

MINUTES

34th MEETING 17 May 2006 Sydney

Members Present

Dr Stephen Blamey (Chair)
Professor Brendon Kearney
Professor Syd Bell
Dr Paul Craft
Dr Kwun Fong
Dr David Wood
Dr Debra Graves
Dr Terri Jackson
Dr Ray Kirk
Associate Professor Donald Perry-Keene
Mrs Sheila Rimmer
Associate Professor John Atherton
Associate Professor Frederick Khafagi
Ms Samantha Robertson
Dr Doug Travis
Dr Mary Turner

Dr David Gillespie

Apologies

Professor John Horvath
Professor Ken Thomson
Dr Jane Hall
Dr Michael Cleary
Dr Ewa Piejko

MSAC Secretariat

Dr Jane Cook
Ms Eliza Hazlett
Mr Bill Matthews
Mr Damian Wilkie

1. OPENING OF MEETING

1.1 Welcome and Apologies

The Chair opened the meeting at 9.30 am and welcomed everyone. He introduced Mark from Auscript and indicated Mark would be recording the meeting to assist the Secretariat in writing the minutes. He welcomed the Communications Officer, Mr Damian Wilkie and the new Secretary, Mr Bill Matthews and noted apologies from Professor Horvath, Dr Jane Hall, Professor Thomson, Dr Piejko and Dr Cleary.

1.2 Conflict of interest and Confidentiality

The following conflicts or potential conflicts of interest were declared:

- Dr Travis – performs radical prostatectomies and does not have the Da Vinci device to perform Laparoscopic Remotely Assisted Radical Prostatectomy. His views are well known and maybe seen as prejudicial.

2. DRAFT MINUTES OF THE THIRTY THIRD MSAC MEETING HELD ON 28 FEBRUARY/1 MARCH 2006

The Minutes from 28 February/1 March were accepted with the following amendments (minor typing and grammatical errors were noted for correction).

Dr Wood sought to clarify the exclusion of patients with fusion in the AIDR review indicating that he felt this was unnecessary as the procedure would not be performed in such patients. His understanding of the agreed AIDR recommendation, page 12 of the minutes, was that the exclusion of patients with “prior fusion” should be omitted from the recommendation.

ACTION:

- 1. Secretariat to check review regarding AIDR. If excluding “prior fusion” is compatible with the content of the report and then advise the Executive if the removal of “prior fusion” would be consistent with the report findings.**
- 2. The minutes are to be amended to correct typing and grammatical errors.**

2.1 Matters arising from the previous minutes

Paper on how the MBS deals with capital costs

Held over until the 35th meeting (Action Officer – Dr Jane Cook).

Application 1072 – Endoscopic Ultrasound for Staging Pancreatic, Oesophageal, Gastric and Hepatobiliary Neoplasms

Probabilistic sensitivity analysis progressing.

Application 1079 – Peripheral Arterial Tonometry with Ascending Aortic Waveform Analysis using the SphygmoCor System

The issues about brachial pressure and the inclusion/exclusion of patients with renal failure and diabetes were clarified in the report. The minute to the Minister is being finalised.

Application 1085 – Carbon Labelled Urea Breath Test

The minute to the Minister is being finalised.

Application 1095 – Computed Tomography Colonography

A discussion about the wording of the recommendation for CTC took place at the executive teleconference on 28 April. The new wording follows.

Computed Tomography Colonography (CTC) is a relatively safe procedure. CTC double contrast barium enema (DCBE) and colonoscopy are associated with a small risk of complications.

Evidence in relation to the comparison of CTC with colonoscopy indicates that CTC is less effective. MSAC recommends that public funding for CTC as a substitute investigation for colonoscopy should not be supported.

On the basis of the strength of evidence pertaining to the effectiveness and cost effectiveness, MSAC recommends that public funding for CTC for exclusion of colorectal neoplasia in symptomatic or high risk patients who are either ineligible for colonoscopy due to patient contraindications, or where there is an inability to perform or complete a colonoscopy, should be supported.

The economic analysis is being revisited, this is progressing.

Reference 32 – Implantable Cardioverter Defibrillators for Chronic heart Failure

The minute to the Minister is being finalised.

Reference 33 – Treatment of Cerebral Aneurysms

The minute to the Minister is being finalised.

Reference 34 – Gamma Knife Stereotactic Radiosurgery

The recommendation is with the Minister for consideration.

Artificial Invertebral Disc Replacement

In addition to the possible amendment to the minutes at agenda item 2, it has been clarified that the DRG did include the cost of the prosthesis.

Application 1105 – Computed Tomography Coronary Angiogram

Doctor Blamey noted that the advisory panel has been set up for Application 1105 CT coronary angiogram.

Other business

Before proceeding to Agenda Item 3, at the Chair's initiation, the Committee had a wide ranging discussion about issues that influence MSAC's consideration of evidence, and the benchmarks used when suggesting funding may be withdrawn from a public funded procedure.

In relation to issues that influence consideration of the evidence the following points were raised:

- Patient access - geographic access, and private access versus public access;
- Medicare versus other sources of funding;
- Pressure on the public hospitals to provide services once they are publicly funded under Medicare;
- Relevance of the procedure in the Australian clinical setting;
- Financial impact – total cost versus cost-effectiveness;
- Prevalence or rarity of the condition; and
- The impact on the prostheses schedule.

In relation to the withdrawal of public funding the following points were raised:

- Withdrawing a service that is already funded would require evidence that the procedure was either unsafe, or not effective (particularly where there are other procedures/technologies that are more effective) or well outside the acceptable level for cost effectiveness.

The Chair also suggested that in line with the actions arising from the MSAC Review the Committee should attempt to adopt a more consistent structure for MSAC recommendations. Dr Blamey outlined a proposed structure and it was agreed the Committee would attempt to use this approach when developing future recommendations.

Discussion ensued on whether economic analysis was a more appropriate term to use than cost effectiveness as MSAC usually does a cost-utility or a cost minimisation analysis. Dr Jackson commented that the Americans use the term "cost-effectiveness" to cover both cost-effectiveness (medical endpoints) and cost-utility (including both quality of life endpoints and patient-valuation of endpoints) studies.

It was also agreed that either in the recommendation or in the summary, the report should be explicit about the population group in which the intervention was assessed. Dr Cook noted that this will assist the Department's implementation process.

3. FINAL REPORTS FOR MSAC ENDORSEMENT

Members were provided with a list of conflicts of interest declared by the Advisory Panels for each of the final reports to be considered.

Advisory Panel Chairs were asked to advise of any additional conflicts when they presented their reports.

3.1 Application 1087 – B-type Natriuretic Peptide

B-type Natriuretic Peptide was discussed at this meeting and is currently under consideration by MSAC.

3.2 – Application 1091 – Laparoscopic Remotely Assisted Radical Prostatectomy (LRARP)

After discussion with Dr Blamey, Dr Travis removed himself from this discussion due to a possible perceived conflict of interest.

Dr Blamey later noted that there were a number of conflicts of interest on the LRARP advisory panel. There were three urologists on the panel; Dr Patel who has gained experience with Da Vinci overseas; Dr Peters who currently uses it at the Epworth in Victoria; and Dr Travis who performs radical prostatectomy but does not use the Da Vinci device. The Consumer representative was Mr Keith Williams who had already undergone prostatectomy but did not specify if it was using the Da Vinci device.

Dr Craft as Chairman of the Advisory Panel opened the discussion on this report and made the following points:

- The technology is for localised prostate cancer, aims at curing the tumour and allows the surgeon greater flexibility in operative movements when compared with the direct laparoscopic method.
- The comparator for the assessment was the open radical prostatectomy which is the procedure that is most likely to be replaced. While there is a lack of randomised data it appears that the procedure does have an acceptable safety when compared with open radical prostatectomy. There was reasonable evidence from prospective case series that recovery from the operation was good and that major complications were rare.
- In terms of effectiveness, the data is limited and this impacted on the economic analysis. The economic evaluation compared the cost of LRARP to the cost of the open prostatectomy. There are increased capital costs associated with the robotically assisted procedure. The cost is greater than for the open procedure, although there is some debate regarding the need for skilled assistant surgeon to be in attendance. The procedure does lead to shorter bed stays, earlier return to work and fewer blood transfusions.
- Dr Craft suggested the dilemma is that it does seem to be an effective and safe procedure but there is a cost attached and it is very difficult to see, because of the lack of evidence, the

health benefits the patient derives from that additional cost.

Associate Professor Perry–Keene then provided a critique of the report making the following points:

- The draft report flowed logically. Open radical prostatectomy is the correct comparator. There is a clinical need and, as long as it is restricted to patients with confirmed localised prostatic cancer, it appears to be as safe and as effective as open radical prostatectomy.
- There is a learning curve for acquiring expertise and therefore there maybe a need for credentialing. In discussion later, the view of the Committee was that this would be best handled by the Colleges.
- The procedure costs more than the comparator and the bulk of the costs are in the consumables for each operation.
- LRARP is probably safer than open radical prostatectomy. It is as effective, it has some utility value above and beyond the standard operation but it comes at a high cost. It is not so much the cost to Medicare but the cost implications for private health insurers, hospitals and perhaps indirectly to the State jurisdictions when pressure comes on those jurisdictions to provide this service.
- In his view on the basis of safety and effectiveness it would not be appropriate to prevent people from being able to perform the procedure, but there are sufficient uncertainties about the cost effectiveness to recommend additional funding.

Dr Blamey asked for comments from the Committee.

- Dr Jackson noted that there is a Medicare number that providers can use and that insurers could choose to cover this procedure with the higher theatre band. Dr Cook indicated the applicant's aims in applying for an MSAC assessment is to get the consumables paid for, the higher theatre band and the payment for a second surgeon.
- The Committee noted the Department's view that a recommendation that allowed existing items to be used for this procedure would lead to pressure on theatre banding costs.
- The Committee suggested public funding should not be supported for it as a separate entity.

The Committee agreed the following recommendation for LRARP.

The MSAC has considered the safety, effectiveness and cost-effectiveness of laparoscopic remotely assisted radical prostatectomy (LRARP) compared with open radical prostatectomy. This procedure is being utilised under current funding arrangements in the public and private sectors in Australia. MSAC finds the procedure is at least as safe as and possibly safer than open radical prostatectomy. The procedure is likely to be as effective and may have some advantages over open radical prostatectomy. At present there is uncertainty about the comparative cost effectiveness. MSAC recommends that current funding arrangements for LRARP remain unchanged.

ACTION

The above recommendation to be forwarded to the Minister for his consideration.

3.3 Application 1092 – Deep Brain Stimulation

Dr Blamey asked the Chairman of the Advisory Panel for Deep Brain Stimulation (DBS), Professor Kearney to open the discussion.

Professor Kearney began by reminding the Committee that this is a review of a 2001 report where interim funding was recommended while data was collected. He made the following points:

- He noted that when MSAC recommended interim funding of DBS almost instantaneously neurosurgeons stopped performing ablative neurosurgery and that the neurosurgeons and neurologists who perform DBS are now more adept. At the present time DBS is only provided in the private sector.
- The original report compared DBS with ablative neurosurgery, but as this is no longer practised, the comparator on this occasion was optimal medical therapy.
- DBS can be associated with stroke, haemorrhage and haematoma and the incidence of those complications is documented in the report, in that sense it is no less safe than ablative surgery and probably safer than ablative surgery, however the report does not make a comparison with optimal medical therapy.
- The procedure has been associated with a number of complications particularly confusion and there are battery and lead problems associated with the implantation of the electrodes and the battery.
- Effectiveness has mainly been measured by the Unified Parkinson Disease Rating Scale (UPDRS) score and whilst there are no randomised control trials in this area the studies internationally do suggest that there are significant reductions in the UPDRS score as a result of this treatment. The four Australian centres have all either presented or published their cases and appear to report a similar improvement in their results.
- A complex cost effectiveness analysis was undertaken to estimate the cost for a one-unit reduction in UPDRS score, which is about \$1000 per UPDRS point and which the Advisory Panel had felt was a reasonable outcome.
- Noted that the procedure is not provided in the public health system.

Dr Blamey asked Dr Kirk to critique the report. Dr Kirk began by saying it was overall a well-written report and then raised the following points:

- Noted that interim funding had been previously provided on the basis of data collection to gain evidence on effectiveness, however the data was not collected.
- Dr Kirk then mentioned a series of editorials regarding the report including data that could be presented in a more meaningful way (handed to the Secretariat).
- Safety was primarily based on case series data and was limited with a lack of long term safety information. It was not possible to compare safety between DBS and the comparator. The expert opinion of the panel suggested that deep brain stimulation was no less safe and probably safer than brain surgery.

- Again, the effectiveness was based on limited data.
- The clinical impact, given the lack of effective alternatives, and considered on a “rule of rescue” basis, is reasonably strong, probably substantial in the sense that it is likely to have a positive effect.

Dr Blamey thanked Dr Kirk. He then commented that a conflict of interest was declared on the Advisory Panel by Mr Raymond Cook who had used the procedure in his clinical practice.

Dr Blamey asked for comments from the Committee:

- Associate Professor Khafagi advised that on page 21 of the report there is a reference to the Itrel device, which is no longer available in Australia, and that it should be deleted. In the last paragraph on the same page there is a list of side effects of pallidal deep brain stimulation, however according to table 7 of the report pallidal deep brain stimulation is specifically excluded from consideration in this report.
- The Committee noted that it had been difficult to get research funding tied to MSAC recommendations and the right conditions to collect data in the Australian setting.
- There is a randomised control trial of DBS to be released in 2008 and the committee agreed that DBS should be publicly funded at this time without the data collection, pending the outcome of ongoing research.
- It was agreed that registration for the Australian data collection could cease.

The Committee agreed the following recommendation for DBS.

MSAC has considered the safety, effectiveness and cost effectiveness of deep brain stimulation for refractory severe Parkinson’s disease compared with optimal medical therapy. MSAC finds that there is sufficient evidence of safety and effectiveness, and that robust information on cost effectiveness is unlikely to emerge but the total cost is acceptable for patients in whom other therapies are insufficient.

MSAC recommends that public funding be provided for patients with Parkinson's disease where their response to optimal medical therapy is not sustained and is accompanied by unacceptable motor fluctuations.

ACTION

- 1. The above recommendation to be forwarded to the Minister for his consideration.**
- 2. Include the previous report as an appendix.**
- 3. Revisions to the report provided by the critique to be made by the project officer.**

Application 1093 – Endovascular Neurointerventional Procedures

Dr Blamey asked Dr Terri Jackson, in the absence of Dr Piejko, the Advisory Panel Chair, to report on Endovascular Neurointerventional Procedures.

Dr Jackson conveyed Dr Piejko's apologies then made the following points:

- Dr Jackson noted the Panel reviewed five separate indications and indicated that Dr Piejko would like the Committee to consider whether there is a sensible way of presenting multiple indications in the report.
- There is limited evidence for any of the indications. The first indication is on arteriovenous malformations. The volume of these procedures is declining, they are relatively rare, there is only very limited data and certainly no data for a cluster analysis. The draft recommendation is that it not be supported for these indications
- The Committee noted that most of the drugs are not listed on the TGA, and that the issue of off-label use has complicated the assessment.

The Committee considered written notes prepared by Dr Piejko. Dr Blamey then asked Associate Professor Khafagi to critique the report.

Associate Professor Khafagi began by commenting on the layout of the report suggesting that the report should consist of five mini reports one for each indication with one introduction. The clinical pathway diagrams should be made more readable by changing them to landscape format. He made the following further points:

- The body of evidence is limited because the procedures are emerging and either the conditions are uncommon or are uncommon indications within common conditions.
- The decision to eliminate drugs (or indications) and devices that were not TGA approved was a complicating factor. He noted that this was not applied consistently across all the procedures. He added there should be consistency as to whether we include or exclude TGA approved items and eliminating non TGA approved items would make the evaluable base of evidence even smaller.
- He noted there were a number of typographical errors in the report, which are noted in his critique. The secretariat to forward to the evaluators.
- For dural arteriovenous fistulae, carotid-cavernous fistulae and intracranial atherosclerosis success and failure were not defined in the clinical decision trees.
- For subarachnoid haemorrhage and vasospasm after subarachnoid haemorrhage he questioned the inclusion of non-TGA approved items and the relevance of the studies to Australian clinical practice.
- For intracranial atherosclerosis he noted a problem with Table 52 of the report and papers that referred to the TIMI Scale, which has been devised for coronary intervention.
- In summary, he thought the presentation of the report could be improved and some

consistency should be applied to consideration of TGA approved versus non TGA approved items.

Dr Blamey asked Dr Jackson if she had anything further to add. Dr Jackson added that these are very rare conditions and the limited evidence was at best experimental.

Dr Blamey noted that the applicant RANZCR indicated satisfaction with the report when asked for comment.

Dr Blamey asked for comment from the Committee:

- In summary the comments were that these were the only procedures available to the patient groups, as a last resort and as they are referred services this would likely control over-use.
- The Committee suggested that a case could be made for public funding of the first two indications (endovascular embolisation of brain arteriovenous malformations and dural fistulae and carotid–cavernous fistulae) as they offer the only treatment options, or that they offer an important adjunct which allows the patient to go on to a more definitive treatment.
- Dr Cook noted that there is an MBS item to administer agents that occlude artery, vein or arteriovenous fistulae.

MSAC agreed to the following recommendation for Endovascular Neurointerventional Procedures:

MSAC has considered the respective evidence for safety, effectiveness and cost effectiveness for endovascular embolisation of brain arteriovenous malformations and dural fistulae and carotid–cavernous fistulae. MSAC finds that there is evidence of safety compared with alternative therapies. There is insufficient evidence to assess effectiveness and cost effectiveness. Given that there are limited treatment options MSAC recommends that current public funding arrangements should continue.

MSAC has considered the strength of evidence for the safety and effectiveness for endovascular treatments for vasospasm as a complication of subarachnoid haemorrhage, intracranial atherosclerosis and intracranial arteries in acute stroke. MSAC finds that there is insufficient evidence of safety and effectiveness. MSAC recommends that public funding for these interventions should not be supported.

ACTION

- 1. The above recommendation to be forwarded to the Minister for his consideration.**
- 2. The report layout - numerous edits suggested by the critiquer passed on to the secretariat.**

The Secretariat has agreed to email the relevant peak bodies and the Committee once the Minister has signed off on recommendations.

4. PROGRESS REPORTS ON APPLICATIONS AND REFERENCES

Dr Blamey asked the Committee members to raise any issues with current Advisory Panel processes.

- Dr Wood advised that the draft evaluation protocol had changed substantially following the first Advisory Panel meeting for the non-fusion stabilisation devices.
- Professor Perry-Keene indicated that the double balloon endoscopy Advisory Panel had its first panel meeting in early May and the evaluation protocol is about to be finalised. He said that Dr Warwick Selby should be on the Advisory Panel. Secretariat to action.
- Dr Blamey noted that the digital mammography reference was received on 28 April 2006. Dr Cook indicated that the applicant is the Screening Section of the Department and the Department is seeking advice from the Diagnostic and Technology Section if it should include a review of its use as a diagnostic tool. Dr Cook suggested we could use the same Advisory Panel as for Breast MRI, as this is almost completed. Dr Craft, the Chair for Breast MRI, agreed to approach the panel to take on this review.

5. OTHER ISSUES

5.1 MSAC Review

Dr Blamey indicated that a late paper was circulated on the establishment of an advisory panel register in addition to a summary of the progress of the MSAC review. He asked Ms Hazlett to speak to this agenda item.

Firstly, Ms Hazlett informed the Committee that the Secretariat is in the process of establishing a register of possible advisory panel nominations across the medical specialties. This may increase the efficiency of the establishment process, as obtaining nominations each time a new application arrives has resulted in significant delays.

Secondly, Ms Hazlett talked more generally of the review, indicating that most action items are progressing and that Mr Wilkie would talk on some aspects of the Communication Strategy at a later agenda item, with communications being one of the key elements of the Review.

Thirdly, Ms Hazlett noted that the recommendation of the review about target benchmarks being developed for time taken at each stage in the MSAC process is progressing. The Secretariat has developed a series of timeframes for each stage, which will be on the website. The Committee considered the draft timeframes and agreed they should go on the website with a statement regarding international timeframes.

ACTION

The MSAC process timeframes are to be placed on the website.

5.2 HTAi Update

Professor Kearney indicated that the organisation of HTAi 2006 in Adelaide was progressing well.

Ms Robertson noted that given the relevance of the conference to the work of the Committee, the Department agrees to cover the cost of attendance by Committee members at HTAi.

Ms Hazlett indicated that the Department (including MSAC) will have a booth at HTAi which Mr Wilkie is organising.

5.3 Horizon Scanning Update

Dr Blamey indicated late papers had been circulated, including the minutes of the last meeting and that members should read about what was happening. Ms Hazlett added that the Department is currently evaluating tenders to support the Horizon Scanning program.

5.4 Nationally Funded Centres

Dr Blamey asked for any comments from the Committee on the Review of the Nationally Funded Centres. Dr Turner commented that the whole NFC program is going to be more streamlined.

5.5 Communication Strategy

Mr Wilkie gave a presentation regarding the communication strategy including a demonstration of the new MSAC website to be launched at HTAi.

Following Mr Wilkie's presentation the following points were made:

- Ms Hazlett reminded members that at the last meeting the members agreed to place references on the MSAC website.
- Dr Blamey suggested putting up links to health technology sites such as INHATA, HTAi, ARHQ and NICE. Mr Wilkie agreed to look into this.
- Mr Wilkie indicated he had emailed members regarding the proposed Member's section for the new website. He suggested it would be used for late papers, contact details for members, evaluators, the Secretariat, and general information pertinent to this Committee.
- Mr Wilkie also indicated that the development of a six monthly newsletter is progressing and it will be launched at HTAi 2006 in hard copy, later editions will be electronic only.

ACTION

Links to other health technology agencies to be placed on the website.

August meeting and other issues

Dr Blamey indicated that there appears to be no final reports for the August meeting and would hope to progress the economic discussion paper.

Dr Blamey noted that there was a possibility that MSAC may do a blood product assessment. Ms Hazlett indicated that the National Blood Authority had been in contact with the Secretariat regarding an assessment and the negotiations are ongoing.

6. CLOSE

Dr Blamey Closed the meeting at 4:22pm.

Please note the next Meeting is in Brisbane on 23 August 2006.