinal fusion.

It was suggested that the Department contact Private Health Insurance funds in an attempt to ascertain the actual utilisation of BMP with spinal fusion. However it was also pointed out that this may be problematic as the data will also include BMP used for non-fusion of long bones.

It was agreed to obtain information regarding the status and indications for BMP from the TGA.

The clinical trials in the report suggest that for a young patient with single level disease in the lumbar spine artificial disc is probably a better alternative to fusion. It was estimated that on this basis only 5% of average lumbar fusion patients would qualify for AIDR.

The MSAC recommendation would include the exclusion criteria from the trials as the technology is not proven in these patient groups. These exclusions could be incorporated into the item description for the MBS.

The Committee agreed that credentialing and qualifications of practitioners doing this procedure were required. It was suggested that the Spine Society be approached for comment on the use of BMP in spinal fusion and if they have any interest in the credentialing of practitioners for this procedure.

It was the decision of the Committee to revisit this report at the Feb/March 2006 meeting depending on the outcome of the inquiries into BMP.

Action:

- **Obtain input from the Spine Society on the use of BMP with spinal fusion and comments on credentialing surgeons for this procedure;**
- **Approach health funds for data on the use of BMP for spinal fusion;**
- **Check TGA status and indications for BMP; and**
- **Rework the effectiveness section and the executive summary.**

3.3 Application 1084 – UroVysion Fluorescence in-situ Hybridization (FISH) assay.

Dr Travis, Advisory Panel Chair, opened the discussion on this assessment:

- This test identifies chromosomal abnormalities. It is a quantitative measure, with a lot of argument about what constitutes a positive and a negative outcome. The test is conducted on free voided urine and detects a problem that practitioners do not and cannot treat;
- The test may detect a genetic disease that is in a pre-clinical state;
- The test is not a physical localizing test, it doesn't tell you where in the bladder the problem is located;
- In terms of the results, there are 7 relatively small studies with heterogeneous populations;
- The test is safe;
- Is it effective – the sensitivity of the test ranges between 48-85% and the specificity is between 34-100%;
- It was difficult to determine where the test sat in the clinical pathway. The test is being proposed for a sub group of patients who have had proven superficial transitional cell carcinoma and are being followed up in a surveillance program. Generally these patients are followed up with cystoscopy, either under general anaesthetic or local anaesthetic. The cystoscopy is necessary for treatment;

- The patient has a choice between general anaesthetic and local anaesthetic. What informs that choice is high risk or low risk patients, keeping in mind there are multiple criteria for defining these groups. The benefit of flexible cystoscopy is that the patient does not have to fast, they walk in, they drive home, there is no sedation, it has a similar impact to having a urethral catheter passed and patients much prefer this option. However if changes requiring treatment are found at flexible cystoscopy it is most likely they will need to come back on another day, on another list and have a general anaesthetic to have treatment;
- The Applicant did not propose a clinical pathway to define the role of the test. The advisory panel suggested that there were 3 possibly appropriate roles for the test - substitution, addition or use as a risk discriminator:
 - Substitution – not possible as the sensitivity is not good enough;
 - Addition – it was felt that both a cystoscopy and a “FISH” would not be done as the FISH is expensive and could not identify the position of the lesion; and
 - Risk discriminator – this was seen as the appropriate place for this test in a clinical pathway.
- If a patient had a positive FISH they went straight to general anaesthetic cystoscopy. If they were FISH negative they still had the flexible cystoscopy. This is the pathway that was used in the economic analysis to look at all of the relative figures of the sensitivities of the false negatives and the false positives and the costs involved in running those two pathways;
- Cytology was not considered a comparator due to the lack of sensitivity and that in general clinical practice it is not widely used for follow-up; and
- The economic analysis found that there was increased cost in identifying first recurrence using FISH.

Professor Bell critiqued this report as follows:

- The report was highly professional, detailed and very easily read;
- It was noted that the application was for FISH to be used as an incremental test in the follow up of transition carcinoma of the bladder rather than a replacement test;
- The report adheres closely to the template contained in MSAC’s guidelines for the assessment of diagnostic technologies;
- The report analysed the evidence well, the research question was answered and the conclusion was reasonable;
- It was suggested that the Background section of the report include- “this is a complex test that will need to be done in selected accredited laboratories and that this is a pathology test that needs to be done by a pathologist”. Going to a pathologist will impact on the cost; and
- The costing of the test – it was suggested that the true cost of this test is higher than that contained in the sensitivity analysis. The price of this test at the Cleveland Laboratory is \$425US, which is considerably more than the reports figures.

The committee discussed the findings of the report and put forward the following recommendation:

“MSAC recommended that on the strength of evidence pertaining to UroVysion fluorescence in situ hybridisation (FISH) assay public funding should not be supported for

this procedure.

The clinical usefulness of the test is limited by the sensitivity and expense of the test and the cost effectiveness was not demonstrated.”

Vote taken - unanimous.

Action:

- **Points raised by Professor Bell (critiquer) to be forwarded to the evaluators for incorporation in the report; and**
- **To put forward the above recommendation to the Minister for Health and Ageing.**

3.4 Application 1081 – Uterine Artery Embolisation

Note:

1. Professor Thomson left the room during this discussion;
2. This report was presented at the August 2005 MSAC meeting; and
3. This report has been reworked since the last MSAC meeting held in August 2005.

Dr Kirk, Advisory Panel Chair, opened the discussion on this assessment.

- Essentially UAE is an intervention for the treatment of symptomatic uterine fibroids. It is an embolic procedure involving the injection of embolic particles into the uterine artery to occlude the artery to result in ischemic necrosis. The comparators include hysterectomy (the surgical removal of the uterus using abdominal, laparoscopic or vaginal access) and myomectomy (surgical removal of fibroids);
- There was some uncertainty around incidence and prevalence of symptomatic uterine fibroids but there seems to be some clinical need for the intervention;
- UAE seemed to be safer than hysterectomy and, based on reasonably limited evidence it may be as safe as myomectomy;
- There was limited data on which the review was based;
- Hysterectomy is more effective than UAE although there are complications and adverse events that are related to hysterectomy that are not found with UAE. UAE was deemed to be as or more effective than abdominal myomectomy;
- Given the findings for effectiveness; it was decided to undertake a cost minimisation approach. Following the discussion at the last meeting, the costing has been revised and reviewed and the comments that were made at the last meeting have been incorporated into the analysis;
- The Advisory Panel felt that:
 - clinical need has been established for UAE in relation to patients with symptomatic uterine fibroids;
 - UAE is clearly as safe or safer than abdominal hysterectomy. On the basis of limited evidence UAE appears to be as safe as or safer than abdominal myomectomy;
 - UAE appears to be less effective in terms of controlling symptoms associated with uterine fibroids compared to hysterectomy but

that needs to be placed in the context of a patient preference for an intact uterus. Consideration needs to be given to the patients who wish to keep an intact uterus and the patients wish to possibly remain fertile; and

- compared to abdominal myomectomy UAE appears to be as effective as or more effective than abdominal myomectomy but again this is based on rather limited data.
- In summary the Advisory Panel found that 2 of MSAC's conditions were met – Clinical need and safety. The 3rd condition of effectiveness was not met with the comparison of hysterectomy, but was possibly met with the comparison for myomectomy. The fourth condition of cost effectiveness for the procedure was not examined in the economic analysis due to lack of demonstrated effectiveness and comparative data; and
- The Advisory Panel felt there was insufficient evidence on UAE's clinical effectiveness and cost effectiveness in regard to uterine fibroids to warrant unrestricted MBS funding. However the evidence suggests that UAE is as safe and potentially clinically effective and potentially cost effective for the treatment of uterine fibroids and on this basis interim funding may be appropriate with a view of further data collection.

Dr Piejko critiqued this report as follows:

- There are some issues regarding the economic analysis. The utilisation of some tests seemed to vary unnecessarily between the different procedures. Minor amendments relating to Hb, MRI and Doppler utilisation were suggested; and
- In comparing UAE to abdominal hysterectomy the report shows that it is safer and recovery is quicker. Comparing with myomectomy is very difficult as myomectomy results could not be extracted.

The Committee suggested that:

- One of the gains for this technology is the shorter recovery after UAE and this should be reflected in the background;
- It was noted that uterine fibroids is not an approved indication for MRI; and
- It was suggested that the financial implications for the Commonwealth – needs clarification and rewriting with a line that says that the total cost to the health care system is less but the cost to the MBS is greater.

The Committee discussed the findings of the report and put forward the following recommendation:

“The evidence suggests that UAE is safe, clinically effective and potentially cost-effective for the treatment of symptomatic uterine fibroids. It appears more effective than myomectomy for the control of menorrhagia and pain but less effective in controlling pressure symptoms.

It is safer but less effective in controlling symptoms compared with hysterectomy.

MSAC recommends that UAE be funded on an interim basis for the treatment of women with symptomatic uterine fibroids with a review within 5 years. MSAC recommends that patients be referred by a specialist gynaecologist”

Supported with data collection to occur.

Vote taken – members agreed to the above recommendation with two abstentions.

Action:

- **The Evaluators to revisit the economic analysis to better reflect the costs of consultations, ultrasound imaging, MRI and FBE tests. The revised report to be provided to the Secretariat for consideration by the Executive; and**
- **The Committee agreed to forward the above recommendation to the Minister for Health and Ageing once the Executive had considered the reworked economic analysis.**

4. PROGRESS REPORTS ON APPLICATIONS AND REFERENCES

No issues were raised concerning current applications and references.

The Committee was advised that panels would be formed in due course to consider the following applications:

Application/ Reference	Date received	Chair	2nd MSAC member	Evaluator
App 1098 – Breast MRI	11 Jul 05	Dr Craft	Dr Graves	CTC
App 1099 – Non-fusion stabilization	19 Jul 05	Prof Thomson	Dr Wood	Adelaide
App 1100 - Injectable Silicone Biomaterial for severe passive faecal incontinence	31 Aug 05	Dr Travis	Dr Piejko	ASERNIP-S
App 1101 - Repetitive Transcranial Magnetic Stimulation	19 Aug 05	Dr Fong	Dr Turner	ASERNIP-S
App 1102 - Double Balloon Electronic Endoscopy System	6 Sept 05	Prof Perry-Keene	Dr Blamey, Dr Gillespie	Adelaide
App 1103 – Preterm Labour Test for Fetal Fibronectin	19 Oct 05	Dr Piejko	Prof Bell	M-TAG

5. OTHER ISSUES

5.1 Horizon Scanning

- TGA will not notify us of new listings they are considering due to commercial in confidence issues.
- Input to Euroscan is significant and will be ongoing.
- Horizon Scanning Website is up and running and is currently being reviewed.
- RSS capability – Medline. Dr Fong to email details to the horizon scanning secretariat.

5.2 MSAC Review

- Ms Bilston advised that we will be providing a quarterly report on the website as an update to the progress of the recommendations.
- Two volunteers were asked for to be on the sub-committee to assist in the implementation of the review - Dr Graves and Dr Gillespie will be on the sub-committee.
- One of the main items to be addressed will be a streamline assessment process for “quick reports”.

5.3 HTAi Conference in Adelaide 2006

Professor Kearney spoke to this item:

- Planning is well underway and that at this stage there will be 3 plenary sessions and numerous parallel panel sessions;
- A leaflet was disseminated asking for presenters; and
- A newsletter will be available in December.

5.4 Nationally Funded Centres

A sub-committee has been established to manage these reviews consisting of Professor Kearney, Dr Travis, Dr Blamey, and Dr Turner.

5.5 MSAC Economic Guidelines – Update

Dr Kirk, Dr Craft and Dr Jackson spoke to this item.

Dr Kirk advised that the Economics Working Party is close to a final draft and it should be ready to present to the March 2006 MSAC. Consultation with the MSAC evaluators is planned for December.

A substantive change is that a societal perspective is to be undertaken. This is an important issue to discuss.

Challenges:

1. Societal perspective
2. Multiple levels of reporting
3. Sub population data for economic analysis

Consideration must be given to the increased complexity that the societal perspective brings to the economic analysis of MSAC assessments.

The difficulty of predicting patient co-payments was raised. It was noted that health benefits/costs were difficult to obtain and it will be even more difficult to obtain societal costs.

There was some discussion on the impact that incorporation of societal costs would have on the MSAC evaluators.

Action:

- **The Economic Working Group to reconsider the Economic Guidelines taking into account members’ comments.**

5.6 MSAC Meeting Dates for 2006

The following were proposed as meeting dates and locations for MSAC meetings for 2006.

Date	Location
28 February and 1 March 2006	Melbourne
17 May 2006	Sydney
23 August 2006	Brisbane
15 November 2006	Canberra

6. CLOSE

The next MSAC meeting is scheduled for 28 February and 1 March 2006 in Melbourne.