

**MINUTES of the
Medical Services Advisory Committee 41st
Meeting
Friday 7 March 2008
Scarborough House, Department of Health Canberra**

1.1 Welcome, introductions and apologies

Members

Dr Stephen Blamey (Chair)
Professor Brendon Kearney (Deputy Chair)
Associate Professor John Atherton
Associate Professor Michael Cleary
Professor Geoff Farrell
Dr Kwun Fong
Professor Richard Fox
Dr Jane Hall
Professor John Horvath
Associate Professor Terri Jackson
Associate Professor Fred Khafagi
Dr Ray Kirk
Dr Ewa Piejko
Mrs Sheila Rimmer
Dr Judith Soper
Professor Ken Thomson
Mr Peter Woodley

DoHA Staff

Mr Tony Kingdon
Ms Jane-Ann Jones
Dr Brian Richards
Mr Bill Matthews
Ms Marcela Valenzuela

DoHA Staff Apologies

Ms Clare Poprawski

Members Apologies

Dr Bill Glasson (Deputy Chair)
Dr Ian Prosser
Dr David Wood
Dr Paul Craft

- The Chair welcomed Professor Farrell to his first MSAC meeting and noted the apologies.

1.2 Conflict of interest declaration

The Chair noted that prior to today's meeting, the Secretariat had sent out to all members a request for information regarding any potential Conflict of Interest with items on the Agenda. He noted no responses had been received.

The Chair asked members to declare any potential Conflict of Interest verbally.

Outcome

- Dr Blamey – declared a conflict with 1113 Endovenous Laser Treatment (ELVT) and with 1112 Intra-gastric Balloon, as he performs an alternative procedure for each. Members agreed that given his Conflict of Interest with the intra-gastric balloon, the Chair should step down and absent himself from the discussion and Professor Kearney, Deputy Chair, would chair this item.
- Professor Thomson – declared a conflict with 1113 ELVT as he has shares in the company that imports the machine. Members agreed that given the Conflict of Interest Dr Thomson should absent himself from this item.
- Dr Fong – declared a potential conflict with 1108 Endobronchial Ultrasound, though, he would not gain financially. Members agreed that this disclosure did not raise a Conflict of Interest.

2.1 Draft minutes and Actions Arising from the 40th MSAC meeting 23 November 2007

Action

- Members were asked to accept the Minutes.

- In response, Dr Judy Soper declared that under Conflict of Interest of the Minutes she is incorrectly referred to as working in a private practice, where it should be noted she is a partner in the practice but does not currently work there.
- Members requested the use of the terminology “clinically relevant” instead of “clinical practice”.
- Subject to these amendments the Minutes of November 23, 2007 were accepted as a true and accurate record of that meeting.

2.2 Actions arising from the minutes of the 40th MSAC meeting

- The MSAC recommendations formulated at the 40th meeting are in the process of being forwarded to the Minister for her consideration.
- Mr Woodley indicated that the Report for the Australia Health Ministers’ Advisory Committee on Neonatal Hearing Screening is close to finalisation.

3 Final Reports for MSAC Endorsement

The Chair advised that there were 4 final reports for consideration at this meeting.

3.1 1106 – Endoscopic Argon Plasma Coagulation

Dr Blamey invited Professor Thomson, Chair of the Advisory Panel, to introduce the report.

Summary of Application

Use of an argon plasma coagulator (APC) involves the instillation of argon gas to assist in the coagulation of intestinal bleeding. This is undertaken whilst performing endoscopic procedures. Current procedures involve the use of standard haemostatic thermal techniques (diathermy unit / heater probe), or laser therapy. APC therapy has an advantage over these therapies in that it can be applied to large surface areas of the intestine.

Safety

Studies suggest that APC is a safe treatment for all seven conditions; however the evidence was sparse in some cases. Where comparative studies were available, APC was at least as safe as the alternative Medicare-listed procedure.

Effectiveness

From the available data, APC was significantly more effective than the heater probe in the coagulation of bleeding ulcers. The studies suggested that APC was at least as effective as any comparative procedure in the treatment of Barrett’s oesophagus, GAVE (gastric antral vascular ectasia, or ‘watermelon stomach’), and radiation proctitis.

There is no comparative evidence available for the use of APC in the treatment of bleeding angiodysplasia, post-polypectomy bleeding or for the ablation of tumor overgrowth through stents; therefore, no estimation of its effectiveness compared to an alternative Medicare-listed procedure could be made.

Economic considerations

A modelled cost-effectiveness analysis was conducted based on the improved effectiveness of APC as determined by the meta-analysis. Based on a number of estimates and assumptions, APC was determined to be more effective and less costly than the comparator, the heater probe.

Critique by Professor Richard Fox

Dr Fox provided a brief critique, indicating that this is a complex report describing the application of a single technology for the treatment of seven distinct conditions. He suggested a simpler approach would have been to link assessment of treatment and economic considerations together for each of the separate conditions.

Discussion

The MSAC consensus was that APC is already widely used in the Australian health care system and while the evidence was centred around Barrett’s Oesophagus and bleeding peptic ulcers there is a strong link with the other indications. This evidence showed that APC is as safe and effective as the comparator and the cost is similar to the comparator. On this basis MSAC made the following recommendation:

Recommendation

MSAC has considered the safety, effectiveness and cost-effectiveness of endoscopic argon plasma coagulation compared with alternative modalities used to secure gastrointestinal haemostasis under certain circumstances and for the ablation of tumorous growth through or over oesophageal stents.

MSAC finds that argon plasma coagulation is as safe as other forms of heat coagulation or local vasoconstrictor therapy in peptic ulcer disease. Although data for the other conditions with low incidence is very limited, argon plasma coagulation is considered by inference to be similar in safety profile for haemostasis of radiation proctitis, haemostasis of bleeding angiodysplasia, coagulation of post-polypectomy bleeding, other allied conditions of low incidence (haemostasis of gastric antral vascular ectasia (GAVE), and ablation of tumorous growth through or over oesophageal stents).

MSAC considers that argon plasma coagulation is at least as effective and as cost-effective as other local methods of treatment of bleeding in peptic ulcer disease.

There are insufficient data to demonstrate effectiveness and cost-effectiveness for haemostasis of radiation proctitis, haemostasis of bleeding angiodysplasia, coagulation of post-polypectomy bleeding, other allied conditions of low incidence (haemostasis of gastric antral vascular ectasia (GAVE), and ablation of tumorous growth through or over oesophageal stents). MSAC considers that the incidence of these conditions is insufficient to allow the collection of these data.

MSAC recommends that public funding is supported for endoscopic argon plasma coagulation as an option for the treatment of peptic ulcer disease and other less common causes of gastrointestinal bleeding including radiation proctitis, bleeding angiodysplasia, post-polypectomy bleeding, gastric antral vascular ectasia (GAVE), and for ablation of tumorous growth through or over oesophageal stents.

Outcome

- Dr Hall abstained from voting as she is currently working with one of the contracted evaluators. All other members voted in favour of the recommendation.

Action

- Recommendation to be forwarded to the Minister.

3.2 1108 – Endoscopic Bronchial Ultrasound

Dr Blamey invited Dr Fong, as chair of the Advisory Panel to introduce the report.

Summary of Application

Endobronchial ultrasound (EBUS) is a minimally invasive procedure that involves an ultrasound probe being introduced into the thoracic region via the bronchial airway. This ultrasound probe can then be used to generate images of pulmonary and mediastinal structures. EBUS imaging can be used alone or to guide sampling procedures such as endobronchial biopsy (EBBX), transbronchial needle aspiration (TBNA) or transbronchial biopsy (TBBX).

Safety

EBUS-guided procedures for non-small cell lung cancer (NSCLC) staging, diagnosis of mediastinal/hilar masses, depth diagnosis of endobronchial cancers and diagnosis of peripheral lung lesions appear to be as safe as other minimally-invasive diagnosis tests.

Effectiveness

Evidence from the literature indicated the diagnostic yield of EBUS-TBNA to be greater than TBNA alone in NSCLC staging and diagnosis of mediastinal/hilar masses. It was also found that the sensitivity and diagnostic yield of EBUS-TBNA was at least equivalent to EBUS-FNA (fine needle aspiration) in specific subgroups.

No trials were identified that compared the diagnostic performance of EBUS with or without EBBX (endobronchial biopsy) to EBBX alone in the depth diagnosis of endobronchial cancers.

The evidence suggests that EBUS-TBBX is equal to the comparators for the diagnosis of peripheral lung lesion. The studies evaluated found that compared to the comparators, EBUS-TBBX produced greater diagnostic yield for regular and smaller (<3cm) peripheral lung lesions.

Economic considerations

The economic analysis indicated that use of EBUS-TBNA was associated with cost savings when compared with TBNA for NSCLC staging or diagnosing mediastinal/hilar masses. The use of EBUS-TBBX for diagnosis of peripheral lung lesions <3cm diameter was estimated to generate cost savings compared with TBBX. This reflected the economic benefits associated with improved yield offered by using EBUS procedures.

EBUS guidance could replace more invasive biopsy modalities such as mediastinoscopy for some patients as first line assessment for lung cancer, thereby generating further costs offsets.

Critique by Dr Farrell

Dr Farrell was satisfied with the report, finding it easy to read and logical, the conclusion was valid, and the economics well-reasoned.

Discussion

The MSAC agreed that EBUS is a less invasive technique, is as safe, more effective and likely to be cost saving when compared to current treatments for the staging of non-small cell lung cancer, and the investigation of mediastinal/hilar masses and peripheral lung lesions. However, the MSAC agreed that there was insufficient evidence at this time to consider funding EBUS for the evaluation of endobronchial cancer. On this basis the MSAC made the following recommendation:

Recommendation

MSAC has considered the safety, effectiveness and cost-effectiveness of Endobronchial Ultrasound (EBUS)-guided procedures for the investigation of non-small cell lung cancer, mediastinal/hilar masses, endobronchial cancer and peripheral lung lesions compared to mediastinoscopy and transbronchial needle aspiration.

The MSAC finds that the EBUS-guided procedures for the staging of non-small cell lung cancer, and the investigation of mediastinal/hilar masses and peripheral lung lesions is safer, more effective and likely to be cost saving when compared to mediastinoscopy and transbronchial needle aspiration.

MSAC finds that, though safe, there is insufficient evidence on the effectiveness and cost-effectiveness of the EBUS-guided procedure for the evaluation of endobronchial cancer.

MSAC recommends that public funding should be supported for EBUS-guided procedures for the staging of non-small cell lung cancer, and the investigation of mediastinal/hilar masses and peripheral lung lesions.

MSAC recommends that public funding should not be supported for the EBUS-guided procedure for the evaluation of endobronchial cancer.

Outcome

- Members voted unanimously for the recommendation.

Action

- Final Report to be forwarded to the Minister.

3.3 1112 – Intra-gastric Balloon

Professor Kearney chaired the item in Dr Blamey's absence, and invited Associate Professor Cleary to introduce the report.

Summary of Application

The intra-gastric balloon is a smooth, spherical, silicone elastomer balloon that is endoscopically inserted into the stomach via the oesophagus and filled with up to 700 ml of normal saline or air. It is designed to remain within the stomach for up to six to twelve months and is then deflated and removed under endoscopic vision. It limits food consumption and promotes weight loss by inducing an early and prolonged feeling of satiety after a small meal. It is not an alternative to surgical weight loss procedures such as vertical banded gastroplasty, gastric bypass or gastric banding.

Safety

The intra-gastric balloon has been proposed for use in clinical practice in addition to conventional obesity treatment (diet, exercise and behaviour modification); therefore additional risks are to be expected. Complications may occur either during the placement/removal of the balloon or during the balloon treatment.

There is a balance between the added health risks associated with the balloon and any potential benefits it may have with regard to weight loss resulting from the balloon treatment. However, although rare, major complications (including gastric perforation and death) have been reported in the literature as being associated with the procedure. Minor complications (nausea and vomiting) have also been associated with the balloon treatment.

Effectiveness

The evidence available at present on the effectiveness of the intra-gastric balloon in the temporary treatment of morbid obesity is inconclusive.

Intra-gastric balloon in combination with conventional obesity treatments are effective at assisting weight loss in morbidly obese patients. However, it is unclear whether they provide any additional benefit to conventional obesity treatments. Furthermore there is little evidence regarding whether any weight loss from intra-gastric balloon is sustained in the long term. More evidence is needed to assess the impact of the intra-gastric balloon, in addition to diet, on short-term weight loss in morbidly obese patients.

Economic considerations

The evaluators and the Advisory Panel concluded that there was insufficient evidence on safety and effectiveness to warrant a full economic evaluation. As an alternative, an analysis of the costs was conducted, which revealed an estimated total cost to the Australian healthcare system of \$23,582,800 per year in addition to the costs of conventional obesity treatment, of which \$1,847,996 would be borne by the Australian Government.

Critique by Dr Soper

Dr Soper indicated that there was limited evidence and only few high quality studies available. To add to available data the comparator was +/- conventional obesity treatment in order to include further studies. The significant side effects of the treatment were a concern. The report was well written and reasonably easy to read considering the limited and contradictory evidence.

Discussion

The MSAC noted that the Australian Government has recognised obesity as one of the national priority health areas. While there appeared to be potential benefits in using the intra-gastric balloon, the MSAC was concerned about the "not insignificant" major complications and the lack of clear evidence of effectiveness. On this basis the MSAC made the following recommendation:

Recommendation

MSAC has considered the safety, and clinical effectiveness of intragastric balloons for the temporary management of morbid obesity in addition to conventional treatment such as diet, exercise and behaviour modification.

MSAC finds that intragastric balloons used for the temporary management of morbid obesity pose additional risks to patients when compared to the standard treatment for morbid obesity and that they do not provide additional clinical benefits over standard treatment.

There may be a role for the temporary placement of intragastric balloons for the management of the super obese patient prior to bariatric surgery, however evidence to support this approach is limited.

MSAC finds that the use of intragastric balloons for the temporary management of morbid obesity is less cost-effective than standard treatment for morbid obesity.

MSAC recommends that public funding is not supported for this procedure.

Outcome

- Dr Blamey abstained from voting due to his stated Conflict of Interest. All other members voted in favour of the recommendation that public funding not be supported.

MSAC accepted the recommendation

Action

- Final recommendation to be forwarded to the Minister.

3.4 1113 – Endovenous Laser Treatment

In Dr Wood's absence, Dr Blamey invited Dr Piejko, as the second MSAC member on the Advisory Panel to speak to this item. Due to his stated Conflict of Interest, Dr Thomson absented himself.

This assessment was first considered by the MSAC at the 23 November 2007 meeting, but was referred back to the Advisory Panel for further economic analysis.

Summary of Application

The ELT procedure involves introduction of a laser probe into the lumen of the saphenous vein, followed by the application of laser energy which occludes the vein. The fibre and catheter are slowly withdrawn, occluding the length of the vein and abolishing venous reflux.

Safety

From the available literature, it appears that the ELT procedure is at least as safe as the comparative procedure of conventional surgical saphenous junction ligation with or without vein stripping.

Effectiveness

From the available literature, ELT appears to be potentially more effective in the short term, and at least as effective overall, as the comparative procedure of saphenous junction ligation and vein stripping for the treatment of varicose veins. This procedure should take less time, be less invasive and therefore patients may spend less time in hospital.

Economic considerations

ELT appears at least as effective as the comparator, with potentially reduced short-term postoperative pain and faster resumption of normal activities. The Advisory Panel felt that the procedure would be cost effective, and possibly cost saving over time. Expert opinion was that there would be an initial increase of approximately 50% in services which will reduce to 10% over 5 years.

At the November 2007 the MSAC suggested that the economic analysis of the report be updated to take into account and model the Australian population with symptomatic varicose veins who would not have had surgery/treatment under the Medicare Benefits Schedule (MBS) but who potentially may opt for this non-invasive treatment were it to become available on the MBS.

Critique by Dr Fong

Dr Fong commented that the draft Report was in the main, well written, appropriately brief and compelling. The main issues are well described and discussed, with a firm conclusion reached for safety, and effectiveness with economic issues clearly articulated.

Discussion

Dr Piejko informed the MSAC that the evaluators had advised that there is no literature which investigates the difference between patient numbers who choose to have surgery versus those who would choose to have laser therapy for the treatment of symptomatic varicose veins. She noted that:

- ELT is not a minor procedure. It is only suitable for patients with large, saphenous varicose veins, as the catheter requires saphenous veins with a minimum 4.5mm in diameter; and
- trivial cosmetic veins are treated with sclerotherapy.

The MSAC's main concern around cost was addressed by a cost-analysis demonstrating that receiving ELT rather than surgical vein stripping for the treatment of unilateral varicose veins is associated with a modest cost saving to the health system of \$93 per patient. The higher procedural fee, capital costs of the ELT equipment, duplex ultrasound, additional sclerotherapy and disposable laser fibre and catheters are offset by reduced staffing costs and a saving in the cost of day surgery, as opposed to hospitalisation. The MSAC agreed with the report as amended and made the following recommendation.

Recommendation

MSAC has considered the safety, effectiveness and cost-effectiveness for endovenous laser therapy for varicose veins compared with saphenous junction ligation with or without vein stripping.

MSAC finds the endovenous laser therapy is at least as safe, effective and cost-effective as saphenous junction ligation and vein stripping for the treatment of varicose veins.

MSAC recommends that public funding is supported for endovenous laser treatment.

Outcome

Professor Hall abstained from voting due to her stated Conflict of Interest. All other members voted in favour of the recommendation that public funding be supported.

MSAC accepted the recommendation.

Action

- Final recommendation to be forwarded to the Minister.

4 Progress Reports on Applications and References

Members noted the progress of applications and references. There were no major issues.

Action

- Progress chart to be updated by Secretariat.

The Chair advised that three new applications have been received and the Department is assessing them for eligibility:

- 1125 - Molecular Testing for Myeloproliferative Disorders;
- 1126 - Subtelomere MLPA test for Developmental Delay / Mental Retardation; and
- 1127 – Genotypic Resistance Testing of Antiretrovirals in HIV.

5 Other Business

5.1 Withdrawn

5.2 Draft Economic Guidelines

The Chair of MSAC's Economics Sub-Committee (ESC), Dr Kirk, spoke to this item. He noted that there are two aspects to the development of these guidelines: the content, and the process of their implementation.

With regard to the content, MSAC endorsed the guidelines, noting that they are a marked improvement on the current guidance, and noting that PBAC had been consulted in their development. Members felt that they required some introductory/contextual information – this will be included, but it needs to be borne in mind that the guidelines are not a 'stand alone' document – they will replace the current economic guidelines in the document 'Funding for new medical technologies and procedures: application and assessment guidelines'. It was also noted that the guidelines will be professionally edited.

With regard to the implementation of the guidelines, it will be important that the ESC sees the evaluators' draft economics protocols at an early stage, to determine the kind of economic evaluation that is required – this will be a decision made by the ESC, not the evaluators. The objective is to avoid the current frequent situation where issues/problems with an economic evaluation are not identified until a draft assessment report is presented to MSAC. A further objective is to formalise the ESC's consideration of the economics content of draft assessment reports in preference to the ad hoc requests for advice that ESC members currently receive. There is also a need to liaise with representatives of PBAC's ESC, to maintain harmonisation in approach and to discuss emerging issues.

The ESC will have further discussions with the Secretariat regarding the implementation process.

Outcome

- Draft economic guidelines endorsed with minor changes and noting that they will be professionally edited.

Action

- Arrange for editing of the guidelines;
- Convene ESC/Secretariat meeting to discuss and agree on the implementation of the guidelines.

5.3 Withdrawn

5.4 Horizon Scanning Update

Professor Kearney advised that this had proven to be a busy program and it was progressing well. He anticipated that the HTA report on Sleeve gastrectomy as a single stage bariatric procedure would be put to MSAC at the May meeting.

Outcome

- Members noted the progress.

5 1119 Capsule Endoscopy for Peutz-Jeghers

The evidence presented in this review at the 23 November 2007 MSAC meeting indicated that capsule endoscopy is a safe method for the surveillance and management of Peutz-Jeghers syndrome (PJS). The MSAC members Professor Geoff Farrell and Dr David Gillespie, both gastroenterologists, were asked to critique this review.

Professor Farrell indicated that they agreed that it is well established in obscure gastrointestinal bleeding as more sensitive than the comparator: Small Bowel Surveillance (SBS) and that the small studies quoted establish this in PJS too. He advised concluded that it is doubtful that there will be any more data than this given the rarity of PJS and no formal economic analysis was done but in comparison to SBS it would be more expensive. On this basis the MSAC made the following recommendation:

Recommendation

That Capsule Endoscopy for Peutz-Jeghers should receive public funding under the existing MBS item.

After minor amendments the Secretariat will circulate the full recommendation out-of-session for final agreement on the wording.

Outcome

- Members voted in favour of the recommendation.

Action

- After members approve wording out-of-session the final recommendation is to be forwarded to the Minister.

5.5 Other Business**Triage and Streamlined Assessments**

Dr Kirk gave a brief outline on the Triage Process and Streamlined Assessments, being developed by the MBS Policy Development Branch in conjunction with Dr Kirk and Dr Cleary. He indicated that this process is ongoing and that a paper on the triage process is expected to be put to the next meeting.

Applications and References

The Chair advised that in future all submissions to MSAC should be prepared using the application template.

Drug Eluting Stents

Ms Rimmer advised that recent published long-term data questioned the safety of drug eluting stents, noting that MSAC supported public funding under the existing MBS stent items in 2003, she suggested that MSAC may wish to re-visit the recommendation.

Professor Atherton responded, advising that in his view the recent data was reassuring, showing that the benefits of the procedure outweigh the risks. He also advised that the TGA were aware of this issue.

MSAC Business Improvements

Mr Woodley gave a brief outline of the audit of the implementation of the recommendations arising out of 2005 MSAC review which is currently being undertaken in the Department. He informed MSAC that there will be a report on all business improvements currently underway at the next meeting.

Action

- Report on MSAC Business Improvements at next meeting

Next meeting

Dr Blamey advised that he will not be available at the date proposed for the 42nd MSAC meeting in Melbourne on Friday 30 May 2008. He proposed Friday 6 June 2008.

Action

- Secretariat to confirm new meeting date with MSAC members.

The meeting closed at 3.00pm.