



MINUTES

33rd MEETING 28 February and 1 March 2006 Melbourne

Members Present

Dr Stephen Blamey (Chair)
Professor Brendon Kearney
Professor Syd Bell
Dr Michael Cleary
Dr Paul Craft
Dr Kwun Fong
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
Associate Professor John Atherton
Associate Professor Frederick Khafagi

Ms Samantha Robertson (the morning of 28 February only)
Professor Jane Hall (1 March only)

Apologies

Dr David Gillespie
Professor John Horvath

MSAC Secretariat

Ms Eliza Hazlett
Ms Robyn Bilston
Dr Jane Cook
Mr Chris Gatenby (28 February only)

1. OPENING OF MEETING

1.1 Welcome and Apologies

The Chair opened the meeting at 9.20 am and welcomed everyone. A special welcome was extended to Professor Khafagi as this was his first meeting and Mr Gatenby, a participant of the Graduate Development Program in the Department.

Apologies were received from Dr Gillespie and Professor Horvath.

1.2 Conflict of interest and Confidentiality

The Chair reminded members that recommendations made at Committee meetings cannot be discussed externally until the Minister has signed off on the recommendations.

Most members stated that they had no new conflicts of interest to declare. The following conflicts or potential conflicts of interest were also declared:

- Professor Khafagi – works for a corporatised/private practice; and
- Dr Wood – has 1,000 shares in ResMed (a manufacturer of respiratory medical devices for the diagnosis and treatment of sleep-disordered breathing).

2. DRAFT REPORT OF THE THIRTY SECOND MSAC MEETING HELD 16 NOVEMBER 2005

The Minutes from 16 November 2005 were accepted with the following minor amendments:

- Some minor typing and grammatical errors;
- BMP is Bone Morphogenic Protein; and
- The pages of the Minutes to be numbered.

2.1 Matters arising

Application 1080 - Coronary Pressure Wire

Members were informed that the additional work on the final report for application 1080 – Coronary Pressure Wire did not significantly impact on the cost effectiveness findings of the report. The MSAC Executive considered the amended report at its meeting of 20 January 2006 and agreed to forward to the Minister the recommendation from the November 2005 MSAC meeting.

Application 1090 – Artificial Disc Replacement

This item was discussed at agenda item 3.8.

Application 1084 – UroVysion Fluorescence in-situ Hybridisation (FISH) assay

The recommendation agreed at the November 2005 MSAC meeting was forwarded to the Minister.

Application 1081 – Uterine Artery Embolisation

The MSAC Executive considered the amended report for application 1081 – Uterine Artery Embolisation out of session. The Executive agreed that the additional work did not alter the conclusions of the report and it was agreed that the recommendation from the November 2005 MSAC meeting should be forwarded to the Minister.

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. This was provided to members as the first step in addressing action 10 from the MSAC Review “Record any conflicts of interest relating to Advisory Panel members and MSAC members in assessment reports.”

The list was compiled from information detailed in the minutes of the Advisory Panel meetings.

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

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

The MSAC is currently reviewing the report for 1072 prior to making a recommendation.

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

Dr Cleary, Chair of the Advisory Panel, opened the discussion on this assessment report:

- The SphygmoCor System is a non-invasive diagnostic technology that enables pulse wave analysis of the central ascending aortic pressure waveform;
- It obtains peripheral arterial pressure waveforms by applying an arterial tonometer to the wrist. This tonometer partly compresses the radial artery at the wrist;

- The pressure wave is calibrated against the brachial blood pressure (measured using a cuff). The average pressure waveform is then converted into an ascending aortic waveform using a General Mathematical Transfer Function. The key variables calculated are the Augmentation Index (measures the stiffness of the vessels) and the Subendocardial Viability Ratio (measure of perfusion);
- It is proposed that this technology is useful in the assessment of hypertension, coronary artery disease (identifies patients who do/do not need an angiogram) and heart failure (differentiates systolic and diastolic failure). For these conditions it is proposed that a change in medical management would occur as a consequence of using SphygmoCor;
- These diseases are associated with a significant burden to the community and this is outlined in the report;
- The comparator technologies agreed by the Advisory Panel were:
 - invasive brachial blood pressure for hypertension;
 - angiography for coronary artery disease; and
 - echocardiogram for heart failure;
- Safety – the technology is safe;
- Effectiveness – three areas were looked at: diagnostic accuracy; impact on management; and impact on health outcomes.
 - Diagnostic accuracy - There were no studies that provided evidence of accuracy for the diagnosis of hypertension, spurious hypertension of youth or heart failure. One study provided evidence of diagnostic accuracy in relation to coronary artery disease. This related to changes in the augmentation index and was considered to be of limited value;
 - Impact on medical management – no studies identified; and
 - Impact on health outcomes – as there was no evidence of improved diagnostic accuracy or an impact on patient management, an assessment of health outcomes was not possible;
- Cost effectiveness analysis was not undertaken as clinical effectiveness could not be established;
- The Executive Summary and conclusion of the report could be enhanced especially in relation to spurious hypertension of youth;
- It was noted that the applicant provided a presentation and demonstration to the Advisory Panel.
- Consideration was given to issues raised by the applicant;
 - the suggested expansion of the literature search criteria would not have highlighted further literature of relevance;
 - the comparators were discussed at length by the Advisory Panel and they were content with those selected;
 - a clear formula for subendocardial viability ratio (SEVR) will be provided in the text of the report; and
 - a journal article identified by the applicant has been included in an appendix to the report.

Measurement of the central aortic pressure gives an indication of the risk of stroke. The brachial pressure may be abnormal however the central aortic pressure may be normal.

The Committee discussed what the actual medical service would be and agreed that this needed to be outlined more clearly in the report. Also the cost of the device (between \$4,000 and \$5,000) is to be included in the report.

Associate Professor Atherton provided the critique for this report:

- The report is well written and easy to read;
- Safety – no risk;
- Effectiveness – the reliance on cuff measurement of brachial blood pressure to calibrate the signal is a limitation. There is some debate about using a generalised transfer function to determine the aortic waveform. There is some prognostic value however it is unclear how this will lead to a change in management or improve outcomes;
- Some editorial comments were provided;
- Why was brachial blood pressure chosen as a reference standard rather than invasive aortic pressure? It was noted that there were either none or possibly one study available for aortic pressure.
- It was not clear from the report why patients with renal failure and diabetes were excluded.

The reason for choosing brachial rather than aortic pressure as the comparator needs to be explained in the report.

The Committee unanimously agreed the following recommendation:

“Peripheral arterial tonometry with ascending aortic waveform analysis using the SphygmoCor System is safe: evidence of effectiveness has not been demonstrated.

MSAC recommends that public funding should not be supported at this time.”

Action:

- **The evaluators to clarify the use of brachial pressure and the inclusion/exclusion of patients with renal failure and diabetes in the report; and**
- **The Committee agreed to forward the above recommendation to the Minister for Health and Ageing.**

3.3 Application 1085 – Carbon Labelled Urea Breath Test

Dr Graves, the Chair of the Advisory Panel, opened the discussion on this report:

- The carbon-labelled urea breath test (C-UBT) is used to identify *H. pylori* by administering labelled urea, which hydrolyses to produce isotopically labelled CO₂. This enters the blood stream, is excreted by the lungs, collected and analysed for the presence of *H. Pylori*;
- The comparators are endoscopy and biopsy;
- MBS item 12533 has been around for 10 years, however this item is to confirm the eradication of *H. Pylori*, or the unusual occasions when endoscopy and biopsy are not available or appropriate;
- It was noted that there were no studies identified that report the use of C-UBT as a second line test to *H. Pylori* serology;
- There are no major concerns with safety. However, the urea can be labelled with either stable or radioactive isotopes of carbon - ¹³C or ¹⁴C. The use of ¹⁴C (the radioactive isotope) is usually not recommended for pregnant women or children;
- Diagnostic sensitivity ranged from 90 to 100%, specificity ranged from 86 to 100%;
- The primary outcome for all of the included studies was improvement or resolution of dyspepsia symptoms. It was noted however that none of the included studies met all of the validity criteria and this may have resulted in some bias; and
- Cost comparisons were done using four alternative management strategies. Endoscopy is more expensive and when considering whole of health system costs there is a potential to save \$15 million.

Dr Cleary presented the critique provided by Dr Gillespie:

- The report uses an appropriate clinical pathway for modelling;
- The comparators are appropriate and the options available are chosen in regular clinical practice;
- Safety – well articulated and established;
- Effectiveness – validity of the tests is established in 12 studies with good levels of evidence. Patient health outcomes were well analysed and are either equivalent or better than alternative clinical pathways when proposed UBT as a first line “test and treat” strategy is employed;
- Cost-effectiveness relies on UBT as a first line investigation resulting in less medication to treat dyspepsia. To achieve this saving, clinical practice would need to change to use UBT early as the predominant clinical pathway in uncomplicated dyspepsia; and
- The report mentions a uniform 5 year survival for gastric cancer which may be overly optimistic. A 15-20% 5 year survival rate would be more realistic and would put a delay in diagnosis of gastric cancer in better perspective.

Some comments were provided on the style and layout of the report.

It was noted that most clinical software packages used by general practitioners have prompts for testing for H Pylori. Change in clinical practice will happen.

The Committee discussed how frequently UBTs should be performed and agreed that the Department could negotiate this detail with the profession, informed by the GESA guidelines, as part of implementing the recommendation. It was also noted that implementation may provide the opportunity to address an historical anomaly whereby UBT is funded through the General Medical

Services Table not the Pathology Services Table of the MBS.

The Committee unanimously agreed to the following recommendation:

“Carbon-labelled urea breath testing is safe. Effectiveness and cost effectiveness have been demonstrated for use as a first line procedure for the diagnosis of *Helicobacter Pylori* infection.

MSAC recommends that public funding should be supported for the use of carbon-labelled urea breath testing as a first line procedure for diagnosis of *Helicobacter pylori* infection.”

Action:

- **The above recommendation to be forwarded to the Minister for Health and Ageing.**

3.4 Application 1095 – Computed Tomography Colonography

Dr Cleary, Chair of the Advisory Panel, opened the discussion on this report:

- Computed Tomography Colonography (CTC) is a minimally-invasive radiological technique for imaging the colon and rectum;
- A spiral CT scanner is used to get multiple sections/slices of the colon and rectum;
- Patients require a bowel preparation and then inflating the bowel with air. This does not require sedation;
- The Advisory Panel expanded the assessment to include a more general research question (review question 1 of the report) –
 - What is the safety, effectiveness and cost-effectiveness of CTC versus Double Contrast Barium Enema (DCBE) and versus colonoscopy for the diagnosis or exclusion of colorectal neoplasia in symptomatic patients or in patients that are asymptomatic but are at high risk of colorectal neoplasia due to a personal or family history of colorectal polyps or cancer?
- The research question developed from the application was very specific (review question 2 of the report) –
 - What is the safety, effectiveness and cost-effectiveness of CTC versus DCBE for the diagnosis or exclusion of colorectal neoplasia in symptomatic or high risk patients who are ineligible for colonoscopy due to patient contraindications or the inability to perform or complete the test?
- Safety – CTC is relatively safe when compared with DCBE and is at least as safe as diagnostic colonoscopy. Both CTC and DCBE expose patients to ionising radiation and are associated with a small risk of perforation;
- Effectiveness – three sub-groups were considered, >10mm polyps, 6 to 9 mm polyps and < 5 mm polyps. It was noted that >10mm was associated with a higher risk of malignancy;
 - Specificity/sensitivity of CTC for >10mm polyps was good, for 6 to 9 mm polyps was moderate and for < 5 mm was poor;
 - The effect of patient characteristics has decreased with the improvement in the sophistication of the CT and the greater experience of CT operators;
- Patients were in favour of CTC over colonoscopy where preference was reported.
- Where colonoscopy has failed, CTC performs well in examining the entire colon and can identify more extra-colonic abnormalities than other diagnostic imaging;

- Cost-effectiveness – the sensitivity analysis looked at three different models. The Rocky study was the only study that compared CTC, DCBE and colonoscopy.
 - *for the 1st research question* - CTC is accurate but more costly than DCBE. CTC is less accurate and less costly than colonoscopy. The Advisory Panel also raised the issue that in some jurisdictions access to colonoscopy was limited; and
 - *for the 2nd research question* - for those who can't have colonoscopy CTC identified additional information and is preferred by patients over DCBE.

It was also noted that while DCBE radiation dose is higher than CTC the radiation dose for CTC is still significant. Advances in technology have decreased the radiation dose per slice versus spiral CT.

Some amendments to the costing to better reflect clinical practice were discussed.

Dr Turner critiqued this report:

- The search strategy to identify literature relevant to the two review questions was clear and seemed to be broad based and exhaustive;
- The authors were careful to note that the evidence assessed related to the study population specified in the questions except for two studies. In these, some patients were known to have cancer or the reason for referral for colonoscopy was not stated;
- A definition of symptomatic should have been included eg does +ve FOBT constitute symptomatic;
- A summary distinguishing high from low risk patients would be beneficial;
- Cost-effectiveness – use and therefore cost of chemotherapy was based on NSW patterns of care studies. It is not stated whether this represented best practice. If this is not best practice, or if it is not known if it is best practice, consideration of whether this would affect the cost effectiveness analysis may be warranted; and
- It was noted that the College of Radiology has expressed concern about the costs.

An appendix could be included that details the definition of symptomatic. From an NHMRC report - a positive screen test is considered symptomatic.

The Committee also discussed the following:

- The report should also discuss the minimum standard of CT scanner used in the studies;
- Figure 11, page 202, it was noted that for symptomatic or high risk asymptomatic patients, a large proportion of these patients would have a colonoscopy unless there is an access issue. The diagram should identify high risk and low risk patients;
- There was not enough study evidence to warrant a Markov analysis. Evaluators to revisit economic analysis – a new chemotherapy regimen is now available that is more expensive.
- The report clearly shows that colonoscopy is better than CTC;
- Both colonoscopy and DCBE can be referred by general practitioners and hence whether general practitioners should also be able to refer CTCs; and
- The MSAC members agreed that support should not be given to fund a test that is less effective than another. The MSAC members agreed to seek the views of PBAC on this issue.

The MSAC unanimously agreed to the following recommendation providing the additional work on the economics does not change the conclusions of the report:

“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.”

Action:

- **Evaluators to revisit the economic analysis as discussed; and**
- **To forward the above recommendation to the Minister for Health and Ageing if the MSAC Executive find that the revisited economics does not impact on the conclusions of the report.**

3.5 Reference 32 – Implantable Cardioverter Defibrillators for Chronic Heart Failure

Associate Professor Atherton, Chair of the Advisory Panel opened the discussion on this report:

- Implantable Cardioverter Defibrillators (ICDs) are well described in the report. The comparator, optimal pharmacological therapy (OPT) is moderately effective;
- Consideration was also given to Cardiac Resynchronisation Therapy (CRT) with a defibrillator (CRT-D) – a patient with CRT alone is still at risk of cardiac death;
- There is little data on the burden of disease – currently there are 2,600 patients annually, 40% are expected to have CRT plus a defibrillator. There are probably 9,000 to 10,000 patients needing the device however current infrastructure may limit the initial usage to approximately 4,000 patients per annum;
- Of the three research questions there was insufficient evidence to answer the third research question – What is the clinical need, safety, effectiveness and cost-effectiveness of CRT-D plus OPT compared with cardiac resynchronisation therapy without defibrillation (CRT) plus OPT in patients with moderate to severe left ventricular dysfunction (LVEF \leq 40%, QRS \geq 120ms and of NYHA classes III-IV)?;
- Safety – low incidence of implantation failure;
- Effectiveness – ICD appears to be effective for patients who have mild to moderate symptoms of heart failure. There is one major study for comparing CRT-D with OPT showing some evidence of improvement with CRT-D;
- Economics – The public and private sector were considered separately. A battery change is required every 7 years usually under local anaesthetic;
 - Reasonably cost-effective; and
 - The total estimated costs are high – for ICD \$120 million in the public sector and \$280 million in the private sector per annum, for CRT-D \$56 million in the public sector and \$140 million in the private sector per annum. This will have a major impact on total Health Care Expenditure.

The Committee acknowledged that funding of this procedure would have a significant impact on States and Territories and Private Health Insurance.

There was much discussion about the price differential between the public and private sectors.

There are now new MBS items for Cardiac Resynchronisation Therapy, 80% of CRTs include a defibrillator and this should be included in the costing. It was also noted that for 20% of CRT an open thoracotomy is required due to the inability to get a lead in the left ventricle. Table 53 acknowledges that 10% would require thoracotomy.

There are no guidelines for optimal medical therapy for these patients however it was noted that it is not recommended to implant ICDs within one month of having a heart attack.

Dr Piejko provided the critique for this report:

- There is good evidence comparing ICD and OPT with OPT alone however there was a lot of heterogeneity in the studies. The report was not able to identify which patients would benefit most from the treatment;
- Safety:
 - difficult to tell where mortality fits; where mortality is due to the device then it should come under safety, but if it is due to cardiac failure/sudden cardiac death then it should be classified under effectiveness. It may be difficult to extrapolate this information from the studies;
- Effectiveness:
 - in the patients with cardiac failure ICD does appear to reduce mortality by all causes and specifically by cardiac causes;
 - The data was not available to discern what increased survival meant to the patients – table 45 shows that mean survival is increased by about 3.5 years when ICD is added to OPT. There is no data to confirm that they have better function or less hospitalisation;
- Cost Effectiveness:
 - The largest group of patients would be >75 years old – is it feasible to extrapolate out for 15 years?
 - In determining the cost, the report uses a failure to implant rate of 2% however as mentioned in the safety section these were mostly due to patient preference/choice;
 - The overall cost is large given the large number of potential patients;
- The report does not provide a sense of natural history of the disease.

It was noted that a report in the New England Journal of Medicine indicated that there had been a number of unexpected deaths in relation to ICDs.

Advice received from the TGA indicates that in recently published results of a ‘look-back’ study of device failures and patient outcomes, only 60 deaths could be directly attributable to device failure in a population of approximately 3.5 million devices implanted. It was noted that this is a very sensitive and conservative market and manufacturers have a very low threshold of incident numbers before some form of action is taken such as product alerts.

It was noted that the average age of these patients was low 60s.

Members agreed unanimously to the following recommendation:

“On the strength of evidence relating to safety, effectiveness and cost effectiveness, MSAC concludes that the use of implantable cardioverter defibrillators for the primary prevention of

sudden cardiac death is beneficial and appropriate for:

- patients with a left ventricular ejection fraction of less than or equal to 30% at least one month after a myocardial infarct when the patient has received optimal medical therapy.
- patients with chronic heart failure associated with mild to moderate symptoms (NYHA II and III) and a left ventricular ejection fraction less than or equal to 35% when the patient has received optimal medical therapy.

On the strength of evidence relating to safety, effectiveness and cost effectiveness, MSAC concludes that the use of combined implantable cardiac resynchronisation and cardioverter defibrillator therapy is beneficial and appropriate for patients with chronic heart failure associated with moderate to severe symptoms (NYHA III and IV), sinus rhythm, a left ventricular ejection fraction of less than or equal to 35% and a QRS duration greater than or equal to 120ms, when the patient has received optimal medical therapy.”

Action:

- **The above recommendation to be forwarded to the Minister for Health and Ageing.**

3.6 Reference 33 – Treatment of Cerebral Aneurysms

Dr Piejko, Chair of the Advisory Panel, opened the discussion of this report:

- This review assessed endovascular approaches (mainly coiling) compared to surgical approaches (mainly clipping) or conservative treatment for ruptured and unruptured aneurysms;
- The mortality rate for patients with ruptured cerebral aneurysms is 30 to 50% with severe morbidity for those who survive;
- The best treatment for a patient is determined by the team treating the patient and is based on an assessment of the patient and the available treatment (including skills) at the centre;
- An assumption was made that all patients will have an angiogram prior to treatment and during treatment;
- Ruptured aneurysms:
 - Safety: difficult to discern whether adverse events are due to the treatment or the underlying disease. Generally complication rates were similar for coiling and clipping;
 - Effectiveness: Coiling was at least as effective or more effective (in centres of excellence) than surgery;
 - Cost effectiveness: Coiling is slightly more expensive than clipping;
 - It was noted that there are ongoing trials looking at different types of coiling. The ISAT indicates that coiling was done 75% and clipping 25% of the time of carefully selected patients.
- Unruptured aneurysms:
 - More difficult to assess – as the question is whether they should they be treated or not. There are no parameters to determine the likelihood of rupture. There are no current trials underway;
 - There is less time in hospital, less time for rehabilitation and possibly less complications where unruptured aneurysms are treated with coiling compared to clipping but there is very limited evidence;

- Costs for coiling and clipping are similar however there are better outcomes with coiling;
- Coiling is a procedure performed throughout the world; and
- Only coiling was looked at in the report as there was little information on other endovascular treatments including glues.

Dr Wood provided the critique on this report:

- This report sets out to assess a potential treatment of approximately 1000 patients affected by cerebral aneurysms per year in Australia. 850 will present for treatment with a rupture and 150 pre rupture;
- The assessment included 182 studies relying heavily on two randomised controlled studies by Koivisto 2002 and Molyneux 2005;
- Large numbers of patients were excluded from studies for reasons that were not specified but clinician preferences were likely to have been a reason, which presents a bias in selection;
- All studies indicated that endovascular or surgical treatment was preferable to conservative or no treatment;
- Expertise was important with a decrease in the number of adverse events associated with the more experienced practitioner; and
- There may be too much detail on the 180 studies – mainly case studies – that do not contribute to the conclusion.

The Advisory Panel discussed the length of stay in hospital. The length of stay in hospital for a patient with a ruptured aneurysm was probably due to the rupture rather than the treatment, however for unruptured aneurysms a differential for the length of stay in hospital was provided.

Endovascular items on the MBS do not include after care consultations and hence the costings include 3 consultations.

The Committee unanimously agreed to the following recommendation:

“Available evidence suggests that endovascular treatment of intracranial aneurysms using coils is as safe and effective as surgical clipping for appropriately selected patients. The procedure is also cost effective when compared with surgery.

MSAC recommends public funding for this procedure.”

Action:

- **The above recommendation to be forwarded to the Minister for Health and Ageing.**

3.7 Reference 34 – Gamma Knife Stereotactic Radiosurgery

Gammaknife was discussed at the meeting and is currently under consideration by the MSAC.

3.8 Application 1090 – Artificial Intervertebral Disc Replacement

The final report for application 1090 – Artificial Intervertebral Disc Replacement was discussed at the November 2005 MSAC meeting. Members requested more information.

Professor Thomson, Chair of the Advisory Panel, explained that at the last MSAC meeting the incorporation of Bone Morphogenic Protein (BMP) in the costings of lumbar spinal fusion was discussed. BMP is expensive and the inclusion of BMP in the costing for spinal fusion would have brought the costings of AIDR and spinal fusion closer together. Information from the Spine Society

indicated that currently approximately 7% of spinal fusion procedures are performed with BMP. There were also some conflicting views between experts in this field regarding the degree of BMP usage with spinal fusion.

Professor Thomson also conveyed that for the cervical region there was no evidence available for the effectiveness of AIDR and that in the lumbar region, AIDR decreased pain and preserved some degree of movement, at an additional cost.

The Committee decided not to include BMP in the costings for spinal fusion. Comment is to be made in the report that 1-11% of spinal fusion includes the use of BMP and that this would affect the cost of spinal fusion. However, it should also be noted that the inclusion of BMP with spinal fusion may also have an impact on the effectiveness of spinal fusion – this was not covered in this review.

Dr Craft provided a comprehensive critique of the report at the last MSAC meeting. Dr Craft concluded that the report had been enhanced by subsequent revisions.

A concern was raised regarding the need to follow-up adverse events with this type of surgery. It was noted that hip and knee reconstructions have a good follow-up mechanism however there is a problem tracking orthopaedic elements that include numerous plates and screws. There would be much smaller numbers of AIDR treatments and a register would be helpful. It was noted that this was not the role of MSAC.

If this procedure is supported it would be for appropriately trained personnel. Credentialing would be done in association with the Spine Society.

The Committee had a strong view that interim funding be supported to enable further data to be obtained in the Australian setting. It was acknowledged that data would not be in the form of randomised control trials but would be in the form of case series.

The Committee unanimously agreed to put forward the following recommendation:

“On the basis of currently available evidence regarding safety, effectiveness and cost effectiveness, MSAC recommends interim funding for single level AIDR in patients with single level intra lumbar disc disease in the absence of osteoporosis who have failed conservative therapy.

MSAC will review this recommendation in three years.

In the absence of adequate evidence of effectiveness, MSAC recommends that public funding for AIDR in the cervical spine should not be supported.”

Action:

- **Check if the DRGs used in the costings include prosthesis. If an amendment is required to the economics component of the report, the MSAC Executive will check to ensure that the change does not affect the conclusions of the report; and**
- **The above recommendation to be forwarded to the Minister for Health and Ageing.**

4. PROGRESS REPORTS ON APPLICATIONS AND REFERENCES

Members noted the progress reports of thirteen applications. No issues were raised concerning these applications.

The Committee was advised that the Advisory Panel was being formed to consider the following application:

Application/ Reference	Chair	2 nd MSAC member	Craft Groups to be approached
App 1105 – Computed Tomography Coronary Angiogram	Associate Professor John Atherton	Professor Brendon Kearney	<ul style="list-style-type: none"> • RANZCR • CHF • The Cardiac Society of Australia and New Zealand

It was suggested that The Australasian Society of Cardio Thoracic Surgeons and the Royal Australian College of General Practitioners (RACGP) be approached to join the Advisory Panel for Application 1105.

It was suggested that the Advisory Panel Chairs and the MSAC Executive could assist in obtaining members for Advisory Panels. Dr Graves also volunteered to approach the CEOs of craft groups when required.

Action:

- **The Australasian Society of Cardio Thoracic Surgeons and RACGP to be approached for nominees to join the Advisory Panel for Application 1105.**

5. OTHER ISSUES

5.1 MSAC Review

Members were advised that late papers were circulated for this agenda item. The Attachments are as follows:

- Attachment A – a paper on the establishment of Advisory Panels;
- Attachment B – a paper on the use of the MSAC website for stakeholder consultation; and
- Attachment C – a table summarising the status of the agreed actions.

The Committee discussed Attachments A and B and were asked to provide comment on Attachment C (particularly the greyed areas of the table) via email to Ms Bilston.

The Committee agreed that a table, similar to Attachment C, should be provided on the MSAC website for all interested parties to keep track of progress in implementing the agreed actions from the MSAC Review.

The Committee noted that the draft economic guidelines were progressing.

Attachment A – The Establishment of Advisory Panels

Members were provided with a brief outline of the 12 month trial being proposed to ensure the timely establishment of Advisory Panels. The proposal includes:

- Retaining craft group involvement;
- Developing an MSAC register of expertise;
- Utilising previously nominated clinical experts; and
- Using applicant nominated clinical experts.

The following was raised in discussion:

- Consider tapping into the registers that have been established by the Prosthesis Device Committee;
- It was noted that most Colleges must go through their Council before putting forward nominees;
- It was noted that it is not a requirement to go to the craft groups for nominees, that members of Advisory Panels were there for their expertise not as a representative of an organisation;
- It would be beneficial to have a combination of approaches;

- The appointment to the register would be at the discretion of the MSAC Executive; and
- The Department would continue to liaise with the Consumers' Health Forum of Australia to ascertain how this approach would apply to consumers.

The Committee agreed to trial the approach outlined in Attachment A.

Attachment B – Stakeholder involvement in the MSAC process

Members noted the proposal to put draft evaluation protocols and draft assessment reports for MSAC referrals on the MSAC website. It was also noted that the implementation of this proposal includes considerable modification to the MSAC website including:

- The creation of a new section for 'consultation documents';
- Developing an electronic document that includes mandatory fields for contact details and providing information to respondents on how comments they provide will be used. Respondents will also be informed that MSAC will not be responding to comments provided; and
- A facility to alert interested parties when consultation documents on specific topics become available.

It was decided to start this approach with the draft protocols for references only.

Action:

- **Members to forward to Ms Bilston comments on Attachment C (the table summarising the status of the agreed actions);**
- **A table (similar to that in Attachment C, summarising the status of the agreed actions) to be placed on the MSAC website;**
- **Implement a 12 month trial for the establishment of Advisory Panels, as outlined at Attachment A; and**
- **Trial the proposal to utilise the MSAC website to obtain feedback from stakeholders on draft protocols, in the first instance for references as outlined at Attachment B.**

5.2 HTAi Conference in Adelaide 2006

Members were provided with the latest version of the program for HTAi 2006 to be held 3 to 5 July 2006.

Members were asked to indicate to Ms Bilston their availability to attend HTAi 2006 and to attend a workshop on the economic guidelines, possibly on the afternoon of 5 July.

Action:

- **Members to indicate their availability to attend HTAi 2006 in Adelaide to Ms Bilston as soon as possible.**

5.3 Horizon Scanning

It was noted that Professor Kearney (Chair), Dr Blamey and Dr Turner are members of HealthPACT.

A number of HealthPACT prioritising summaries have been provided to Euroscan.

The following prioritising summaries were noted:

- screening and the subsequent early treatment for gestational diabetes;

- digital mammography for the screening of women for breast cancer – this could progress to a referral; and
- tomotherapy for radiation and treatment planning in cancer patients – some jurisdictions are keen to progress.

Other issues – Nationally Funded Centres

Professor Kearney (Chair), Dr Blamey, Dr Turner and Dr Travis are members of a working group to review the AHMAC applications for the Nationally Funded Centres (NFC) program. A contractual arrangement is in place with AHMAC for MSAC to conduct these reviews.

Guidelines have been developed for the assessment of the applications. The guidelines will be provided in the papers for the next MSAC meeting.

The reviews for new NFCs include:

1. Pulmonary Thromboendarterectomy
2. Peritoneal Cancer
3. Selective Dorsal Rhizotomy

Reviews of existing NFCs include:

1. Paediatric Liver Transplantation Program - Austin Hospital, Melbourne
2. Paediatric Liver Transplantation Program - Royal Children's Hospital, Brisbane
3. Paediatric Liver Transplantation Program - Royal Prince Alfred Hospital, Sydney;

The final decision in relation to implementing the outcomes of these reviews will lie with AHMAC.

Action:

- **The NFC assessment guidelines to be provided at the next MSAC meeting.**

6. CLOSE

The meeting closed at 12.55 pm.

The next MSAC meeting is scheduled for 17 May 2006 in Sydney.