

Minutes - 28th Meeting

Meeting Minutes - Twenty Eighth Meeting - 17 November 2004 - Canberra

Members Present

Dr Stephen Blamey (Chair)
Associate Professor John Atherton
Dr Michael Cleary
Dr Kwun Fong
Dr Debra Graves
Professor John Horvath
Dr Terri Jackson
Professor Brendon Kearney
Dr Ray Kirk
Dr Michael Kitchener
Associate Professor Donald Perry-Keene
Professor Alan Lopez
Dr Ewa Piejko
Mrs Sheila Rimmer
Professor Jeffrey Robinson
Dr Doug Travis

MSAC Secretariat

Ms Brenda Campe
Dr Jane Cook
Ms Janette Dunn
Mr Peter Woodley

Visitors

Ms Judy Blazow
First Assistant Secretary
Department of Health and Ageing

Professor Karen Facey
Evidence Based Health Policy Consultant Scotland

Associate Professor Richard King
Internal Medicine Physician
Previous MSAC member

Ms Joan Stieber
Senior Health Policy Analyst, USA

Apologies

Professor Syd Bell
Dr Paul Craft
Dr Gerry FitzGerald
Professor Jane Hall
Ms Rosemary Huxtable
Professor Michael Solomon
Professor Ken Thomson

1. Opening of Meeting

1.1 Welcome and Apologies

The Chair opened the meeting at 09:05 and welcomed everyone.

1.2 Conflict of Interest and Confidentiality

The Chair advised members of the conflict of interest and confidentiality agreements. Members noted the following potential conflicts of interest:

- Associate Professor John Atherton advised of his possible conflict of interest as a referrer of drug eluting stents.
- Dr Kwun Fong advised of his possible conflict of interest as a referrer of DEXA scans.
- Dr Ray Kirk advised of his standing potential conflict of interest as an employee of a Contractor to MSAC.
- Dr Michael Kitchener advised of his possible conflict of interest as a provider of bone mineral densitometry testing.
- Associate Professor Donald Perry-Keene advised of his possible conflict of interest as a referrer of bone mineral densitometry testing.
- Dr Doug Travis advised of his possible conflict of interest as the Vice President of the Victorian Australian Medical Association.

2. Draft Report of the Twenty-Seventh MSAC Meeting held 18 August 2004

The Minutes from the 18 August 2004 meeting were accepted with minor amendments. Moved by Dr Kitchener and seconded by Dr Jackson.

2.1 Matters arising

2.1.1 Application 1058 – QuantiFERON TB Gold

Purpose: To inform MSAC members of the status of the report.

Background:

QuantiFERON-TB Gold is a test used to help detect latent infection with mycobacterium tuberculosis as well as to help detect active tuberculosis. Dr Michael Kitchener as Chair of the Advisory Panel spoke to this item. The QuantiFERON-TB test has changed many times since the inception of this review, which has involved revisions to the draft assessment report. The Applicant has informed the Advisory Panel that they have another technology that supersedes QuantiFERON-TB Gold and that they have unpublished data on sensitivity and specificity.

On 12 November the Applicant chose to withdraw this application, and expressed an intention to submit a new application.

Action:

- The Department to inform appropriate stakeholders of the Applicant's decision to withdraw the application.

2.1.2 Application 1067 – Genotypic resistance testing of antiretrovirals in HIV

Purpose: To seek MSAC's endorsement of the draft assessment report and to draft a recommendation to the Minister.

Background:

Patients with human immunodeficiency virus (HIV) infection are treated with antiretrovirals in order to reduce viral load and ultimately slow disease progression. Mutations often develop in HIV and genotypic resistance testing allows for the detection of genetic mutations in HIV that result in drug resistance.

The report was presented to the August 2004 MSAC meeting and it was found that further work on the economic analysis was required.

Dr Ewa Piejko spoke to this item saying that this test appeared safe but there was little evidence to demonstrate effectiveness and cost-effectiveness. Professor Jane Hall critiqued the economic section of the report and provided comments that were tabled at the meeting.

The Committee noted that, to the extent that public funding is available for this test, it is provided by the States and Territories.

There was discussion on the current funding arrangements and current clinical practice.

MSAC agreed to the following recommendation:

"MSAC found that genotypic resistance testing of antiretrovirals in HIV appeared to be safe and leads to changes in clinical management but there is insufficient evidence on effectiveness and cost-effectiveness to support Medicare funding."

Action:

Evaluators:

- To incorporate minor amendments to the report as directed.

Department:

- To send the recommendation to the Minister for endorsement.

3. Final Reports for MSAC Endorsement

3.1 Reference 19 – Bone Densitometry testing

Purpose: To seek MSAC's endorsement of the draft assessment report and to draft a recommendation to the Minister.

Background:

This reference was a referral from the Department to review the Medicare Benefits Schedule (MBS) item numbers relating to bone densitometry testing to determine the effectiveness of monitoring and the relevance of the indications in current clinical practice. This was referred to supplement an application received from Osteoporosis Australia. The Osteoporosis Australia application has been put on hold pending the decision from the Pharmaceutical Benefits Advisory Committee (PBAC) concerning the extension of indications to drug therapy used in the treatment of osteoporosis. Dr Piejko, Chair of the Advisory Panel, spoke to this item saying that while members of the Advisory Panel had been interested in looking at age related risk factors for osteoporosis, this was outside the remit of this review. She added that there was very little data on monitoring bone mineral density and the effectiveness of management but there was evidence to support DEXA as being effective in measuring bone mineral density.

Associate Professor Atherton critiqued this report adding that the evidence to predict future fractures using bone mineral densitometry testing for the selected indications was weak.

Dr Cook spoke on the review saying that, due to a lack of evidence, the report was unable to address the Department's initial questions concerning utilisation and appropriate timing of testing. Therefore, the Department will withdraw the referral and use the report for departmental information.

Action:

Evaluators:

- To ensure all studies that meet the inclusion criteria are included in the report; and
- To incorporate minor amendments as directed.

Department:

- To inform stakeholders that the referral has been withdrawn.

3.2 Reference 26 – Positron Emission Tomography (PET) for epilepsy

Purpose: To seek MSAC's endorsement of the draft assessment report and to draft a recommendation for the Minister.

Background:

Positron emission tomography (PET) is a minimally invasive method of nuclear medicine imaging that uses short lived radiopharmaceuticals to detect and assess perfusion and metabolic activity in various organ systems. PET is intended to image the functional metabolic activity of neurological structures and aid in the diagnosis and treatment planning for medically refractory epilepsy.

Associate Professor King, Chair of the Advisory Panel, spoke to this item saying that the review looked at patients with refractory epilepsy where surgery was being

considered. He added that the patient numbers were small. The Advisory Panel concluded that PET for epilepsy was safe, effective and likely to be cost saving. Dr Michael Cleary critiqued the report and suggested some minor changes. The Committee agreed to the following recommendation with Dr Kitchener and Dr Jackson abstaining:

"In relation to positron emission tomography (PET) prior to surgery in patients with refractory epilepsy, where there is no focus with concordant results on usual structural imaging and EEG, this assessment finds the technology:

- Is safe;
- Provides additional localising information in some patients, for whom a proportion will have good post-surgical outcomes as a consequence; and
- Is likely to be cost-effective in the long term.

MSAC recommended that public funding should be supported."

Action:

Evaluators:

- To incorporate minor amendments to the report as directed.

Department:

- To send the recommendation to the Minister for endorsement.

3.3 Reference 30 – Drug Eluting Stents

Purpose: To seek MSAC's endorsement of the draft assessment report and to draft a recommendation to the Minister.

Background:

Drug eluting stents are used in the treatment of coronary artery heart disease. The stents are inserted into the coronary arteries narrowed by atherosclerosis by a percutaneous procedure using a catheter loaded with the stent and an inflatable balloon.

This reference was received from the Health Policy Advisory Committee on Technology (HealthPACT). The procedure of inserting stents is currently covered under the MBS.

Associate Professor Richard King spoke to this item, saying that the objective of the report is to provide advice to the States and Territories. He added that drug eluting stenting appeared to be safe and effective. Cost-effectiveness was difficult to determine as there was a paucity of Australian data. The issue was whether overseas trial data was relevant to the Australian setting.

Dr Fong critiqued the report and agreed it could be used by the States and Territories as a guide for utilisation within the hospital settings.

It was noted that the review only reported on de novo single vessel lesions.

There was discussion on safety as it had been reported that some stents were presenting with deflation difficulties. It was noted that the Therapeutic Goods Administration had not felt this was a major problem and related to both bare metal stents and drug eluting stents. It was agreed that this information should be included in the safety section of the report.

The Committee agreed to the following finding:

"MSAC found that on the strength of current evidence regarding drug-eluting stents:

- The technology is as safe as bare metal stents for the treatment of de novo atherosclerotic lesions of the coronary arteries at up to one year post-procedure;
- The technology is more effective than bare metal stents in reducing the rates of revascularisation procedures at up to one year;
- There is insufficient evidence at this time to demonstrate a difference in the rates of myocardial infarction, coronary artery bypass grafting or mortality in patients receiving this technology compared to those receiving bare metal stents;
- There is some evidence that the technology is more effective than bare metal stents in reducing the rates of revascularisation at up to one year in patients with diabetes, long lesions greater than 18mm and small vessels less than 2.5cm. However there is insufficient evidence at this time to demonstrate any additional benefit in these and other subgroups of patients at high risk of stent restenosis;
- Cost-effectiveness is based on de novo single vessel lesions; and
- On the basis of trial data alone, the technology is cost-effective if a cost of \$3,700 to \$6,200 is considered acceptable to avoid a target lesion revascularisation. However a sensitivity analysis to estimate the cost-effectiveness in Australian clinical practice indicates that the cost per target lesion revascularisation avoided may be higher than this figure. Australian clinical practice data is required to resolve this uncertainty."

Action:

Evaluators:

- To incorporate minor amendments to the report as directed.

Department:

- To send the advice to the Minister noting that this may be used by the States and Territories to guide utilisation.

4. Progress Reports on Applications and References

The Chair advised members that the progress reports were available for information.

5. Other Issues

5.1 Meetings for 2005 – date and venue

Purpose: To confirm meeting dates and venues for 2005

Background:

Members were given the opportunity to nominate their preferred days.

The following meeting dates and venues were agreed:

29th MSAC meeting

Wednesday 2 March in Melbourne
30th MSAC meeting
Wednesday 18 May in Sydney
31st MSAC meeting
Wednesday 24 August in Brisbane
32nd MSAC meeting
Wednesday 16 November in Canberra

5.2 MSAC Review

Purpose: To update members on the progress of the review and to agree to action items.

Background:

Mr Woodley was invited to address the Committee. He thanked MSAC members for their feedback and added that there were still members he needed to approach. There were several common themes emerging from responses that included:

- Clear reasons for decisions
- Timely decisions
- Consistent use of evidence, and
- Including others in MSAC processes.

There was a discussion on how MSAC could respond to these issues. MSAC endorsed actions to commence before the conclusion of the review:

Clear reasons for decisions:

- Publish minutes of MSAC meetings on the web site,
- Develop and publicise guidelines and criteria for referring to MSAC technologies already in use.
- Produce a more standard template for MSAC reports, including sections that summarise expert opinion and a consumer perspective, to the extent that they might diverge from the published evidence.
- Publish with each assessment report a concise, 'plain English' summary of the basis for the recommendation, and distribute to interested organisations.

Timely decisions:

- Develop guidelines to allow for abbreviated assessments where either:
 - technologies are low cost and low risk,
 - there is insufficient evidence on which to base an assessment, or
 - extensive Level 1 evidence already exists.

Consistent use of evidence:

- Provide clearer direction to Advisory Panels about the nature of their involvement and their relationship with MSAC (Secretariat to prepare a standard presentation for Advisory Panel chairs, in consultation with Dr Blamey).
- Develop a standard format for protocols.

- Develop guidelines on the relationship of evidence requirements to other factors such as the nature of the procedure or technology, the size of the target group, and access to alternative treatments.
- Investigate a process of peer review for all assessments likely to lead to a negative recommendation.

Including others in MSAC processes

- Provide to applicants a copy of the assessment protocol, and any amendments if and as they occur.
- Provide to applicants a further copy of a draft assessment report if, following MSAC's consideration, the report changes significantly.
- Review the requirement for Advisory Panel members to maintain confidentiality.
- Hold regular seminars for industry and other potential applicants, and meetings with peak bodies to explain processes and receive feedback.

Action:

Department:

- Draft a letter from the Chair to stakeholders who contributed to the review; and
- Implement actions agreed by MSAC.

5.3 Guidelines for MSAC Assessment of Diagnostic Technologies

Purpose: To inform members of the progress of the document.

Background:

The NHMRC Clinical Trials Centre has developed guidelines to assist in assessing diagnostic technologies.

The Chair spoke to this item, observing that it was a comprehensive report.

There was discussion on trialling the template with live reviews to ascertain whether there was sufficient flexibility to manage issues that often arise with MSAC reviews such as:

- "small ticket item" services;
- small burden of disease services;
- screening technologies;
- interventional treatments and
- grey areas eg: where services are used for both diagnosis and monitoring.

Action:

Department:

- Ask the NHMRC Clinical Trials Centre to provide an update after the evaluators had assessed the guidelines.

5.4 HTAi Conference update

Purpose: To inform the members of the progress of the conference plans.

Background:

The 2006 HTAi conference is being held in Adelaide. At least 500 participants are expected. MSAC, PBAC, and the Asian Pacific health international organisation are all planning to hold meetings to coincide with the HTAi.

The HTAi working party includes: Dr Stephen Blamey, Professor Brendon Kearney, Professor Guy Maddern, Professor Lloyd Sansom and Ms Rosemary Huxtable.

Priorities are organising the scientific committee, marketing, sponsorship, budgets and funding agreements.

The Chair encouraged all members to consider attending the 2005 HTAi Conference 20-22 June in Rome.

5.5 HealthPACT update

Purpose: To update members on the HealthPACT.

Background:

HealthPACT was set up to provide advice on the implications of new medical technologies. Horizon scanning reviews are undertaken and some technologies are referred to MSAC for a full health technology assessment.

Professor Kearney spoke to this item and informed members that HealthPACT met on 10 and 11 November and a full report will be presented to MSAC at the March meeting.

Issues the committee needed to address included its governance and funding arrangements, and the relationship to MSAC and AHMAC.

Action:

- HealthPACT to provide a report to MSAC at the March 2005 MSAC meeting.

5.6 Positron Emission Tomography (PET)

Purpose: To seek MSAC's endorsement of unqualified public funding on the MBS for PET for solitary pulmonary nodules and non-small cell lung cancers, to replace the current interim funding arrangements.

Background:

A PET working group has been formed consisting of Professor Brendon Kearney, Dr Michael Kitchener, Associate Professor Richard King and Professor John Simes, and Departmental officers to review PET indications.

Associate Professor King and Professor Brendon Kearney spoke to this item. There was discussion on the data collection requirements for PET indications, particularly for demographic and specificity data. There was discussion about how specificity data would be collected with the introduction of public funding and it was suggested that a random audit could be undertaken to determine utilisation patterns in Australia.

There was discussion on the issue of non-funded PET centres accessing public funding as currently only approved PET centres can access such funding. It was agreed that this was a matter for the department to advise on.

The Committee agreed to the following recommendation with Dr Fong and Dr Kitchener abstaining:

"MSAC agreed that public funding for PET for solitary pulmonary nodules and non-small cell lung cancers should be supported."

Action:

Department:

- Send the recommendation to the Minister for endorsement.

6. Close

Professor Facey and Ms Stieber thanked the Committee for allowing them to participate in the meeting.

The Chair thanked members for attending and closed the meeting at 14:45pm.