



Minutes - 31st Meeting

Minutes 31st Meeting - 24 August 2005 - Brisbane

Members Present

Dr Stephen Blamey (Chair)
Associate Professor John Atherton
Professor Syd Bell
Dr Paul Craft
Dr Kwun Fong
Dr Debra Graves
Professor Jane Hall
Dr Terri Jackson
Professor Brendon Kearney
Dr Ray Kirk
Dr Michael Kitchener
Dr Ewa Piejko
Professor Jeffrey Robinson
Professor Ken Thomson
Dr Gerry FitzGerald
Professor John Horvath
Dr Jane Cook
Mrs Sheila Rimmer
Dr Michael Cleary
Dr Doug Travis

Apologies

Professor Alan Lopez
Professor Michael Solomon
Associate Prof Don Perry-Keene
Ms Samantha Robertson

MSAC Secretariat

Ms Eliza Hazlett
Ms Robyn Bilston
Mr Rob Seawright

1. Opening of Meeting

1.1 Welcome and Apologies

The Chair opened the meeting at 9.15 am and welcomed everyone.
Apologies were received from Associate Professor Don Perry-Keene, Professor Alan

Lopez, Professor Michael Solomon and Ms Samantha Robertson.
The Chair introduced Ms Robyn Bilston and Ms Eliza Hazlett as the two new co-directors of the Department's Health Technology Section.

1.2 Conflict of interest and Confidentiality

The Chair reminded members of the conflict of interest and confidentiality agreements.

With regard to confidentiality the Chair pointed out that issues discussed at MSAC are not to be discussed outside the committee except for the purpose of obtaining information that is pertinent to the committee's deliberations.

The following conflicts or potential conflicts of interest were declared:

- Professor Kearney stated that he is the director of a Pathology and Research Institute;
- Professor Thomson stated that he would have a potential pecuniary interest in Applications 1080, 1081 (closely associated with drafting of this application), 1082, 1042 and Reference 27. Professor Thomson indicated that he would excuse himself during the committee's discussion of application 1081;
- Dr Travis stated a standing conflict regarding prostate treatment. Dr Travis also noted that application 1084 was submitted by the company - Urology Solutions. In the past Dr Travis had excused himself from the committee's deliberations on applications from that company as its principal was both a friend and colleague. Dr Travis informed the committee that the principal in question has since sold the company;
- Associate Professor Atherton stated that he was on an executive committee writing national heart care guidelines. Associate Professor Atherton also informed the committee that he has been asked to deliver a presentation at a heart failure meeting sponsored by Guidant later this year (but organized by a committee of cardiologists) and that honorariums may result although this has not been discussed;
- Dr Michael Kitchener stated a conflict in relation to application 1082 as a provider of that service and one of its comparators lipiodol;
- Dr Paul Craft is the Director of the Cancer Unit at Canberra Hospital and indicated that he occasionally refers patients for the procedures in application 1082 and reference 27 – both these procedures being performed at Canberra Hospital;
- Professor Jane Hall stated that her family trust has shares in CSL and DCA (aged care and radiology). It was agreed that Professor Hall would provide further clarification in writing in this regard.
- Dr Ray Kirk stated a conflict with application 1042. During the preparation of the report Dr Kirk was the Director of NZHTA, the MSAC evaluators who undertook the review and is named as one of the authors.

Action:

- Professor Jane Hall to provide further clarification in writing regarding the nature and extent of any potential conflict arising from having shares in CSL and DCA.

2. Draft Report of the Thirtieth MSAC Meeting held 18 May 2005

The Minutes from the 18 May 2005 meeting were accepted without amendment by the Committee.

2.1 Matters arising

Dr Kitchener noted that the minutes of the May meeting had not been circulated to members prior to receiving agenda papers for the current meeting. It was agreed that future minutes would be circulated to the committee, well in advance of upcoming meetings.

2.2 Brachytherapy – amendment to recommendation

The Chair advised the committee that although MSAC and the Minister had thought that they were re-affirming the recommendation (and interim item) from the previous MSAC review of brachytherapy, because the staging system for prostate cancer had changed since the last review the recommendation in the new report now excludes a patient sub-group (T2c).

Original Review Recommendation "clinical stages T1, T2a, T2b"

T1 (clinically apparent tumour)

T2a (Tumour involves 1 lobe)

T2b (Tumour involves both lobes)

2nd Review Recommendation "clinical stages T1, T2a, T2b, T2c"

T1 (clinically apparent tumour)

T2a (Tumour involves one half of one lobe or less)

T2b (Tumour involves more than half of one lobe, but not both lobes)

T2c (Tumour involves both lobes)

The Chair noted that it was always MSAC's intention to cover all of stage 2 with that recommendation and proposed the following amendment.

May Recommendation to be amended as follows:

"Following a re-assessment of further evidence as to the safety, effectiveness and cost effectiveness of brachytherapy for the treatment of prostate cancer, interim public funding should continue for patients with prostate cancer meeting the following criteria:

- at clinical stages T1 and T2 with Gleason Scores of less than or equal to 6, prostate specific antigen (PSA) of less than or equal to 10ng/ml, gland volume less than 40 cc and with life expectancy of more than 10 years; and
- where the treatment is conducted at approved sites."

Actions:

- The Department to send the amended recommendation to the Minister for endorsement; and
- The Evaluators to reflect the changed recommendation in the body of the report and to clarify that the recommendation relates to the American classification for staging.

3. Final Reports for MSAC Endorsement

3.1 Application 1083 – Intrastromal Corneal Ring Segments (ICRS) for Keratoconus and Ectasia

The Chair of the Advisory Panel, Dr Travis summarized the report and noted the following key issues:

- Intrastromal corneal ring segments (ICRS) are small semicircular plastic segments that are inserted, usually under topical anaesthesia, into stromal channels outside the central visual axis of the eye to reinforce the corneal stroma;
- ICRS aim to improve visual acuity without removing any corneal tissue or touching the central cornea;

- The comparator for ICRS is corneal grafting;
- A major problem with the review was the lack of data and comparative studies as well as the quality of evidence provided (mostly level IV). Nevertheless the procedure appeared reasonably safe.
- The thrust of the information suggests that the procedure is reasonably effective, however, by no means universally successful and some people's vision had been made worse by the procedure.
- As there were no comparative studies, information from the Corneal Graft Register was included to see what sort of improvements one obtains from corneal grafting. It would appear that corneal grafts are slightly better than ICRS;
- A minimal cost study was undertaken to outline the costs of the procedure compared with costs of corneal grafting. ICRS is around \$1000 to \$2000 cheaper than corneal grafting; and
- No cost effectiveness analysis was undertaken as effectiveness could not be established on the evidence currently available.

In its discussions the committee noted that the comparator corneal grafting was not universally available.

Professor Bell provided the critique of the report making the following key points:

- The report was a well written and concise account of the value of ICRS in keratoconus and corneal ectasia. It was suggested, however, that there may be a need to qualify ectasia as corneal ectasia in the title;
- The executive summary although brief was generally informative and could be improved by two additions. Firstly in "Clinical Need" a major indication for the use of ICRS is either a failure in some patients of corneal contact lenses to correct a problem or an intolerance of the lenses. Secondly, the "Effectiveness Section" would benefit with a summary of the aggregation of those measurements of best corrected visual acuity (BCVA) in table 9 and uncorrected visual acuity (UCVA) shown in table 11;
- Some inaccuracies in the presentation of data in the various studies included in the review were also noted;
- In the section headed "Is it Effective" the results are expressed necessarily in some very technical terms such as log MAR, as a measure of visual acuity and the various measurements of topographic changes in the cornea. It was questioned whether such terms would be readily understood by people other than ophthalmic surgeons.

Recommendation

"MSAC recommends that on the strength of evidence pertaining to Intrastromal corneal ring segments for ectasia and keratoconus public funding should not be supported for this procedure.

The evidence pertaining to this procedure is immature and small in volume. It is not possible to be confident that the benefits demonstrated are durable and the lack of published comparative clinical studies does not allow for any cost effectiveness analysis."

Actions:

- The Department to send the recommendation to the Minister for endorsement; and
- The Evaluators to incorporate the suggested changes to the report.

3.2 Application 1081 – Uterine Artery Embolisation

The Chair of the Advisory Panel, Dr Kirk summarized the report and noted the following key issues:

- Uterine artery embolisation (UAE) is a uterine conserving, minimally invasive technique, that treats symptomatic uterine fibroids. Interventional radiologists usually perform uterine artery embolisation upon referral from a gynaecologist with the patient under mild intravenous sedation and local anaesthesia;
- Existing procedures for the treatment of symptomatic uterine fibroids fall into two main categories – uterine removal and uterine-conserving. If there is no desire for childbearing, the standard treatment for symptomatic uterine fibroids is hysterectomy. A range of uterine-conserving (although, not necessarily fertility-sparing) treatments are also available including hormonal suppression therapy, hysteroscopic resection and myomectomy;
- Comparator technologies include: abdominal, vaginal or laparoscopic hysterectomy and myomectomy;
- On the basis of the evidence available UAE appeared to be as safe as or safer than hysterectomy. None of the comparative studies reported cases of death, septic shock, serious non-target embolisation or uterine perforation;
- Major complications of haemorrhage, deep vein thrombosis and organ damage were more prevalent after hysterectomy when compared with UAE. On the basis of limited evidence, UAE appears as safe, or safer than myomectomy;
- The higher rate of early menopause after UAE compared with myomectomy is the most concerning safety outcome but overall myomectomy was associated with a higher rate of safety related complications when compared with UAE;
- When compared with hysterectomy, UAE was less effective at controlling menorrhagic symptoms. UAE patients are more likely to need further treatment, however, this minimally invasive procedure is associated with a significantly reduced convalescence time, when compared with hysterectomy;
- The evidence base for the effectiveness of UAE compared with other uterine conserving treatments was limited with no comparative studies available for quality of life, sexual function, fibroid recurrence, uterine size and the time to relieve symptoms. However, the evidence that was available indicated that UAE patients were more likely to report completely or significantly resolved menorrhagic and pain symptoms compared with abdominal myomectomy;
- Although UAE appears to be as safe as or safer than abdominal myomectomy and just as effective, the study on which these conclusions are predominantly based has a small sample size. Owing to a lack of demonstrated effectiveness and comparative data for UAE and its comparators (hysterectomy and myomectomy), a cost-minimisation analysis rather than a cost effectiveness analysis was conducted;
- A non-randomised controlled trial is currently being undertaken at the Wesley Hospital, in Brisbane. While several years away from publishing data the trial will assess UAE, hysterectomy and myomectomy patients in terms of symptom control, quality of life and sexual function.

The Chair noted that interventional radiologists have developed a database which may provide more information around effectiveness and cost effectiveness of this procedure.

Dr Piejko provided a critique making the following key points;

- Hospital data was not comprehensive because a significant amount of treatment for fibroids is not captured – the main one being hysterectomy for reasons other than malignancy. Consequently it is difficult to define the patient population in question;
- The data from the studies of hysterectomies performed (some vaginal but mostly abdominal) had not been separated out into safety and effectiveness. It

- was suggested that the committee should also look at separating out the myomectomy data into safety and effectiveness as well;
- The assumption that the main treatment for fibroids is hysterectomy rather than medical management was questioned and it was noted that there were no studies on the outcomes of medical management.
- Agreed that while hysterectomy was more effective than UAE in relieving symptoms and the effects are permanent, UAE appears safer due to less risk of haemorrhaging, blood transfusion, wound infection, shorter hospital stay and lower risk of post-embolism syndrome;
- It was noted that there is a lack of data on myomectomy and it was suggested that UAE appeared to be marginally safer. Moreover, for those women who desire a uterine conserving procedure UAE would appear to be the preferred option; and
- The limited nature of the available data precluded a robust effectiveness and cost effectiveness analysis.

Professor Thomson absented himself from the deliberations at this point.

The Committee noted that the Advisory Panel and the Department had been working closely with the evaluators to appropriately address cost effectiveness issues.

The Committee agreed that there were a number of inaccuracies in the cost effectiveness section and that too many assumptions had been made making the analysis unnecessarily complex.

Actions:

- The Evaluators to revisit the economic analysis and incorporate suggested changes to the report in light of Committee feedback; and
- The report to be reconsidered at the November MSAC meeting.

3.3 Application 1082 – SIR- Spheres for the treatment of non resectable liver tumours

The Chair of the Advisory Panel, Dr Cleary summarised the report and noted the following key issues:

- MSAC had previously reviewed SIR-Spheres in March 2002 and had recommended against public funding on the grounds that while the data suggested that the procedure was reasonably safe and that there was evidence of anti-tumour activity, there was insufficient evidence of effectiveness and cost effectiveness;
- SIR-Spheres are yttrium-90 microspheres that are implanted into malignant liver tumours for the purpose of selectively delivering high doses of ionising radiation to the tumour;
- SIR-Spheres are used to treat patients with hepatic metastases secondary to colorectal cancer (CLM) in the absence of extrahepatic metastases, when the hepatic metastases are not amenable to surgery or radiofrequency ablation. They may be used in combination with systemic chemotherapy or hepatic arterial chemotherapy. SIR-Spheres are also used to treat primary non-resectable, non-ablatable hepatocellular carcinoma (HCC); however, this indication is not as common as CLM in Australia;
- There is limited comparative evidence available to enable an assessment of the safety of SIR-Spheres compared to other therapies used in the treatment of liver tumours;
- In addition to the safety issues relating to patients treated with SIR-Spheres, safety issues arise for personnel involved in implanting SIR-Spheres and handling the device. From the available information it appears that the doses

- of radiation delivered to personnel are reasonably low and are within ranges recommended by the National Occupational Health and Safety Commission;
- In terms of effectiveness for CLM, all six studies published since the 2002 MSAC review demonstrated anti-tumour activity with the use of SIR-Spheres, however only the van Hazel trial used standardised criteria to measure tumour response. This study found a statistically significant increase in tumour response rates in patients treated with SIR-Spheres and systemic chemotherapy compared to those treated with systemic chemotherapy alone;
 - The studies in question, however, used chemotherapy regimens that are likely to have been replaced by the new chemotherapy protocols. There are no studies which compare the survival advantage of SIR-Spheres over current chemotherapy regimens;
 - In terms of effectiveness for HCC two case series recorded partial complete tumour response in 50% of patients and demonstrated that SIR-Spheres had an anti-tumour activity, however, the evidence of effectiveness was weak. Moreover, there were no comparative studies to draw any conclusion about the effectiveness of SIR-Spheres compared with the existing treatment for HCC. Consequently as effectiveness could not be established no cost effectiveness evaluation was carried out; and
 - A trial based economic model supplied by the applicant and a modelled economic evaluation were used to evaluate the cost-effectiveness of SIR-Spheres and systemic chemotherapy in patients with CLM. The trial based economic model is based on the van-Hazel trial which compared SIR-Spheres and 5-fluorouracil plus leucovorin systemic chemotherapy (5-FU/LV) to 5-FU/LV systemic chemotherapy alone. This economic model showed that the addition of SIR-Spheres to 5-FU/LV results in an acceptable cost per life year gained compared to 5-FU/LV alone. Sensitivity analyses show that this cost per life year gained has a wide range and indicates that the incremental cost-effectiveness ratio is particularly sensitive to changes in survival estimates.

Dr Craft critiqued the report providing the following key points:

- This is a well written report. Dr Craft confined his comments to CLM as he accepted that there was insufficient data to justify the use of SIR-Spheres for the HCC indication;
- With regard to safety, SIR-Spheres is quite a toxic procedure and it was difficult to get an idea of the rate of toxicity of the treatment. For instance, while there is about 1% treatment related deaths in the setting of advanced metastatic cancer – as this was a palliative treatment – too many treatment related deaths would be unacceptable;
- It would be instructive for the report to have included some actual data from the new chemotherapy protocols developed over the last few years - putting the 1% treatment related deaths in context;
- In terms of effectiveness, the size of the van Hazel trial and the lack of data comparing SIR-Spheres with the new chemotherapy regimens presented some uncertainty;
- Prior to 2002 no trial in advanced colorectal cancer ever showed a significant survival benefit – the new chemotherapy regimens have changed the outlook significantly for metastatic colorectal cancer. In this regard the advisory panel may have considered doing an indirect comparison of SIR-Spheres with the new chemotherapy protocols which may have provided a better estimate of effectiveness; and
- The assumptions in the costing models are problematic from a clinical perspective with a number of inaccuracies highlighted for amendment. Addressing these inaccuracies was likely to improve the cost effectiveness of SIR-Spheres.

The Committee felt it was important to highlight that the safety of using SIR-Spheres in conjunction with improved chemotherapy regimens has not been assessed and that this should be reflected in the MSAC recommendation.

Recommendation

1st indication

"MSAC recommends that on the strength of evidence pertaining to the treatment of patients with hepatic metastases secondary to colorectal cancer which are not suitable for resection or ablation, that interim public funding should be supported for first line treatment by administration of SIRS-Spheres in combination with systemic chemotherapy using 5FU and leucovorin, with the collection of survival data. This data should be reported to MSAC within three years."

2nd Indication

As there is currently insufficient evidence pertaining to the treatment of non-resectable, non-ablatable hepatocellular carcinoma with SIR-Spheres, MSAC recommends that public funding should not be supported at this time."

Actions:

- The Department to send the recommendation to the Minister for endorsement; and
- The Evaluators to incorporate the suggested changes to the report.

3.4 Application 1076 – High Energy – Transurethral Microwave Therapy (HE-TUMT) for Benign Prostatic Hypertrophy

The Chair of the Advisory Panel, Dr Kitchener summarized the report and noted the following key issues:

- High-energy transurethral microwave thermotherapy (HE-TUMT) is a minimally invasive technology for the treatment of benign prostatic hyperplasia (BPH). The procedure involves a microwave antenna being positioned within the prostatic fossa, which then produces microwave energy to destroy obstructive prostatic tissue;
- The vast majority of patients attend day surgery with local anaesthetic rather than a doctor's room (although theoretically possible) for this procedure;
- The applicant had asked for HE-TUMT to be compared with existing pharmacological therapy, however, the advisory panel were of the opinion that transurethral resection of the prostate (TURP) was the gold standard for this condition i.e. most people would start off with pharmacotherapy – if this failed would then move onto TURP. Nevertheless, a couple of papers did compare HE-TUMT with medical therapy and these were included in the assessment as well as minimally invasive techniques such as transurethral needle ablation (TUNA);
- HE-TUMT is safer than TURP with a lower incidence of post-operative complications as well as a lower rate of ejaculatory and erectile dysfunction. HE-TUMT has slightly worse side effects when compared to drug treatment and a slightly better safety profile when compared to other minimally invasive procedures;
- In terms of effectiveness, in patients with moderate-to-severe symptoms at baseline, HE-TUMT leads to significant and sustained improvements in subjective measures such as lower urinary tract symptoms and improved quality of life, as well as in objective measures such as maximum urinary flow rate and post-void residual volume. As shown in the safety assessment, HE-TUMT has a minimal impact on sexual function;
- However, improvements following TURP tend to be both more rapid initially and significantly greater in the long-term, compared with HE-TUMT, for all objective and subjective measures except sexual function;

- HE-TUMT also results in a higher rate of treatment failure necessitating further treatment, compared with TURP (6.5–12.2% vs. 4.8–9.6% at 12 months respectively; 19.5–25.8% vs. 4.8–11.0% at 3 years respectively). Treatment failure with HE-TUMT is usually a result of a lack of, or decline in, effectiveness, while complications such as urethral strictures and bladder neck stenosis are the typical reasons for further treatment in patients treated with TURP; and
- HE-TUMT is not quite as cost effective as TURP but the difference is only small. When compared to pharmacotherapy HE-TUMT is safe, more effective and cost effective and with limited evidence probably equivalent to other minimally invasive procedures.

Dr Fitzgerald provided the critique and made the following points:

- The procedure appears safer than TURP across a range of complications but with a slightly higher rate of complication than pharmacotherapy;
- The procedure seemed effective in relieving symptoms;
- The applicant's request to have pharmacotherapy as the only comparator was not sustainable and agreed that TURP was a reasonable alternative.
- In terms of costs of implementation the report made no mention of capital costs or how many units may be needed; and
- In summary HE-TUMT is safe and effective and a reasonably sound alternative treatment.

The Committee questioned the accuracy of the utility values (being based on a small group of patients) and felt that a sensitivity analysis on this was required to determine if this was a significant factor and would change cost effectiveness outcomes.

Provisional Recommendation

"On the strength of evidence relating to safety, effectiveness and cost-effectiveness, the MSAC recommends that public funding should be supported for HE-TUMT in patients with moderate to severe symptoms of benign prostatic hypertrophy."

Action

- The Evaluators to revisit the economic analysis and provide the revised report to the Secretariat for consideration by the Executive.

3.6 Reference 27 – Vertebroplasty & Kyphoplasty for the treatment of vertebral compression fracture

The Chair of the Advisory Panel, Professor Thomson summarized the report and noted the following key issues:

- Vertebroplasty is a procedure used to stabilise fractured vertebrae in order to relieve pain. With osteoporotic vertebrae, the goal is to fill the spaces in porous bone with the artificial bone cement and thus strengthen the bone so that it is unlikely to fracture, or fracture further, and reduce pain from bone rubbing on bone;
- In general, patients are selected on the basis of incapacitating pain, unresponsive to conservative treatment, as well as physical indications found through imaging and clinical assessment;
- It is performed under imaging guidance and is commonly undertaken in a day surgery suite;
- Kyphoplasty is a modification of the vertebroplasty technique. It involves inserting a high pressure small balloon catheter into a vertebra at the point where it has collapsed. The balloon is inflated with a liquid under pressure to raise the bone and correct abnormal wedging of the fractured vertebra. Once

the balloon is maximally inflated, it is then deflated and removed, and the space that has been created is filled with artificial bone cement. Kyphoplasty is commonly done under general anaesthesia in an operating theatre, although it can be done under local anaesthesia;

- The comparator for vertebroplasty was medical management as most patients were not suitable for surgery;
- In terms of safety there were very few studies that looked at adverse events – the major one being cement leakage but overall vertebroplasty appears to be a largely safe procedure although there is insufficient evidence to determine if it is as safe as, or safer than, medical management;
- With regard to effectiveness, the limited evidence available would seem to indicate that vertebroplasty is more effective than conservative medical management at relieving pain within 24 hours in patients with osteoporotic vertebral compression fracture. There was, however, no difference in the effectiveness of vertebroplasty, compared to usual care, at relieving pain in the longer term (6 weeks to 12 months). In the longer term, both types of treatment appear to be equally effective. These results may or may not be supported in non-randomised controlled trials that are awaiting publication;
- Overall, vertebroplasty appears to be more effective than conventional medical management at treating symptomatic vertebral compression fracture in the short term, and as effective in the long term;
- As there was limited evidence available to assess the clinical effectiveness of vertebroplasty a cost effectiveness analysis was not undertaken. As a general indication, however, the cost associated with performing one vertebroplasty procedure in 2004 was estimated to be \$3,951. The total annual cost for maintaining conservative medical treatment of an average patient with symptomatic vertebral compression fracture was estimated to be \$4,868; and
- With regard to Kyphoplasty, the concept of actually straightening out the spine and improving spinal curvature and increasing vertebral height was spurious and there was almost no data to assess.

Professor Kearney provided the critique and made the following key points:

- The report outlined clearly the state of the literature on this technology but could be improved by editing;
- Although the technology was developed for treating neoplastic disease of the spine, its major use is for osteoporosis of which there are now epidemic numbers in our society. In that sense the technology was responding to a real clinical need;
- The technology was effective for pain relief but only in the short-term and no different to outcomes achieved through medical management after 12 months;
- The consensus would seem to be that the complication rates in this group of patients are probably acceptable. It was concerning that the effect of stiffening the vertebra with these techniques on the remaining vertebrae was unknown – is this technology responsible for other fractures or is because of the underlying disease. There was little mention in the report of the impact of these treatments on the intervertebral disc (the support between the vertebra);
- There are concerns regarding kyphoplasty because of its expense but also other factors such as its mechanical effects on the spine and the intervertebral disc are as yet unknown. This kind of information was unlikely to become available in clinical trials.

Recommendation

1st indication

"On the strength of the evidence relating to the safety, effectiveness and cost-effectiveness of vertebroplasty, MSAC recommends interim public funding for:

- Vertebroplasty in patients with painful osteoporotic vertebral compression fractures confirmed by diagnostic imaging and not controlled by conservative medical therapy;
- Vertebroplasty in patients with pain from metastatic deposits or multiple myeloma in a vertebral body.

This procedure should be performed by appropriately qualified medical practitioners and this recommendation to be reviewed within five years."

2nd indication

"MSAC found that there is insufficient to support public funding for kyphoplasty at this time."

Actions:

- The Department to send the recommendation to the Minister for endorsement; and
- The Evaluators to incorporate the suggested changes to the report.

3.7 Application 1042 – Cardiac Resynchronisation Therapy (CRT)

Background:

The details of this procedure are set out in the minutes of the MSAC meeting of 2 March 2005.

The Chair of the Advisory Panel, Associate Professor John Atherton, summarised the report and made the following key points:

- The report had previously been presented to MSAC on 2 March 2005, however, three days after the committee considered it, the CARE-HF study was presented at the American College of Cardiology and published in the New England Journal of Medicine – which compared CRT and standard treatment and demonstrated a clear improvement in the reduction of mortality. This being the case it was considered appropriate to re-open the application and to repeat the literature review up to the point of publication of the CARE-HF study.
- The findings of the report presented to MSAC in March had demonstrated clinical need for patients meeting the following criteria: damaged ventricles, very symptomatic despite medical therapy and dyssynchrony of both left and right ventricles.
- It appears that safety was established in the short-term and effectiveness demonstrated in improving symptoms, quality of life, reducing hospitalisation and a trend to reducing mortality, however, owing to the lack of long-term data cost effectiveness was unable to be demonstrated. The main focus of the updated report therefore is on effectiveness and cost effectiveness.
- For effectiveness there were four high quality randomised trials with a new one looking at over 800 patients. Overall in almost all the studies there was improvement in the primary end point (time of death or reduction in hospitalisation). Improvement in symptoms over 18 months and improvement in quality of life over six months. Reduction in cardiovascular hospitalisation reduced down to 39 months.
- In terms of cost effectiveness, the analysis was based on the CARE-HF trial and the MIRACL study looking at total costs of all devices and equipment costs included at current market rates and an assumed generator change every five years: Public sector cost – an additional \$13,700 at 29 months - Private sector cost – an additional \$26,000 at 29 months.
- With an estimated 3,800 people eligible to have CRT and approximately 386 new patients per year – additional costs to the public sector would be \$8.9million per annum and \$16million per annum to the private sector.

- Overall the conclusion of the advisory panel was that there was certainly a clinical need for this technology, it appears to be safe, appears to be effective in improving symptoms, in reducing hospitalisation, improving quality of life and in reducing mortality out to 29 months and appears to be cost effective based on the projected cost utility analysis.

Although an apology Professor Lopez had prepared a written critique which made the following key points:

- The Report is well written, presented in a logical format and reasonably easy to read;
- The strength of the report lies in the comprehensive coverage of evidence to date and the interpretation and synthesis of this material. A limitation of the report is the ambiguous use of "treatment" in various parts of the report. Although treatment was defined as CRT plus optimal pharmacological treatment, it was generally unclear whether the author was referring to CRT alone or CRT plus optimal pharmacological treatment;
- The section pertaining to economic evaluation was overly cumbersome and difficult to read. A clearer overview of the section together with a better use of sub-headings to accommodate gradual development of the model would improve logic, structure and readability;
- The report has adequately addressed the review questions but presentation and structure may be improved in certain sections to aid comprehension; and
- Conclusions followed nicely from the report and provide a well-rounded summary of strengths and weaknesses of the report.

The Committee agreed that the cost effectiveness should be based on five year figures as this was more clinically appropriate than "lifetime".

Recommendation:

"On the strength of evidence relating to safety, effectiveness and cost-effectiveness, MSAC recommends that public funding should be supported for the use of cardiac resynchronisation therapy in patients who have moderate to severe chronic heart failure (NYHA class III or IV) despite optimised medical therapy and who meet all of the following criteria – sinus rhythm, a left ventricular ejection fraction of less than or equal to 35% and a QRS duration greater than or equal to 120ms."

Action:

- The Department to send the recommendation to the Minister for endorsement; and
- The Evaluators to incorporate the suggested changes to the report.

3.5 Application 1080 – Coronary Pressure Wire

The Chair of the Advisory Panel, Associate Professor John Atherton outlined the report's findings, however, a quorum was not present to finalise a recommendation.

Action:

- This review to be considered at the November MSAC meeting.

4. Progress Reports on Applications and References

The Chair enquired whether there were any issues concerning current applications and references. There were none.

The committee were advised that panels would be formed in due course to consider the following applications: Breast MRI and Non-fusion stabilization. If any members were interested in participating on these reviews they should contact the secretariat or the Chair.

5. Other Issues

5.1 Horizon Scanning

Professor Kearney referred the Euroscan report to the committee and noted that the Horizon Scanning committee was up and running and that it was forwarding reports to Euroscan and in turn were receiving reports from Euroscan which were then sent to the health technology committees in each of the jurisdictions.

5.2 MSAC Review

Ms Bilston informed the committee that an implementation timetable would be circulated along with the minutes from this meeting and that the Department would work closely with the Executive to prioritise implementation tasks.

Action:

- Implementation timetable to be circulated to members with the minutes.

5.3 HTAi Conference in Rome

Attendees: Chair, Professor Kearney and Mr Woodley.

Professor Kearney noted that the meeting was scientifically very good and that the attached report prepared by Mr Woodley was a comprehensive summary of proceedings.

5.4 MSAC Economic Guidelines

Dr Kirk indicated that the working group was due to meet in Melbourne in October with the view to having a near final draft ready for discussion at MSAC in November. Dr Kirk noted that there were a number of outstanding issues that the committee, as a whole, needs to address before the guidelines can be signed off.

Ms Hazlett to advise when new contracts for MSAC evaluators have been signed to enable consultation to continue.

Options for engaging MSAC evaluators in the development of the guidelines were discussed.

5.5 Nationally Funded Centres (NFCs)

Professor Kearney noted that MSAC was in the process of setting up a sub-committee in anticipation of a number of NFC references being referred to it from AHMAC.

5.6 MSAC Membership

The Chair noted that the future composition of the committee was still to be finalised and members would be notified of the outcome in due course.

The Chair noted that Dr Michael Kitchener, a founding member in 1998, had indicated that he wished to retire from the committee. The Chair, on behalf of the

entire committee thanked Dr Kitchener for his huge contribution over the last seven years.

6. Close

The next MSAC meeting is scheduled for 15-16 November 2005 in Canberra.