

# **Minutes - 29th Meeting**

**2 March 2005 Melbourne**

## **Members Present**

Dr Stephen Blamey (Chair)  
Associate Professor John Atherton  
Professor Syd Bell  
Dr Michael Cleary  
Dr Paul Craft  
Dr Kwun Fong  
Dr Debra Graves  
Professor Jane Hall  
Dr Terri Jackson  
Professor Brendon Kearney  
Dr Ray Kirk  
Dr Michael Kitchener  
Associate Professor Donald Perry-Keene  
Dr Ewa Piejko  
Ms Samantha Robertson  
Professor Jeffrey Robinson  
Dr Doug Travis

## **Apologies**

Dr Gerry FitzGerald  
Professor John Horvath  
Professor Alan Lopez  
Mrs Sheila Rimmer  
Professor Michael Solomon  
Professor Ken Thomson

## **MSAC Secretariat**

Dr Jane Cook  
Mr Tony Coles  
Ms Janette Dunn  
Ms Alex Lloyd  
Mr Rob Seawright  
Mr Peter Woodley

## **Visitors**

Dr John Primrose  
Pharmaceutical Medical Advisor  
Department of Health and Ageing

## **1. Opening of meeting**

### **1.1 Welcome and Apologies**

The Chair opened the meeting at 0900 and welcomed everyone.

Apologies were received from Dr Gerry FitzGerald, Professor John Horvath, Professor Alan Lopez, Mrs Sheila Rimmer, Professor Michael Solomon and Professor Ken Thomson.

The Chair introduced Ms Samantha Robertson, Acting Assistant Secretary, Medicare Benefits Branch, as the department's MSAC representative.

The Chair advised members that Dr John Primrose, previous Medical Advisor to MSAC, was joining the meeting to present Application 1042 - Biventricular synchronisation therapy for severe heart failure.

### **1.2 Conflict of interest and Confidentiality**

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

- Associate Professor John Atherton advised of his possible conflict of interest as a referrer of cardiac synchronisation therapy.
- Professor Brendon Kearney advised of his potential conflict of interest as Director at the Institute of Medical and Veterinary Science (a provider of pathology services).
- Dr Ray Kirk advised of his standing potential conflict of interest as an employer of a Contractor to MSAC.
- Dr Michael Kitchener advised of his possible conflict of interest as a provider to the sentinel node procedure. He also declared a potential conflict with Reference 25 – Magnetic resonance cholangiopancreatography, whereby he would abstain from the vote.
- Professor Jeffrey Robinson advised of his potential conflict of interest as Chair of the Board of Repromed and indicated that he would abstain from voting in matters relating to References 6a and 6b.
- Dr Doug Travis advised of his possible conflict of interest as the Vice President of the Victorian Australian Medical Association. He also advised of his conflict of interest with Application 1068 – Prostate specific antigen near patient testing for diagnosis and management of prostate cancer and noted that he would leave the room for this discussion.

## **2. Draft Report of the twenty-eight MSAC Meeting held 17 November 2004**

The Minutes from the 17 November 2005 were accepted with minor amendments by the Committee.

## 2.1 Matters arising

### 2.1.1 Reference 6a - Surgical Retrieval of Sperm for Intracytoplasmic Sperm Injection; and Reference 6b - Intracytoplasmic Sperm Injection Using Ejaculated Sperm

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

**Background:** The Chair spoke to this item and explained that this was a referral from the Medicare Benefits Branch in October 2000. The reviews were put on hold pending the outcome of the UK Working Group, established by the Medical Research Council and the Human Fertilisation and Embryology Authority to review the safety of assisted reproductive technologies (ART).

The UK Working Group contained little information on intracytoplasmic sperm injection (ICSI). The report concluded that the main outcome risk for ART is multiple births, which does not appear to be specific to ICSI, but there is a forty per cent increase in foetal abnormalities.

The Committee noted that Australia has a comprehensive database and it is expected that the utilisation rate should not exceed international rates. It was noted that ART multiple births were decreasing in Australia. The underlying rate of foetal abnormalities is small. The alternative is donor sperm. This is seldom the preferred option of informed couples with infertility.

The Chair added that ART is currently funded and that about sixty per cent of invitro fertilisation uses ICSI. The Chair added that the previous MSAC recommendations remain appropriate.

Dr Craft critiqued the report and agreed with the Chair that the UK Working Group report provided little material information not available when MSAC previously reviewed this issue and agreed the MSAC recommendations were appropriate.

**MSAC Recommendation:** The following recommendations were accepted with Professor Robinson abstaining.

#### **Surgical Sperm retrieval and intracytoplasmic sperm injection:**

"MSAC recommended that on the strength of evidence pertaining to surgical retrieval of sperm for intracytoplasmic sperm injection, public funding should be supported for percutaneous needle aspiration and open (surgical) biopsy procedures for the surgical retrieval of sperm, and intracytoplasmic sperm injection using surgically retrieved sperm for men with azoospermia (obstructive or non-obstructive), severe oligospermia, anejaculation not responsive to electroejaculation or vibrostimulation, radical prostatectomy, complete teratozoospermia, complete necrozoospermia or complete sperm immotility."

#### **Intracytoplasmic sperm injection using ejaculated sperm:**

"The MSAC recommended that, on the strength of the evidence pertaining to the safety, effectiveness and cost-effectiveness of intracytoplasmic sperm injection using ejaculated sperm, public funding should be supported for use of this procedure in couples with male factor infertility, under the following circumstances:

- when there are severe semen abnormalities and fertilisation with standard IVF is highly unlikely to be successful; and
- when a previous cycle of IVF, fertilisation has failed."

**Action:**

- The Department to send the recommendation to the Minister for endorsement; and
- The Evaluators to incorporate the minor amendments to the report as directed.

**3. Final Reports for MSAC Endorsement****3.1 Application 1042 - Biventricular synchronisation therapy for severe heart failure**

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

**Background:** Dr Primrose addressed this item. Biventricular pacing is used for patients with moderate to severe heart failure. The aim is to restore synchronisation between the left and right ventricles. There was a clinical need for this procedure in patients with Grade III – cardiac failure with mild dyspnoea on exertion and Grade IV - cardiac failure with dyspnoea at rest, according to the New York Heart Association classification.

The procedure appears to be safe and is as effective as pharmacotherapy. Fatality from implantation is rare. There is good evidence that cardiac resynchronisation therapy improves haemodynamic parameters, which results in reduced hospitalisation. Cardiac resynchronisation therapy is more expensive than the comparator, pharmacotherapy, due to hospitalisation. It was noted that initial hospitalisation was not taken into account for pharmacotherapy.

The Companion Trial's end point was hospitalisation or death and the survival end point was difficult to demonstrate. The projected benefit from the trial over a five-year period indicates that the cost-effectiveness ratio would drop but Grade four cardiac patients would be unlikely to survive the five years to show procedural benefit. The Companion Trial showed that there were improved outcomes with the addition of a defibrillator.

Associate Professor Perry-Keene critiqued the report and said that although there was some good factual data there was insufficient long-term data. He agreed that the technology was more expensive than pharmacotherapy.

There was discussion on the predicted outcomes over five years and the members agreed there was insufficient long-term data to show there is a significant impact on patients' lives, and the time and cost of hospitalisation.

**MSAC Recommendation:** Pending

The Executive subsequently informed the committee that its recommendation should be held over in order to take into account the outcome and analysis of a belated but relevant report on this subject.

**3.2 Application 1065 – Sentinel Node Biopsy**

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

**Background:** Dr Piejko addressed this item saying that sentinel node biopsy is a diagnostic procedure used as an alternative to breast cancer surgery with the comparator being axillary clearance, which in itself has a high incidence of morbidity, mainly lymphoedema.

The assessment resulted from concerns that the most common cause of secondary lymphoedema is axillary node dissection.

Sentinel node biopsy appears to reduce morbidity, hospitalisation and assists in the management of breast cancer. The procedure can be performed at the same time as breast surgery/axillary clearance.

Australia is participating in international trials, which will provide long-term outcomes. The report results are expected in five years.

Dr Piejko said that the procedure appeared to be safe and effective but there was insufficient long-term data. Cost-effectiveness was based on cost minimisation, the cost to avoid lymphoedema. Therefore, the procedure appeared cost-effective.

Professor Robinson critiqued the report and agreed the procedure appeared safe and effective and added that long-term data would provide survival outcomes. The studies did not rely on consecutive patients and did not reveal whether using both diagnostic techniques (dye and gamma probe) provided a better result. He added that the procedure appeared to be a learning curve and this was dependent on a number of factors – site of injection; time from diagnosis and biopsy; and the type of pathology service requested.

**MSAC Recommendation:** The following recommendation was accepted with Dr Kitchener abstaining.

Sentinel node biopsy appears to be safe and effective in identifying sentinel lymph nodes resulting in the reduction of complications due to axillary lymph node dissection, in particular lymphoedema. Long term outcomes are uncertain. MSAC recommends that interim funding for sentinel lymph node biopsy should be provided pending the outcome of trials already in progress and should be reviewed in five years.

**Action:**

- The Department to send the recommendation to the Minister for endorsement;
- The Evaluators to incorporate the minor amendments to the report as directed.

### **3.3 Application 1068 – Prostate Specific Antigen (PSA) near patient testing for diagnosis and management of prostate cancer**

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

**Background:** Dr Travis left the meeting for this discussion. Professor Kearney addressed this item saying that PSA testing is an established laboratory test and that the Application was seeking its use in the surgeons' rooms following a diagnosis of prostate cancer and surgery. Rise in PSA results in changes in patient management. He added that the test was safe but there was no evidence to assess effectiveness and cost-effectiveness compared with laboratory testing methods.

Dr Graves critiqued this report saying that it was a good report and that safety was only established in the laboratory environment, where quality assurance can be guaranteed.

There was discussion on the use of the test in the specialists' rooms but the Committee

concluded that there was insufficient supporting evidence. MSAC agreed that the test should remain in the laboratory setting.

**MSAC Recommendation:**

"MSAC recommended that on the strength of evidence pertaining to safety, effectiveness and cost-effectiveness of prostate specific antigen testing for the diagnosis and management of prostate cancer, the current funding arrangements remain unchanged."

**Action:**

- The Department to send the recommendation to the Minister for endorsement;
- The Evaluators to incorporate the minor amendments to the report as directed.

**3.4 Reference 20 – Carotid Percutaneous Transluminal Angioplasty with Stenting**

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

**Background:** Dr Travis addressed this item. Carotid percutaneous transluminal angioplasty with stenting (CPTAS) is a minimally invasive, replacement procedure for carotid endarterectomy. The procedure is similar to coronary angiogram and the evidence showed that using a neuroprotection device made the procedure safer. Neuroprotection was not used if there was difficulty getting the balloon past the lesion. The procedure can be done using local anaesthetic and patients who are not considered suitable for a general anaesthetic and/or open surgery would benefit from this procedure.

The studies used both symptomatic and asymptomatic patients and there was some discussion as to whether asymptomatic patients should be treated.

The studies were based on comparisons with carotid endarterectomy and balloon angioplasty and described the technology in clinical practice. The safety and effectiveness of CPTAS appeared to be the same as carotid endarterectomy when neuroprotection was used. The procedure was more expensive than the comparator, due to the cost of the device used, without a measurable gain.

Dr Jackson critiqued the report and agreed that the procedure appeared as clinically equivalent for safety and effectiveness as carotid endarterectomy when using neuroprotection and agreed that the procedure was more expensive.

**MSAC Recommendation:**

"MSAC found that the safety and effectiveness of carotid percutaneous transluminal angioplasty with stenting (CPTAS) with neuroprotection is equivalent to carotid endarterectomy (CEA) in patients who meet the usual clinical indications for CEA. Additional effectiveness has not been demonstrated for CPTAS over CEA.

Neuroprotection devices should be used for CPTAS where feasible.

The unmeasured value of patient preference has been recognised. However, direct healthcare costs of CPTAS are higher, without a measurable improvement in outcome.

CPTAS should be funded for patients who meet the criteria for CEA but are unfit for open surgery (CEA). At current costs public funding for CPTAS is not recommended for other patient groups."

**Action:**

- The Department to send the recommendation to the Minister for endorsement;
- The Evaluators to incorporate the minor amendments to the report as directed.

**3.5 Reference 25 – Magnetic Resonance Cholangiopancreatography (MRCP)**

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

**Background:** Professor Kearney addressed this item and informed the members that this was the second review of this procedure. The assessment compared the roles of MRCP and ERCP in the management of gall bladder and common bile duct disease. The procedure appeared to be as safe and equivalent in term of effectiveness in specificity and sensitivity to ERCP. MRCP was cost-effective in making a diagnosis. There was a place for both MRCP and ERCP in the clinical setting. CT-IVCP was also considered but there was little evidence of its effectiveness.

Dr Kitchener critiqued the report saying it was comprehensive and he agreed that the procedure was safe, effective and cost-effective.

**MSAC Recommendation:**

The following recommendation was agreed with Dr Kitchener abstaining:

"MSAC recommended that on the strength of evidence pertaining to the safety, effectiveness and cost-effectiveness of magnetic resonance cholangiopancreatography public funding should be supported for this procedure when referred by specialists."

**Action:**

- The Department to send the recommendation to the Minister for endorsement;
- The Evaluators to incorporate the minor amendments to the report as directed.

**3.6 Reference 31 – Endometrial Ablation Techniques for Chronic Menorrhagia**

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

**Background:** Dr Piejko addressed this item saying that the assessment reviewed first and second-generation techniques for treating endometrial ablation techniques for chronic menorrhagia. The patients were women who have completed child bearing and the procedure offered these women an alternative to hysterectomy.

Each study compared different technologies and the measurement of menorrhagia was subjective. The outcomes sought were no further treatment and no hysterectomy.

The second-generation techniques were as safe and effective as the first generation techniques but the second-generation techniques were more expensive.

Dr Kirk critiqued the report and agreed the second-generation techniques appeared as safe and effective as the first generation techniques.

There was discussion on the economic model used. The model was based on UK NICE data, where women present for treatment at age 41, whereas the Australian data suggests that women present for treatment at age 48. The model needs to reflect the Australian setting before a decision can be finalised.

**Action:**

- The Department to rework the economic considerations and present the report to the May 2005 MSAC meeting.

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

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

**5. Other issues****5.1 MSAC Review**

**Purpose:** To update members on the progress of the review.

**Background:** Mr Woodley spoke to this item and highlighted areas that needed the member's attention. The Chair asked that small focus groups of two to three members discuss the different issues raised by the review and collate these in a submission for the May 2005 MSAC meeting.

Mr Woodley informed members that an MSAC Economic Working Party has been set up to design guidelines for the economic considerations and this group met 1 March 2005. Members included Dr Craft, Professor Hall, Dr Jackson and Dr Kirk. A workshop will be organised for the Tuesday 17 May 2005 to discuss issues.

**Action:**

- The Department to organise teleconference for the focus groups and prepare papers for the May meeting.

**5.2 Guidelines for the Assessment of Diagnostic Technologies**

**Purpose:** To endorse the document.

**Background:** The guidelines are intended to assist in the assessment of diagnostic technologies and are currently being used by evaluators for a small number of MSAC reviews.

The members noted that this would be a changing document due to the development of the economic guidelines and agreed it could be distributed after some minor amendments.

**Action:**

- The Evaluators to incorporate the minor amendments to the document as directed.

**5.3 HealthPACT update**

**Purpose:** To update members on HealthPACT.

**Background:** Professor Kearney spoke to this item and informed members that HealthPACT was established a year ago as part of MSAC's fourth term of reference. HealthPACT would operate as a sub-committee of MSAC and would provide updates on horizon scanning technologies. It is envisaged that HealthPACT would provide

approximately 50 prioritising summaries on new and emerging technologies. MSAC agreed with this arrangement.

#### **5.4 HTAi Conferences - 2005 in Rome and 2006 in Australia**

**Purpose:** To update members on the arrangements for the HTAi 2005 and 2006 conference.

**Background:** The Chair spoke to this item and encouraged all members to indicate their interest in attending the 2005 conference in Rome. The department will indicate how many members can be supported and it is expected these members would contribute their expertise to the 2006 conference. He added that the Commonwealth and MSAC were major sponsors of the 2006 conference.

**Action:**

- Members to indicate their interest in attending the 2005 conference.

#### **6. Close:**

The next MSAC meeting is scheduled for Wednesday 18 May 2005 in Sydney, venue to be confirmed.