



## MINUTES of the Medical Services Advisory Committee 39<sup>th</sup> meeting held on Friday 31 August 2007 at the Mercure Hotel, Brisbane

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### 1.1 Welcome, introductions and apologies

**Members** present: Dr Stephen Blamey (Chair), Professor Brendon Kearney, Dr Bill Glasson, Associate Professor John Atherton, Dr Michael Cleary, Associate Professor Paul Craft, Ms Catherine Farrell (via teleconference), Professor Richard Fox, Dr David Gillespie, Dr Jane Hall, Professor John Horvath (via teleconference), Associate Professor Terri Jackson, Associate Professor Frederick Khafagi, Dr Ray Kirk, Dr Ewa Piejko, Mrs Sheila Rimmer, Dr Judith Soper, Professor Ken Thomson, Dr Mary Turner,

**Apologies** received from: Dr David Barton, Professor Geoff Farrell, Dr Kwun Fong, Dr David Wood, Dr Ian Prosser,

**DoHA** staff: Ms Megan Morris, Dr Brian Richards, Mr Peter Woodley, Ms Clare Poprawski, Mr Bill Matthews, Mr Phil Dunkley, Ms Rhiannon Humphries, Ms Seemal Reddy

Dr Stephen Blamey announced that five new members have been appointed to MSAC by the Minister for Health and Ageing, the Hon Tony Abbott. He welcomed the new members who were able to attend the meeting.

The current MSAC members introduced themselves and gave a brief description of their background. The new members then introduced themselves and outlined their experience and qualifications to the committee.

#### **Outcomes**

- MSAC members noted the appointment of the new MSAC members.
- MSAC members noted apologies.

### 1.2 Conflict of interest declaration

The Chair asked members to declare potential conflict of interest.

#### **Outcome**

- Associate Professor Craft orders Positron Emission Tomography scans but receives no financial reward.
- Dr Soper has a private Medical Resonance Imaging practice and CT with the ability to do CTCA.
- Professor Thomson has two 64 slice CT scanners.

- Dr Glasson refers Ocular Coherence Tomography but receives no financial reward.

## **2.1 Draft minutes from the 38<sup>th</sup> MSAC meeting 25 May 2007**

### **Outcome**

- Members accepted the minutes of the 38<sup>th</sup> meeting held on 25 May 2007 with one minor edit.

### **Action**

- Minutes to be edited accordingly.

## **2.2 Matters arising from the minutes of the 38<sup>th</sup> MSAC meeting**

Dr Blamey advised that for the assessment of Application 1112 Intra-gastric Balloon that similar devices would be included in the scope of the assessment.

Members noted the completed actions arising from the 38<sup>th</sup> MSAC meeting.

## **3 Final Reports for MSAC Endorsement**

Dr Blamey advised that there were three final reports for consideration at this meeting. Dr Blamey briefly outlined the MSAC process for the benefit of the new members.

Dr Blamey invited Associate Professor Khafagi as chair of the Advisory Panel for Reference 35(a) to introduce the reports. He began by giving the background to previous MSAC assessments of Positron Emission Tomography (PET).

### **Introduction**

In 2000 MSAC evaluated the clinical effectiveness of positron emission tomography (PET) with [F-18]-fluorodeoxyglucose (FDG) for several indications including those currently under review ie., recurrent colorectal cancer, ovarian cancer and melanoma. The 2000 evaluation found insufficient evidence at that time from which to draw definitive conclusions about the clinical effectiveness and cost-effectiveness of FDG PET.

Interim funding was subsequently provided for nine clinical indications. A condition of interim funding was that the funded centres would participate in a prospective study which would collect data including patient demographics, pre-PET and post-PET management plans and disease progression during follow-up.

Associate Professor Khafagi then addressed the common features of the reports for colorectal cancer, ovarian cancer and melanoma.

### **Safety**

The MSAC 2000 review found that FDG PET was safe. The main technological advance since the original review has been the incorporation of CT scanners into PET scanner gantries, allowing the rapid sequential acquisition of both CT (anatomical) and PET (functional) images to produce co-registered (“fused”) PET/CT images; the CT component incurs an additional radiation exposure. However, in the context of patients with suspected recurrent cancer, these radiation exposures are considered acceptable.

## **Effectiveness**

### *Diagnostic performance*

For each of the indications reviewed there is now abundant literature evidence that PET – and in particular, PET/CT – has greater diagnostic accuracy for the detection and restaging of recurrent disease compared to conventional imaging (most commonly CT scanning).

However, for each of the clinical pathways, it was acknowledged that, in the Australian context, patients would come to PET having had a range of conventional imaging studies (again, usually including CT). The evidence favouring the *incremental* diagnostic accuracy of PET or PET/CT is more limited, but is nevertheless consistent with its superior *comparative* accuracy.

### *Clinical effectiveness*

The most relevant measure of the clinical utility of PET should be its ability to influence management. Drawing heavily on the Australian data collection study, as well as considerably more limited data in the published literature, the Advisory Panel found that PET resulted in important changes in management in a substantial proportion of patients for each indication considered. The most common change in management resulted from disease upstaging by PET, so that many patients were able to avoid having radical surgery, with its attendant morbidity, which they would otherwise have undergone with mistakenly curative intent.

## **Economic analysis**

A cost-consequence analysis was performed, examining the cost of PET against the consequences of avoiding radical surgery which was unlikely to benefit the patient found (by PET) to have incurable or extensive disease.

### *Cost of PET in Australia*

As part of the Australian PET data collection project, the cost of providing PET services in each of 8 funded centres was estimated. There were limitations in the data as presented in the costing report, and the range of estimated costs of a PET scan varied very widely. However, these represent the best available estimates of the current cost of PET in Australia.

Associate Professor Terri Jackson provided an economic critique that covered the three reports.

In summary she explained that the report places no value on patients avoiding surgery in the last days of a disease - there is no point to futile surgery. Associate Professor Jackson advised that this concept should have been included as part of the economic analysis. She indicated that it wasn't clear from the reports how much surgery was saved by the use of PET.

The Reports include well-documented and well-conducted modelling of potential clinical and economic outcomes. This modelling demonstrates the value of Probabilistic Sensitivity Analysis, but its usefulness would have improved with graphic display on the Cost Effectiveness Plane.

Decisions about subsidy come down to huge uncertainties in available clinical, quality of life and costing evidence, including:

- what percentage of cancer patients have disseminated disease by the time they're staged (and how do you know this without using PET?);
- value to patients of avoiding futile surgery (beyond the benefit of avoiding surgical mortality);
- patient evaluation of risks of incorrect upstaging and missed opportunity for cytoreduction surgery;
- 'true' cost of PET scans (wide range between sites; uncertain capacity utilisation);
- 'true' rate of changed management for patients having PET scans (will patients and clinicians still want to 'do everything possible'?; will all patients with cancer recurrence be restaged using PET or just 'surgical candidates'?).

### 3.1 Reference 35(a) PET for Colorectal Cancer

Associate Professor Khafagi then introduced PET for colorectal cancer.

#### Summary

This report focuses on an assessment of FDG–PET performed for the evaluation of two recurrent colorectal cancer indications. The specific research questions for this review were:

1. What is the value of the addition of PET/CT in the assessment of patients with isolated pulmonary or hepatic metastatic disease, following previous therapy for colorectal carcinoma that is apparently resectable and potentially curable as determined by conventional staging?
2. What is the value of the addition of PET/CT in patients with suspected locoregional recurrence of colorectal cancer that is potentially resectable as determined by conventional staging?

- Safety

PET is considered a safe procedure. PET/CT is not associated with any additional safety concerns as the exposure to ionising radiation is acceptable and the use of IV contrast agents is not standard. Patients undergoing PET/CT will have additional radiation exposure from the CT component, but doses used are typically lower than with diagnostic CT. The potential long-term effects of exposure to ionising radiation are unlikely to be of major concern to these patients, given their reduced life expectancy.

- Effectiveness

PET has greater diagnostic accuracy than conventional imaging in staging patients with potentially resectable colorectal liver metastases and in detecting recurrent colorectal cancer.

For hepatic metastatic disease PET detects additional sites of disease in 18% to 40% of patients, with a positive predictive value of between 63% and 100% (based on four studies). No accuracy studies in patients with pulmonary metastatic disease were identified.

For suspected locoregional recurrence, the evidence of the additional value of PET over that of conventional imaging (CT) is limited. One study showed PET has a sensitivity and specificity of 89% in diagnosing recurrent colorectal cancer in patients with an elevated carcinoembryonic antigen and a negative or equivocal CT. In a subgroup of 30 patients with suspected rectal cancer and abnormal

findings on CT, PET/CT was highly accurate with a sensitivity of 100 per cent and a specificity of 96 per cent.

There is evidence that the use of PET in patients with recurrent or metastatic colorectal cancer leads to changes in the management of a substantial proportion of patients. The most frequent major change in management following PET was the avoidance of planned surgery. There is some uncertainty regarding the magnitude of these effects.

The Australian PET data collection study showed that for patients with potentially resectable hepatic or pulmonary metastases, PET:

- identified additional sites of disease in 44% of patients, (23% of those with predominant hepatic metastases pre-PET and 41% of those with predominant pulmonary metastases pre-PET);
- did not confirm abnormalities which were detected in the pre-PET evaluation in 37% of patients;
- led to changed management plans in 49% of patients with presumed isolated hepatic or pulmonary metastases;
- avoided surgery in 32% of all patients (88% of patients were planned for surgery pre-PET); and
- added chemotherapy for 18% of all patients.

The main treatment change likely to follow PET in patients with recurrent CRC is the avoidance of surgery: both “open-and-close” or exploratory laparotomy procedures; and radical surgery with curative intent.

Avoiding open-and-close or exploratory laparotomy procedures will improve patient outcomes. Expert opinion is that avoiding radical surgery leads to improved patient outcomes in terms of quality of life, but definitive evidence for whether this outweighs any potential benefit of surgery is lacking.

- **Economic Considerations**

In the staging of patients with metachronous colorectal liver metastases PET/CT leads to:

- lower costs with a mean cost savings of \$213,860 per 100 patients;
- the avoidance of non-beneficial operations for 20% of patients;
- the avoidance of associated surgical complications for 4% of patients;
- the avoidance of perioperative mortality in 1% of patients;
- potentially detrimental health outcomes in 5% of patients through overstaging of disease. In these patients, potentially curative surgery may be delayed although not necessarily denied; and
- potential mean net financial cost savings of between \$2.54 million and \$4.23 million depending on utilisation.

In patients with suspected locoregional recurrence of colorectal cancer PET/CT leads to:

- lower costs with a mean cost savings of \$464,096 per 100 patients;
- the avoidance of operations that cannot, or are unlikely to, provide long-term benefit for 36% of patients;
- the avoidance of associated surgical complications for 19% of patients;
- avoidance of perioperative mortality in 1% of patients;

- potentially detrimental, health outcomes in 14% of patients through overstaging (5%) or a missed or delayed diagnosis of local recurrence (9%). In these patients, potentially curative surgery may be delayed although not necessarily denied; and
- potential mean net financial cost savings of between \$3.69 million and \$6.16 million depending on utilisation.

For each colorectal indication:

- annual total costs to the Medical Benefits Scheme using the Australian cost study data are estimated to be between \$1.03 million and \$4.65 million.

The economic analysis considered patients planned for surgery. In patients not planned for surgery the net financial impact is not known but is likely to be less favourable.

Associate Professor Atherton provided a critique of PET for Colorectal Cancer.

He made the following points:

- the review questions have been clearly defined and generally the level of evidence supporting the use of PET in addition to standard care is reasonable for hepatic metastatic disease, almost absent for pulmonary metastatic disease and limited for locoregional recurrent disease;
- the main value of PET is in detecting additional sites of distal metastatic disease or excluding locoregional recurrent disease which allows “non-beneficial” surgery to be avoided - an observational Australian registry reports that this leads to a change in management in a substantial proportion of patients mainly by avoiding surgery - evidence from published studies is supportive - expert opinion suggests that this will lead to better outcomes;
- in the economic analyses, it is suggested the 5% (95% CI 1-14%) of patients with colorectal liver metastases and 14% (95% CI 4-27%) of patients with suspected locoregional recurrence could have potentially detrimental health outcomes by incorrectly avoiding potentially curative surgery through overstaging or missed diagnosis of disease;
- according to cost-consequence analyses modelled to 3 months post-PET, it appears that PET will be cost-saving when used in patients who would otherwise have undergone surgical procedures for presumed recurrent CRC;
- the question of leakage to patients who are not being considered for surgery is well addressed in the report - it is likely that PET will be less cost-effective in such patients;
- the report is limited by the available evidence, especially in relation to pulmonary metastatic disease and locoregional recurrence; and
- in summary he outlined points of discussion for the MSAC.
  - Whether pulmonary metastatic disease should be included in a potential positive recommendation.
  - Whether the benefit of avoiding “non-beneficial” surgery will outweigh the potential harm caused by delayed “beneficial surgery” with false positive results. Expert opinion suggests it will.
  - The possible issue of leakage to patients who would not otherwise have been considered for surgery. The registry suggests that leakage will occur.

A general discussion by the MSAC then followed resulting in the following recommendation.

## **Recommendation**

MSAC has considered the safety, effectiveness and cost-effectiveness of PET and PET/CT using [F-18]-fluorodeoxyglucose (FDG) in addition to conventional staging for:

- apparently isolated hepatic or pulmonary metastases of colorectal cancer, or
- suspected locoregional recurrence of colorectal cancer

in patients who are being considered for surgical resection with curative intent.

MSAC finds that FDG PET and PET/CT are safe.

MSAC finds that PET and PET/CT provide incremental accuracy over conventional staging alone for metastatic and recurrent colorectal cancer.

MSAC finds that PET and PET/CT are likely to improve patient outcomes through the avoidance of radical surgery which is unlikely to provide long-term benefit. MSAC finds that PET and PET/CT are likely to be cost-saving for patients with metastatic or recurrent colorectal cancer who are considered for surgery with curative intent after conventional staging.

MSAC recommends that public funding is supported for this procedure when referred by a specialist.

## **Outcome**

- Members voted unanimously on the recommendation.
- MSAC accepted the recommendation.

## **Action**

- Recommendation to be forwarded to the Minister for his consideration.
- The typographical errors and amendments to be forwarded to the evaluators.

### **3.2 Reference 35(a) PET for Ovarian Cancer**

Dr Blamey invited Associate Professor Khafagi, as chair of the advisory panel to introduce the report.

## **Summary**

The specific research question for this review was:

1. What is the value of the addition of PET/CT in the assessment of patients with suspected locoregional recurrence of epithelial ovarian cancer considered to be potentially resectable on conventional staging?

- **Safety**  
PET is considered a safe procedure. PET/CT is not associated with any additional safety concerns as the exposure to ionising radiation is acceptable and the use of IV contrast agents is not standard. Patients undergoing PET/CT will have additional radiation exposure from the CT component, but doses used are typically lower than with diagnostic CT. The potential long-term effects of

exposure to ionising radiation are unlikely to be of major concern to these patients, given their reduced life expectancy.

- Effectiveness

The main potential impact of PET in patients with recurrent ovarian cancer is in the selection of patients most likely to benefit from secondary cytoreductive surgery. The use of PET as an additional test may achieve this by detecting recurrent disease at metastatic or anatomically inaccessible sites that is likely to preclude radical surgery.

PET is more accurate than conventional imaging, with an incremental sensitivity of 83- 88% and specificity of 71-100% for detecting recurrence. The evidence indicates that the addition of PET to conventional imaging is likely to increase the accuracy for confirming recurrence and staging recurrent disease.

A prospective Australian study reported that in the staging of recurrent ovarian cancer PET/CT:

- changed management plans in a total of 59% of patients;
- avoided surgery in 23% of all patients;
- in patients planned for surgery pre-PET, 54% avoided surgery, however 57% of patients being evaluated for suspected recurrence of ovarian cancer were not planned for surgery pre-PET;
- added chemotherapy in 16% of patients and avoided it in 13% of patients; and
- actual management was consistent with post-PET management plans in 68% of patients.

Whilst PET leads to the avoidance of surgical morbidity and mortality in patients who avoid radical surgery, expert opinion is that this leads to improved patient outcomes, but definitive evidence for whether this outweighs any potential benefit of surgery is lacking.

- Economic Considerations

In the staging of women with recurrent ovarian cancer planned for secondary cytoreductive surgery, PET/CT leads to:

- lower costs with a mean cost savings of \$313,937 per 100 patients;
- the avoidance of secondary cytoreductive surgery for 49% of patients;
- the avoidance of associated surgical morbidity for 19% of patients;
- the avoidance of perioperative mortality rate in 1% of patients; and
- potentially detrimental health outcomes in 13% of patients through overstaging of disease. In these patients, potentially curative surgery may be delayed although not necessarily denied.

Limited information about this specific patient group suggests that modelled estimates of avoidance of surgery through PET and associated cost savings and health outcomes may be an overestimate. Therefore, the results need to be interpreted cautiously.

For the staging of women with recurrent ovarian cancer planned for secondary cytoreductive surgery using PET/CT:

- annual total costs to the Medical Benefits Scheme using the Australian cost study data are estimated to be between \$0.27 million and \$1.76 million;

- there may be a potential mean net financial cost savings of between \$0.17 million and \$1.96 million depending on utilisation.

Professor Thomson provided a critique of PET for Ovarian Cancer.

Professor Thomson made the following points:

- he was not sure of the value of PET/CT in the assessment of patients with suspected recurrence of ovarian cancer after reading this report, but did come to the conclusion it would not cost much money and it would save some women unnecessary surgery - the cost of chemotherapy he suggested would remove any perceived savings and he did not see this considered in the report;
- patient management was changed –surgery was avoided and other treatments altered but effect on survival was not clearly defined; and
- the report was generally easy to read, however there was a great deal of complicated discussion on the limited data.

MSAC then had a general discussion resulting in the following recommendation.

### **Recommendation**

MSAC has considered the safety, effectiveness and cost-effectiveness of PET and PET/CT using [F-18]-fluorodeoxyglucose (FDG) compared with conventional staging for women with suspected locoregional recurrence of epithelial ovarian cancer considered to be potentially resectable.

MSAC finds that FDG PET and PET/CT are safe.

MSAC finds that PET and PET/CT are more accurate than conventional staging for recurrent ovarian cancer.

MSAC finds that PET and PET/CT are likely to improve patient outcomes through the avoidance of radical surgery which is unlikely to provide long-term benefit. MSAC finds that PET and PET/CT are likely to be cost-saving for women with recurrent ovarian cancer who are considered suitable for secondary cytoreductive surgery after conventional staging.

MSAC recommends that public funding is supported for this procedure when referred by a specialist.

### **Outcome**

- Members voted unanimously on the recommendation.
- MSAC accepted the recommendation.

### **Action**

- Recommendation to be forwarded to the Minister for consideration.
- Some corrections to the report and amendments to be forwarded to the evaluators.

## **3.3 Reference 35(a) PET for Melanoma**

Dr Blamey invited Associate Professor Khafagi, as chair of the advisory panel to introduce the report.

## Summary

This report focuses on an assessment of FDG–PET performed for the evaluation of recurrent melanoma. The specific research question to be addressed is:

1. What is the value of the addition of PET/CT to the assessment of patients with biopsy proven recurrence of malignant melanoma considered on conventional staging to be potentially resectable with curative intent?
- **Safety**  
PET is considered a safe procedure. PET/CT is not associated with any additional safety concerns as the exposure to ionising radiation is acceptable and the use of IV contrast agents is not standard. Patients undergoing PET/CT will have additional radiation exposure from the CT component, but doses used are typically lower than with diagnostic CT. The potential long-term effects of exposure to ionising radiation are unlikely to be of major concern to these patients, given their reduced life expectancy.
  - **Effectiveness**  
The main potential impact of PET in patients with recurrent melanoma is in the selection of patients most likely to benefit from surgery. The use of PET as an additional test may achieve this by detecting distant metastases that are likely to preclude curative surgery.

PET/CT appears to be more sensitive and specific for the detection of regional nodal metastases and distant metastases than CT alone in patients with clinically suspected recurrence of melanoma. PET alone appears to be more sensitive than CT for N- and M-staging in these patients. Specificity also appears to be greater, though this did not reach statistical significance. PET had a sensitivity and specificity of  $\geq 85\%$  for detecting recurrence in all tumour sites combined, and for lung and lymph nodes individually. Accuracy appears to be lower for brain and skin metastases.

No evidence was found for the additional value of PET over conventional staging. However, given the evidence for greater accuracy of PET compared with CT, PET is likely to be of additional value over CT alone, but this benefit could not be quantified from the available data.

A prospective Australian study reported that for potentially resectable recurrence of melanoma PET/CT:

- changed management plans in a total of 62% of patients;
- avoided surgery in 35% of patients (surgery was planned in 95% of patients);
- chemotherapy was added in 13% in patients who avoided surgery;
- changed the extent of planned surgical procedure in 10% of patients post-PET; and
- actual management was consistent with post-PET management plans in 67% of patients.

These data provide evidence that the use of PET in patients with recurrent melanoma leads to changes in the management of a substantial proportion of patients. PET also leads to the avoidance of surgery in a subset of these patients. Expert opinion is that avoiding surgery leads to improved patient

outcomes, but definitive evidence for whether this outweighs any potential benefit of surgery is lacking.

- Economic Considerations

In the patients with recurrent melanoma in craniocervical, axillary or ilioinguinal lymph nodes PET/CT leads to:

- lower costs with a 52% probability that mean cost savings would be \$7,762 per 100 patients;
- an 85% probability of the avoidance of operations that are unlikely to provide long-term benefit for 11% of patients;
- associated reduction in surgical complications for 9% of patients;
- the avoidance of perioperative mortality in 1% of patients;
- potentially detrimental health outcomes in 7% of patients in whom potentially curative surgery might be delayed, although not necessarily denied, through overstaging of disease;
- annual total costs to the Medical Benefits Scheme using the Australian cost study data are estimated to be between \$1.10 million and \$5.95 million; and
- potential mean net financial cost savings costs for the population planned for lymphadenectomy are between \$0.078 million and \$0.124 million depending on utilisation. The net financial impact for other groups of patients in whom surgery may be planned remains unknown.

Dr Cleary provided a critique of PET for Melanoma.

Dr Cleary made the following points:

- this was a well written and comprehensive review - the review was constrained by the limited literature relating to clinical outcomes;
- the assessment of projected utilisation was well structured and it is noteworthy that there was concordance between the current utilisation data and the projected utilisation based on the clinical incidence of the disease;
- the research question was appropriate and related to the follow up of the earlier MSAC review - the diagnostic test is assessed from the perspective of being an additional test on top of conventional staging;
- direct evidence was limited - no studies linked improved health outcomes with the use of PET as a diagnostic test in the management of melanoma cancer;
- some studies provide indirect evidence - the studies have limitations in that they do not specifically relate to the research question as they used "suspected disease" rather than "actual disease" biopsy proven as inclusion criteria;
- the specific Australian data collection (Fullham 2006) found changes to management plans in 62% of cases and avoidance of surgery in 35% of cases and change in extent of surgery in 10% of cases - although indirect evidence, this is a detailed analysis of current Australian practice which demonstrates change in clinical practice based on access to PET scanning; and
- overall there is no significant cost difference between the 2 arms of the analysis ie., with and without PET as part of the diagnostic workup.

A general discussion of the report by the MSAC then followed resulting in the following recommendation.

## **Recommendation**

MSAC has considered the safety, effectiveness and cost-effectiveness of PET and PET/CT with [F-18]-fluorodeoxyglucose (FDG) compared with conventional staging for patients with biopsy-proven recurrent malignant melanoma considered to be potentially resectable with curative intent.

MSAC finds that FDG PET and PET/CT are safe.

MSAC finds that PET and PET/CT are more accurate than conventional staging for recurrent melanoma.

MSAC finds that PET and PET/CT are likely to improve patient outcomes through the avoidance of radical surgery which is unlikely to provide long-term benefit. MSAC finds PET and PET/CT to be potentially cost-saving compared with conventional staging for patients with biopsy-proven lymph node recurrence of melanoma who are considered for lymphadenectomy with curative intent. Cost savings may be greater in patients with visceral recurrences considered for curative surgery, but this could not be quantified.

MSAC recommends that public funding is supported for this procedure when referred by a specialist.

## **Outcome**

- Members voted unanimously on the recommendation.
- MSAC accepted the recommendation

## **Action**

- Forward the recommendation to the Minister for his consideration
- Forward suggested amendments to the evaluators.

Associate Professor Khafagi acknowledged the outstanding work of the advisory panel and the evaluators in the preparation of the three PET reports.

Dr Blamey acknowledged the hard work that Associate Professor Khafagi had put into the assessment and the high standard of the reports. He added that this report should be used as a model template and that the inclusion of the consumer views could be a feature of all future MSAC reports.

## **4 Progress Reports on Applications and References**

Dr Blamey advised that an application had been received for Clinical Gait Analysis however it was not eligible for MSAC assessment. Dr Richards explained that the service was largely being performed by a group of allied health professionals and as such was ineligible for assessment.

Dr Blamey advised that an application had been received for MammaPrint however it was not eligible for MSAC assessment as the testing for MammaPrint is undertaken outside of Australia.

Dr Blamey advised that an application had been received for Liquid Based Cytology which has been deemed eligible for MSAC assessment. At their recent teleconference, the MSAC Executive agreed that due to the potential impact of Liquid

Based Cytology on the current assessment of Reference 39 Human Papilloma Virus Triage for Pap Smears, that Reference 39 would be placed on hold pending the outcome of the assessment of Liquid Based Cytology.

Dr Blamey advised that an application had been received for Computer Assisted Total Knee Arthroplasty which has been deemed eligible for MSAC assessment.

The committee discussed whether specific brands or generic devices should be assessed where more than one device or technology is available in the market but only one applicant has sought an MSAC assessment. It was suggested that the Secretariat seek legal advice on this matter.

### **Outcome**

- Members noted current progress of all applications and references.

## **5 Other Business**

### **5.1 Capsule Endoscopy Data Collection**

M-TAG has advised that there is insufficient data in the Pill Cam data collection report for a comprehensive analysis to be completed. The MSAC agreed that further data is to be requested and the updated PiICAM Data Report will be presented at the November MSAC meeting.

### **Outcome**

- Members noted the data collection report.
- The MSAC requested that further data be presented at the November MSAC meeting.

### **5.2 AMA Submission – Hysteroscopic Sterilisation**

In March 2005, the Minister endorsed the conditional use of Item number 35633 until November 2007 for Hysteroscopic Sterilisation on the basis that MSAC would review additional data about patient outcomes to be collected by the manufacturer.

Members of the Committee advised that there has been a shift in clinical practice with this technology since the original MSAC assessment. A recommendation is to be made by MSAC at the November 2007 meeting based on the previous assessment together with the new evidence from Pivotal Trial Report.

The MSAC also requested that the Department review the evidence on safety to confirm the safety of the procedure.

### **Outcome**

- The original report and an updated to summary is to be included in the papers for the November 2007 MSAC meeting.

### **Action**

- Hysteroscopic Sterilisation to be included on the November 2007 MSAC meeting agenda.

- Preparation of an updated summary of Hysteroscopic Sterilisation for the November 2007 MSAC meeting.

### **5.3 Economic Subcommittee Update**

It was hoped that a draft review of the MSAC Economic Guidelines could be forwarded to the Economic Sub-committee in late October/early November for their consideration and consequently presented to MSAC in November 2007. However the preferred contractor, Professor Tony Harris of Monash University, had indicated that the work could not be completed until March 2008.

#### **Outcome**

- Members noted the Economic Subcommittee update.

### **5.4 Point of Care Testing Interim Report**

Data analysis is currently being undertaken and is expected to be completed by March 2008. Interim reports and papers will be circulated to a working party of the MSAC prior to the final report being made available to the full MSAC.

#### **Outcome**

- Members noted the Point of Care Testing Interim Report update.

### **5.5 Horizon Scanning Update**

Professor Kearney provided an update on Horizon Scanning, including the recent HealthPACT meeting held 17 August 2007. HealthPACT has recommended that MSAC undertake an assessment of Familial Hypercholesterolemia.

Professor Kearney has also indicated that PBAC have approached HealthPACT as they are interested in setting up a similar concept to Horizon Scanning in regards to pharmaceuticals.

Dr Blamey indicated that he has been the MSAC Representative to HealthPACT for some time and other MSAC members may have an interest in taking on this role.

#### **Outcome**

- Members noted the Horizon Scanning update.

### **5.6 Next meeting**

Dr Blamey advised that the 40<sup>th</sup> MSAC meeting will be held in Canberra on Thursday 22 and Friday 23 November 2007.

#### **Outcome**

- Members noted the dates for the next MSAC meeting to be held in Canberra.

### **5.7 HTA Review**

Ms Morris gave a brief background on the Banks Review and the HTA Review for the benefit of the new members.

## 5.8 1105 – CT Coronary Angiography

At the 25 May 2007 MSAC meeting the MSAC agreed the following recommendation for the 4<sup>th</sup> indication in the assessment of multi-slice computed tomography coronary angiography (MSCTCA) with the proviso that a rudimentary economic analysis be completed:

*MSAC has considered the safety, effectiveness and cost-effectiveness for multi-slice computed tomography coronary angiography (MSCTCA) compared with invasive coronary angiography (CA) for the following indications:*

- *evaluation of patients with symptoms consistent with coronary ischaemia;*
- *exclusion of coronary artery anomaly or fistula;*
- *evaluation of coronary arteries in patients with cardiomyopathy; and*
- *evaluation of coronary arteries in patients undergoing non-coronary cardiac surgery.*

*MSAC finds based on the available evidence that MSCTCA is safer than CA, by avoiding the risks associated with an invasive procedure.*

### **Indication 4**

- *Limited good quality evidence suggests that MSCTCA is as effective as CA in ruling out coronary artery disease in patients prior to non coronary cardiac surgery.*
- *Cost minimisation studies suggest MSCTCA is less costly than CA in ruling out coronary artery disease in patients prior to non coronary cardiac surgery.*
- *On the basis of limited evidence of effectiveness, the MSAC recommends that public funding is supported for MSCTCA in patients undergoing non-coronary cardiac surgery.*

On presentation and review of the updated data, MSAC agreed to uphold the recommendation from the 25 May 2007 MSAC meeting but requested refinements to the analysis for the 4<sup>th</sup> indication.

### **Outcome**

- MSAC agreed that more work needs to be completed on Indication 4 – more data is required on the numbers of patients that have had valve surgery
- MSAC agreed to uphold the recommendation for Indication 4 from the 25 May 2007 MSAC meeting pending the outcome of the further analysis.

### **Action**

- Project Officer, Advisory panel chair and evaluators to work together to complete the analysis for indication 4 and present to the MSAC Executive.

The meeting closed at 3.30pm on Friday 31 August 2007.