



Australian Government  
Department of Health and Ageing

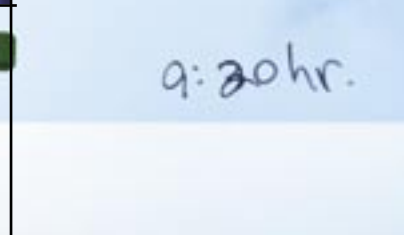
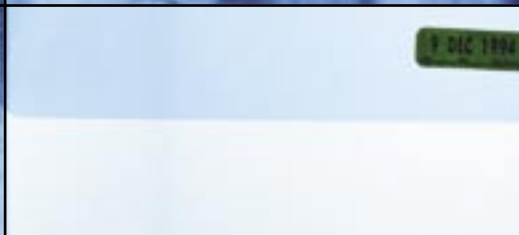
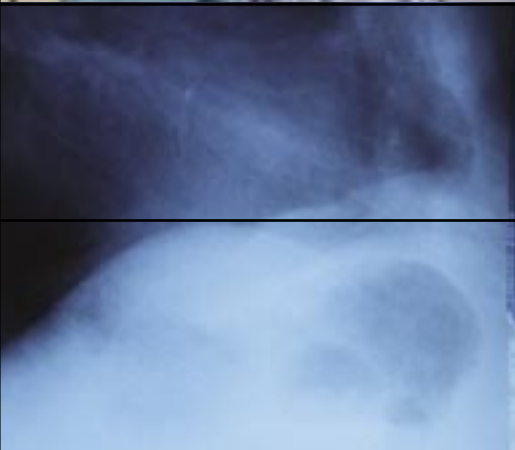


Medical Services Advisory Committee  
Strengthening evidence-based health care in Australia



# ANNUAL REPORT 2002-03

# MEDICAL SERVICES ADVISORY COMMITTEE



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MEDICAL  
SERVICES  
ADVISORY  
COMMITTEE

ANNUAL  
REPORT

2002–03

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# FOREWORD

## COMMENT FROM THE AUSTRALIAN GOVERNMENT MINISTER FOR HEALTH AND AGEING



The MSAC was established in 1998 as an independent scientific committee to advise the Australian Government on the circumstances under which new and existing medical procedures and technologies should receive public funding based on their performance relative to other available options.

The MSAC plays a significant role in ensuring that Medicare funding for medical procedures is based on an assessment of evidence on their safety, effectiveness and cost-effectiveness. The quality of the work of the MSAC since its inception has continued to improve and receives international recognition.

However, as it is important that this quality is maintained, the MSAC has instigated a review to consider whether its methodologies and processes can be further refined. Another review has looked at ways to implement the MSAC's findings to ensure that new technologies are used in a manner consistent with the evidence on clinical effectiveness and cost-effectiveness.

I would like to thank the members of the MSAC and its many Supporting Committees as well as Departmental staff and contracted evaluators for their commitment to strengthen evidence based medicine in Australia. I am grateful for their contribution of clinical expertise and impartial policy input.

I look forward to continuing to receive quality and timely advice from the Committee.

Tony Abbott  
Minister for Health and Ageing

# REPORT FROM THE CHAIR



Welcome to the MSAC Annual Report which contains information about the technologies we have reviewed between 1 July 2002 and 30 June 2003.

The MSAC assessment process has been streamlined with 14.9 months being the average time taken to assess an application from eligibility to final MSAC consideration. The MSAC is also reviewing its internal processes for decision making and issues around consistency and implementation of its decisions. The MSAC received 15 new submissions for review in 2002–2003 and had 38 evaluations in progress at the end of this period. Thirteen evaluations were completed with a brief overview of each technology and the MSAC's recommendation included in this Annual Report.

The Committee continues its work with Horizon Scanning and the Australian Health Ministers' Advisory Council (AHMAC) and has enjoyed undertaking references of national significance.

The MSAC is recognised as a world leader in health technology assessment and presented its reviews at the recent Health Technology Assessment

International conference in Canada. Australia is bidding to host this conference in 2006.

In particular, I would like to thank the previous Minister for Health and Ageing, Senator Kay Patterson, who was very supportive of our activities, and encouraged the further development and refinement of evidence-based medicine in Australia. I look forward to working with the new Minister, the Hon Tony Abbott.

I would like to thank my MSAC colleagues, the numerous Supporting Committee members, Departmental staff and contracted evaluators who have generously contributed their valuable time, expertise and experience to the assessment process throughout the year.

**Stephen Blamey MBBS, FRACS**

Chair, Medical Services Advisory Committee



# MSAC MEMBERSHIP

The MSAC is a multi-disciplinary expert body comprising members with a diverse range of individual expertise including pathology, surgery, specialist medicine and general practice, clinical epidemiology and clinical trials, health economics, consumer issues and health administration and planning.

With the exception of the Australian Health Ministers' Advisory Council representative, the MSAC members are appointed as individuals on the basis of recognised expertise in their chosen field rather than as representatives of particular organisations.

**Dr Stephen Blamey (Chair)** is a general surgeon in public and private practice in Melbourne. He specialises in gastro-intestinal surgery, endoscopy and laparoscopic surgery and is a member of the senior medical staff at Monash Medical Centre. He operates a day endoscopy hospital and has published research on various aspects of surgery.

**Professor Bruce Barraclough** is Chairman of the Australian Council for Safety and Quality in Health Care, Chairman of the Board, NSW Institute for Clinical Excellence, and Past President of the Royal Australasian College of Surgeons. He is University of Sydney Professor and the Director of Cancer Services, Northern Sydney Area Health Service.

**Professor Syd Bell** is a pathologist and the Area Director of Microbiology in the South East Sydney Area Health Service. He was Director of the Area Pathology Service from 1986 until May 2001. Professor Bell is the Commonwealth Government's pathology advisor to the Pathology Services Table Committee.

**Dr Paul Craft** is a medical oncologist in public and private practice and is the Director of the Medical Oncology Unit at the Canberra Hospital. He is a past member of the Council of the Australian Cancer Society and of the Scientific Subcommittee of the Consultative Committee on Diagnostic Imaging. Dr Craft has conducted research in cancer medicine, particularly in patterns of treatment and guideline implementation.

**Professor Ian S Fraser AO** is an expert in reproductive medicine. He is a Professor in Reproductive Medicine at the University of Sydney and Head of the Department of Reproductive Endocrinology and Infertility at the Royal Prince Alfred Hospital, Sydney. He is the past President of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists. Professor Fraser has major clinical interests in menstrual disorders, contraception, menopause, infertility, endometriosis and gynaecological endoscopic surgery.

Professor Fraser resigned from the Committee on 7 February 2003.

**Professor Jane Hall** is a health economist whose current research interests include the investigation of individual decision making, valuation of health and health care benefits, and social welfare measurement. Professor Hall is the Founding Director of the Centre for Health Economics Research and Evaluation, and Professor of Health Economics in the Faculty of Business, University of Technology, Sydney. Among her current research projects are studies of media reporting of health policy issues, an evaluation of genetic testing, and the role of private health insurance. Her previous research includes economic evaluation studies in many areas of health services and public health. Professor Hall is involved in health policy and planning issues both in Australia and internationally and has served on numerous advisory committees and working parties.

**Dr Terri Jackson** is a health economist whose major research interest is on issues of technical efficiency in the provision of hospital-based care and in funding systems which make use of casemix adjustment. Dr Jackson is Senior Research Fellow in the School of Public Health at LaTrobe University. She is currently undertaking studies on the cost effectiveness of appendicitis diagnosis and management, and of the use of positron emission tomography (PET) scanning for several cancers.

**Ms Rebecca James** is an independent consumer representative. She has a background in health policy and public management, having worked in senior positions in government and the private sector. She is a strong advocate for consumer participation in clinical trials and for public health research. Ms James has a particular interest in cancer and neurosciences.

**Professor Brendon Kearney (Deputy Chair)** was formerly joint Chief Executive Officer of the Royal Adelaide Hospital and the Institute of Medical and Veterinary Science and is currently Executive Director, Clinical Systems in the Department of Human Services, South Australia. Professor Kearney has wide experience in health administration, having been Chairman of the South Australian Health Commission and Chair of the Australian Health Technology Advisory Committee. He is a member of the National Health and Medical Research Council and the National Quality and Safety Committee. Professor Kearney has been involved in reviews of health services in most States, and produced the blueprint for Management of Elective Surgery in South Australia, as well as establishing the Superspecialty Services Guidelines System in Australia.

**Associate Professor Richard King** is a consultant gastroenterologist and Program Head of Medicine for Southern Health in Victoria. He has served on the Medicare Benefits Advisory Committee and chaired the Inquiry into Cardiac Services in Victoria.

**Dr Ray Kirk** is an expert in health services research and evaluation and health technology assessment. He is the Foundation Director of the New Zealand Health Technology Assessment Unit and is a clinical Senior Lecturer in Public Health at the Christchurch School of Medicine and Health Sciences. He is also an appointed member of the Community and Public Health Committee of the Canterbury District Health Board.

**Dr Michael Kitchener** specialises in nuclear medicine in both private and public hospital practice in South Australia and is a member of the Royal Australasian College of Physicians. He is a past President of the Australian and New Zealand Association of Physicians in Nuclear Medicine and is currently Chairman of the Joint Nuclear Medicine Credentialling and Accreditation Committee and a co-opted Management Committee member of the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical, Management Committee.

**Mr Lou McCallum** is a consumer representative and was Chairperson of the Consumers' Health Forum of Australia (CHF) from 2000 – 2002. The CHF is the national voice for health consumers in Australia and has over one hundred member organisations in all States and Territories. Mr McCallum has worked in community non-government organisations for fifteen years and currently works as a consultant in international health.

Mr McCallum completed his term of appointment on 30 June 2003.

**Dr Ewa Piejko** is a general practitioner working in the western suburbs of Melbourne. Her special interests include promotion of General Practice, standards and vocational training. She is a member of the Royal Australian College of General Practitioners' Victoria Faculty Board and of the Victorian Metropolitan Alliance responsible for vocational GP training in Melbourne. She has also had extensive involvement as an examiner for the Fellowship of Royal Australian College of General Practitioners and the Victorian Censors panel.

**Mr Chris Sheedy** is Assistant Secretary of the Diagnostics and Technology Branch of the Commonwealth Department of Health and Ageing in Canberra.

**Professor John Simes** is a clinical epidemiologist at the School of Public Health, University of Sydney, as well as a consultant medical oncologist at Royal Prince Alfred Hospital. Professor Simes is the Director of the National Health and Medical Research Council's Clinical Trials Centre in Sydney and is a member of many international committees planning clinical trials for research in cancer and cardiovascular disease. His research interests include clinical trials methodology, quality of life assessment and integrating trial evidence with the goal of improving health outcomes.

**Professor Richard Smallwood AO** served as Chief Medical Officer from 1 November 1999 to 30 June 2003. He has provided support to the Minister and the Department of Health and Ageing across the full range of professional issues, including health and medical research, public health, medical workforce, quality of care, evidence-based medicine and development of an outcomes-focussed health system.

**Dr Robert Stable** is the representative of the Australian Health Ministers' Advisory Council. He is a former Chair of the Council and is the Chief Executive of the Queensland Department of Health. His major interests are related to the roles of leadership and management in the provision of efficient and effective quality health services.

**Professor Bryant Stokes** is a neurosurgeon in private practice and is a Senior Neurosurgeon at the St John of God (Subiaco) and Royal Perth Hospitals; Clinical Associate Professor (Neurosurgery), University of Western Australia; Member, Royal Australasian College of Medical Administrators; Associate Fellow, Australian College of Health Service Executives; Director, Medical Research Foundation, RPH. He is also a past President of the AMA (WA Branch) and past President of the Neurosurgical Society of Australasia. He is also a member of the National Expert Advisory Group on Safety and Quality in Australian Health Care.

**Professor Ken Thomson** is a radiologist and Professor/Director of Radiology at the Alfred Hospital, Melbourne. His interests are in interventional radiology and computer applications in radiology. He is a Council Member of the Royal Australian and New Zealand College of Radiologists and was awarded an honorary FRCR in 1987. He has published on contrast media and cardiovascular interventional techniques and obtained an MD from Melbourne University in 1996. His particular research interests are endografts, recanalisation techniques for occluded vessels and renal artery stenting.

**Dr Doug Travis** is a urologist in private practice in the western suburbs of Melbourne. He heads a Urology Unit and serves as a Visiting Medical Officer. Dr Travis has been in consultant practice for 11 years.



# THE MSAC

The MSAC was established by the then Minister for Health and Family Services, Dr Michael Wooldridge, in the 1997–98 Federal budget as a measure aimed at improving health outcomes for patients by ensuring that all new medical procedures attracting Medicare benefits were supported by scientific evidence as being safe, clinically effective and cost-effective.

The MSAC has built on the work of previous advisory bodies such as the Australian Health Technology Advisory Committee (AHTAC) and the Medicare Benefits Advisory Committee (MBAC), and complements the functions and activities of the Medicare Benefits Consultative Committees (MBCC), Pathology Services Table Committee (PSTC) and the Diagnostic Imaging Management Committee.

The terms of reference of the MSAC are to:

1. advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost effectiveness and under what circumstances public funding should be supported;
2. advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost effectiveness;
3. advise the Minister for Health and Ageing on references related to new or existing medical technologies and procedures; and
4. undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC), and report its findings to the AHMAC.

## CONDUCT OF BUSINESS

The MSAC has well established formal operating guidelines, which govern the conduct of all MSAC business. The Committee's guidelines pay particular attention to conflict of interest and confidentiality issues, with all MSAC and the MSAC Supporting Committee members required to sign deeds of confidentiality and make declarations in relation to conflict of interest at meetings and teleconferences.

# THE MSAC ASSESSMENT CYCLE

The MSAC adopts an evidence-based approach to assessments of new medical technologies and procedures. It undertakes a transparent assessment approach by following a standard evaluation cycle in consultation with stakeholders. The MSAC assessment cycle involves five stages from application to possible funding, as indicated below. The MSAC's role ends with the formulation of advice to the Minister for Health and Ageing and does not include Medicare fee setting or associated funding administration issues.

## Stage 1 – Eligibility

The first stage of the MSAC assessment cycle involves consideration within the Department of Health and Ageing of an application's eligibility for assessment by the MSAC. The principle eligibility criteria are clinical need in Australia, and whether the service meets the conditions for funding under Medicare Benefits arrangements. This stage relates to applications from the medical industry, medical profession and others, noting that matters are also referred to the MSAC by the Minister, Department or AHMAC.

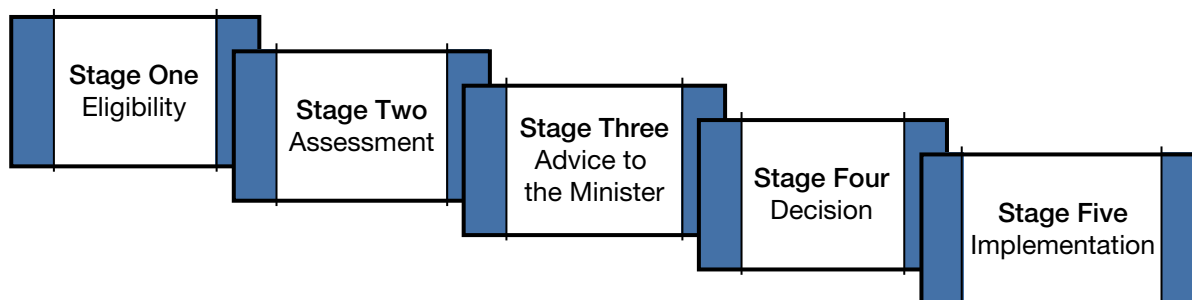
## Stage 2 Assessment

If an application is considered eligible for review it moves to the assessment stage. The MSAC utilises independent evaluators to conduct the majority of the evidence-based assessment. This involves the development of an evaluation protocol and assessing the available evidence on the safety, clinical effectiveness and cost-effectiveness of the technology or procedure.

The MSAC appoints a specialist Supporting Committee, chaired by a member of the MSAC, to assist in the assessment of each application or reference. This provides expert input into the assessment process as well as ensuring that the evaluators' assessment is clinically relevant. Members of the Supporting Committee are drawn from nominees of relevant medical colleges and associated bodies with expertise relevant to the technology being reviewed.

The applicant is invited to comment on the draft assessment report within 28 days before the MSAC considers it. The draft assessment report is also sent to the relevant area of the Department for comment in case of implications in other areas.

## The MSAC Assessment Cycle



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## Stage 3 – Advice to the Minister

In formulating recommendations to the Minister, the MSAC considers a range of information. This includes the assessment report and any feedback on the report received from the applicant.

The MSAC recommendations generally fall into one of three categories:

- the evidence is strong and supports public funding;
- the evidence does not support public funding; or
- the evidence is inconclusive but suggests that the procedure could be safer, more effective, or more cost-effective than comparable procedures that attract public funding. In these circumstances, the MSAC may recommend interim funding to enable data collection and further evaluation of the procedure.

## Stage 4 – Decision

The Department makes a submission to the Minister for Health and Ageing that combines the MSAC's final assessment report and recommendations with policy advice from the Department. The Minister considers this information and makes a decision to endorse or reject the MSAC's recommendations. To date the Minister has endorsed all MSAC recommendations.

## Stage 5 – Implementation

If the Minister endorses a recommendation for public funding of a new medical service, the appropriate consultative committee draws on the MSAC's findings to determine the structure of the MBS item(s) and to determine funding levels. The appropriate committee is determined primarily by the nature of the service. They include the Medicare Benefits Consultative Committee, the Diagnostic Imaging Management Committee and the Pathology Services Table Committee.



# MSAC SUPPORT

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## **DEPARTMENTAL SUPPORT**

The MSAC receives support for its activities from the MSAC Secretariat located in the Department of Health and Ageing. The Secretariat undertakes all of the administrative arrangements associated with MSAC meetings, receipt of applications and the dissemination of MSAC reports following the Minister's endorsement.

The MSAC also receives valuable support from Project Managers in the Health Technology Section who provide support and direction during the MSAC assessments. Key aspects of their role include working with Supporting Committee members and contracted evaluators to ensure evaluations are conducted in accordance with the agreed guidelines. Other responsibilities are liaison with applicants, Committee members, consumers, professional bodies, medical industry, other health funding and regulatory agencies, and international health technology assessment agencies.

## **MSAC CONTRACTED EVALUATORS**

The MSAC utilises both Departmental expertise and independent evaluators in conducting assessments. In July 2001, the MSAC contracted five research agencies in Australia and one in New Zealand to provide valuable assessment and research support.

Adelaide Research and Innovation, the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S), the Medical Technology Assessment Group (M-TAG), the Monash Institute of Health Services Research, the NHMRC's Clinical Trials Centre (NHMRC-CTC), and the New Zealand Health Technology Assessment Unit (NZHTA) have long term contracts to assist and strengthen MSAC assessments.

# 2002-03 MSAC ASSESSMENT ACTIVITY

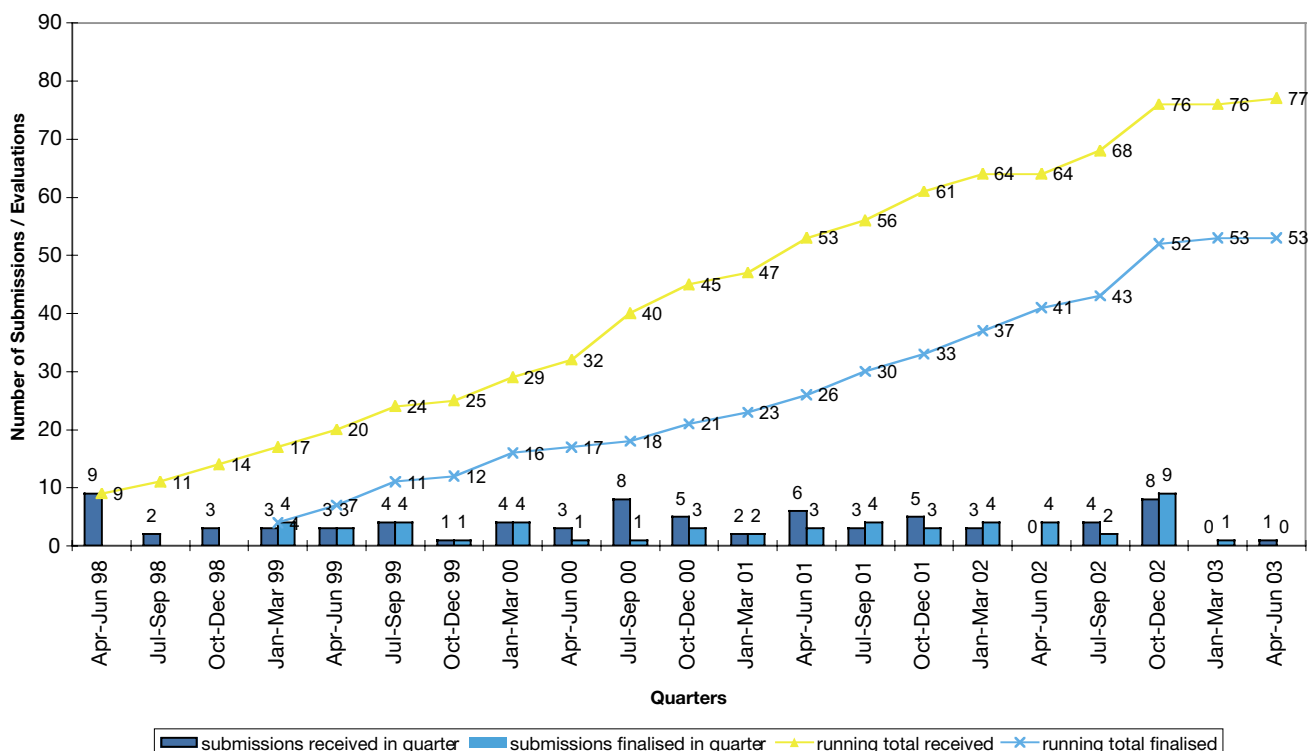
The MSAC has received 77 applications or references for review and, of these, has completed 53 health technology assessments since its establishment in April 1998. Many of these applications and references involved multiple evaluations.

Figure 1 provides a summary of assessment activity from April 1998 to June 2003. The MSAC received 15 new submissions for review in 2002–2003 and had 38 evaluations in progress at the end of this period.

The MSAC completed 13 evaluations through to Ministerial endorsement in 2002–03 (refer Figure 1). Full reports are available from the MSAC website or hard copies can be obtained by contacting the MSAC Secretariat. The 13 evaluations in 2002–03 took on average 14.9 months to complete from submission of application or reference to final MSAC consideration.

It should be noted that although the MSAC completed other reviews, they had not been endorsed by the Minister within the 2002–03 timeframe and have not been included as a completed review.

**Figure 1: New Submissions and Completed Evaluations**



## PROFILE OF MSAC SUBMISSION MAKERS

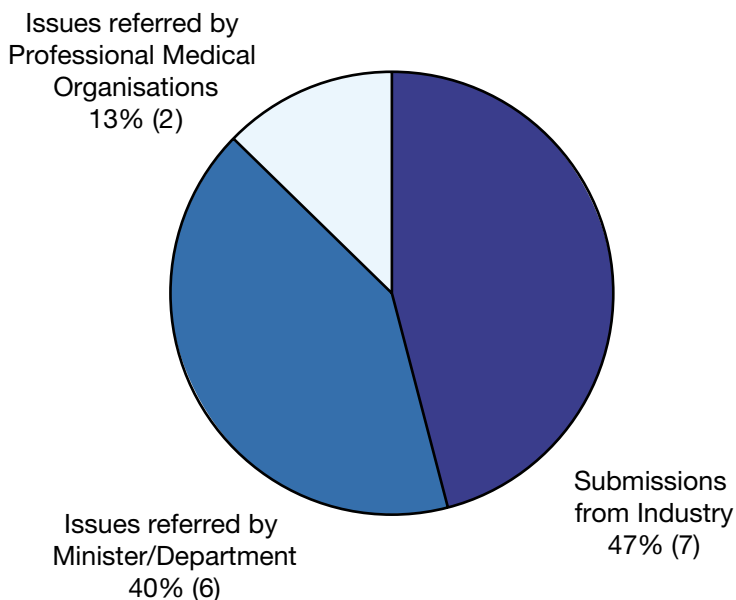
As Figure 2 illustrates, the number of applications and references that were submitted to the MSAC in 2002–03 was 15, which is four more than for the 2001–02 period. Of these, the majority came from the medical industry although referrals from the Minister and the Department of Health and Ageing increased significantly.

## 2002–03 ASSESSMENT OUTCOMES

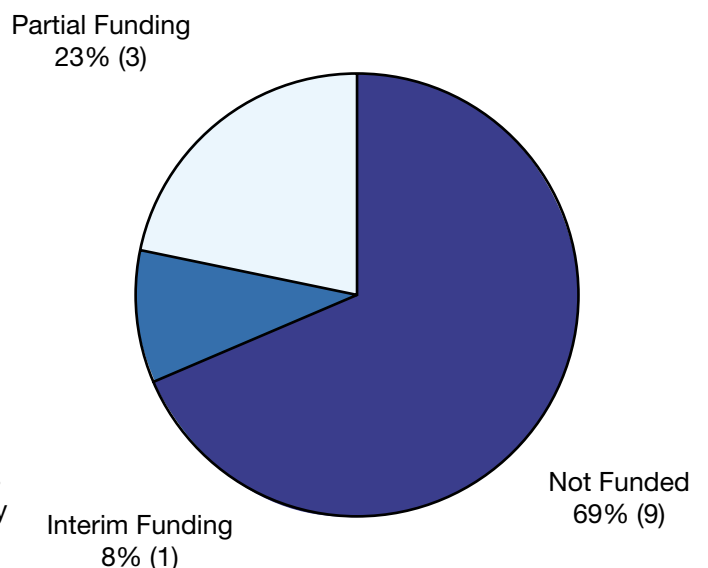
As mentioned previously, of the 13 assessments in 2002–03, 31 per cent of these reviews resulted in unrestricted funding, interim funding pending further data collection and assessment, or funding for specific indications only (refer Figure 3).

For the 2002–03 period, 69 per cent of evaluations recommended against public funding, however, it should be noted that this does not prevent the MSAC from considering an application for the same procedure at a later date should additional evidence become available.

**Figure 2: 2002-03 Breakdown of MSAC Submissions**



**Figure 3: 2002-03 MSAC Recommendations**



# 2002-03 HIGHLIGHTS

## AUSTRALIAN HEALTH MINISTERS' ADVISORY COUNCIL WORK PROGRAM

The Australian Health Ministers' Advisory Council (AHMAC) is the primary national advisory body to the Health Ministers of the Federal, State and Territory Governments. During the year, the MSAC achieved significant progress in completing an agreed health technology assessment work program from AHMAC.

During 2002 – 03 the MSAC endorsed the AHMAC sub-committee's completed assessment of the Nationally Funded Centre (NFC) for the Paediatric Heart Transplant Unit at the Royal Children's Hospital in Melbourne with the recommendation that the Centre remain funded under NFC status for a further three years.

A review of imaging modalities used in the diagnosis and treatment of Coronary Artery Disease has been completed by the MSAC and the report forwarded to the AHMAC. Flowing from this review the MSAC has commenced a full health technology assessment of drug eluting stents.

A review of lymphoedema therapies is nearing completion.

Following consideration of two detailed proposals to AHMAC on "The Introduction of New Technology in the Public Health System", and "The Establishment of a Horizon Scanning Unit", AHMAC agreed that further development of capacity to assess new technologies was needed.

The AHMAC agreed to the establishment of a Horizon Scanning Unit to provide early warning and technology advice to the Committee. The Horizon Scanning Unit will be funded jointly by the AHMAC and the MSAC and will commence operation in 2003/2004.

The AHMAC also agreed to establish an AHMAC/MSAC Technology Advisory Committee to oversee the operation of the Horizon Scanning Unit and

to advise Health Authorities on the impact of the introduction of new and existing technologies in the Australian health care system. This Committee has representatives from each of the Commonwealth, States and Territories, and New Zealand departments having responsibility for health, the MSAC and the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

## INTERNATIONAL ACTIVITIES

The MSAC continued to be represented at international events. Our peer associations, Health Technology Assessment International (HTAi) and International Network of Agencies for Health Technology Assessment (INAHTA) annual conferences were held in Canada in June 2003 and a number of the MSAC members presented papers.

### The International Clinical Trials Symposium: Improving Health Care in the New Millennium, Sydney, October 2002

This symposium was hosted by the National Health and Medical Research Council's Clinical Trials Centre. The focus of this symposium was clinical trial design, trial methodology and the application of technology in this field. Discussion of ethics, guidelines, the relevance of trials to individual patients and the future research agenda clarified issues in these areas.

A number of the MSAC members presented papers at the symposium and an exhibition booth advising delegates on how the MSAC works, the major issues facing the MSAC, and how research links with the MSAC process, operated during the event.

The MSAC, through the Australian Government Department of Health and Ageing, was a principal sponsor of this event.

## **Health Technology Assessment International, Canmore, Canada, 2003**

The main theme of this conference was “improving outcomes through health technology assessment”. Several MSAC members presented at this conference and a cervical screening poster was displayed. These activities were a successful promotion of the MSAC’s work.

This was the first conference of Health Technology Assessment International (HTAi) which replaced the International Society of Technology Assessment in Health Care (ISTAHC). The MSAC looks forward to continuing its relationship with the new HTAi.

## **Dissemination Activities**

In establishing the MSAC in 1998, the agreed dissemination strategy focussed on establishing and refining assessment procedures to ensure timeliness and consistency between reviews.

## **Website**

The MSAC website continues to evolve and aims to keep stakeholders informed of MSAC activities. MSAC Secretariat makes itself available by phone or by email to answer any queries or receive any feedback on all aspects of the MSAC process.

## **MSAC Newsletter**

The MSAC Newsletter continues to provide information to national and international bodies about the technologies we have reviewed and the decisions taken by the Minister for Health and Ageing on them. In 2002–03, a lengthy delay between editions of Newsletters occurred as a result of our working on more effective and focussed strategies of communication to meet the needs of stakeholder groups.

During 2002–03, the Minister for Health and Ageing endorsed 13 assessment reports. The following is a brief description of each reviewed technology, the MSAC's recommendation and the date the Minister accepted these recommendations. The full assessment reports are available on the MSAC website or by contacting the MSAC Secretariat.

## Genetic Test for Fragile X Syndrome – August 2002

There are two molecular genetic techniques used in the diagnosis of fragile X; polymerase chain reaction (PCR), a form of nucleic acid amplification; and Southern Blot. Fragile X testing is most accurate if a combination of both techniques is employed, depending on the exact fragile X genotype.

The fragile X mutation involves an expansion of a section of DNA on a gene specific to fragile X mental retardation. The expanded section of DNA consists of repeated trinucleotides with the sequence cytosine–guanine–guanine (CGG).

There are two principal recognised mutations for fragile X based on the number of CGG repeats: the full mutation, in which there are more than 200–230 repeats; and the premutation, which consists of between 55 and 230 repeats. PCR is most useful for accurate determination of CGG repeat numbers for normal, premutation and grey zone genotypes, while Southern blot analysis is best suited to detecting full mutations or large premutations. PCR amplifies deoxyribonucleic acid (DNA) samples containing the CGG repeats obtained from blood or mouthwash into millions of copies to calculate the number of repeats. Southern blot analysis involves isolating a portion of DNA from a blood sample and cutting it into fragments before 'blotting' them onto a charged surface to estimate the size of the repeats.

### **Recommendation**

Public funding was recommended for Nucleic Acid Amplification (NAA) in those with specific

clinical features of Fragile X (A) syndrome, including intellectual disabilities and in first and second degree relatives of individuals with Fragile X (A) mutation; and Southern blot where the results of NAA testing are inconclusive.

## Percutaneous Transluminal Coronary Rotational Atherectomy for Lesions of the Coronary Arteries – September 2002

Percutaneous Transluminal Coronary Rotational Atherectomy (PTCRA) is a cardiac interventional device used to relieve the burden of coronary artery stenosis. Rather than increasing luminal diameter by arterial stretching and plaque fracture as with percutaneous transluminal coronary angioplasty (PTCA), PTCRA uses an abrasive, diamond-coated burr to debulk existing plaque and calcified lesions into small particles of approximately 5µm. On rotation the burr selectively removes hard tissue whilst soft tissue is deflected by the elastic recoil of normal segments of vessel.

### **Recommendation**

The MSAC recommended that on the evidence pertaining to PTCRA public funding is supported for the following specific indications: for revascularisation of complex and heavily calcified coronary artery lesions which cannot be treated by PTCA alone or when previous PTCA attempts have not been successful; and for revascularisation of complex and heavily calcified coronary artery stenoses where coronary artery bypass graft (CABG) surgery is contra-indicated.

The MSAC recommended that on the evidence pertaining to PTCRA public funding should not be supported for the following indications: for revascularisation of coronary artery stenoses which can be satisfactorily treated by PTCA alone, with or without stent placement; and for revascularisation

of coronary artery in-stent restenoses as a result of prior coronary artery intravascular interventions (since no long-term data exist and short-term data are conflicting).

### **Intravascular Brachytherapy for In-Stent Restenosis – October 2002**

Intravascular Brachytherapy (IVB) is a technique that applies radiation at the site of plaques within the coronary artery of patients where a previously implanted stent begins to fail and arterial narrowing recurs. IVB can be done in either of two ways – using a catheter to introduce beta (B) or gamma (Y) radiation or alternatively by implanting a radioactive stent (typically involving B radiation).

IVB aims to improve blood flow and reduce repeat stenosis (i.e. narrowing) of the coronary artery. Another objective of IVB is to decrease the need for repeat percutaneous transluminal coronary angioplasty – PTCA (balloon dilation of the vessel).

#### ***Recommendation***

The MSAC recommends that on the strength of evidence pertaining to intravascular brachytherapy for the treatment of coronary artery restenosis, interim public funding should be supported for this procedure.

This recommendation is to be reviewed no later than three years from the date of this report to ascertain whether longer term safety, effectiveness, and cost-effectiveness has been proven and to determine the place of evolving technologies such as drug-coated stents in the treatment of in-stent restenosis.

### **Thyrogen as a Diagnostic Agent for Well-differentiated Thyroid Cancer – October 2002**

Thyrogen™ (thyrotropin alpha for injection) contains a highly purified recombinant form of human thyroid-stimulating hormone (rhTSH) which is used with radioactive iodine imaging and serum thyroglobulin (Tg) testing, for the detection of well-differentiated thyroid cancer.

#### ***Recommendation***

The MSAC recommended that on the strength of evidence pertaining to the diagnostic use of recombinant thyroid-stimulating hormone in well-differentiated thyroid cancer, public funding should be supported for this procedure only in patients in whom thyroid hormone treatment (THT) withdrawal is medically contraindicated. In addition, on the basis of the current evidence, both rhTSH-stimulated whole body scanning and serum Tg testing should be undertaken concurrently. The MSAC recommends that public funding for rhTSH should not be supported in patients who are able to tolerate THT withdrawal, on the basis of lower diagnostic accuracy and a high cost-effectiveness ratio.

### **Intra-articular Viscosupplementation for Treatment of Osteoarthritis of the Knee – March 2003**

Viscosupplementation involves an intra-articular (IA) injection into the synovial cavity of the knee to replenish the affected joint. The product is provided in either 2ml vials or prefilled syringes, however, injection schedules differ from product to product. If effusion is present, it is recommended that aspiration of the joint be performed prior to the injection of the viscosupplement.

#### ***Recommendation***

The MSAC recommended that on the strength of evidence pertaining to intra-articular viscosupplementation for treatment of osteoarthritis of the knee, public funding should not be supported for this procedure.

### **Intradiscal Electrothermal Annuloplasty – A Treatment for Patients with Chronic Low Back Pain Due to Annular Disruption of Contained Herniated Discs – December 2002**

Intradiscal electrothermal annuloplasty is an invasive procedure that provides an alternative treatment option for patients with chronic low back pain

originating from internal disc disruption (IDD). This assessment only refers to the heating of the annulus, rather than other intradiscal regions. The procedure is undertaken using three pieces of equipment: an introducer needle, a flexible catheter and a heat generator. The introducer needle is a contourable 17 – gauge needle with stylet that provides access to the intradiscal space. The SpineCATH™ is a flexible catheter with a moveable tip that contains a heating element comprised of copper wire. The catheter is used in conjunction with the ORA–50 S programmable generator, which allows temperature–monitored heating of the catheter tip.

The procedure is performed with local anaesthesia and mild intravenous sedation. The introducer needle is inserted into the painful disc under biplanar fluoroscopic control. The flexible catheter is then threaded from within the nucleus pulposus of the disc to reach the annulus from the inside and pass circumferentially around the lateral and posterior annulus. The catheter tip is slowly heated to a temperature of up to 90°C for 15–17 minutes. During this time, the patient is monitored for the onset of new radicular symptoms or severe back pain.

### ***Recommendation***

Since there is currently insufficient evidence pertaining to intradiscal electrothermal annuloplasty, a treatment for patients with chronic low back pain due to annular disruption of contained herniated discs, the MSAC recommended that public funding should not be supported at this time for this procedure.

### **M–VAX™ – A Treatment for Patients with Advanced Stage III Melanoma – October 2002**

M–VAX™ is a vaccine composed of autologous melanoma cells modified with hapten dinitrophenyl (DNP). The vaccine induces a cell–mediated immunity, which results in a delayed inflammatory response. The vaccine is manufactured with tumour cells obtained from the patient at the time of lymph node resection. Typically, a tumour of at least 3cm in diameter is required to harvest sufficient cells to produce the patient–specific vaccine. Vaccination commences after recovery from surgery and

involves seven intradermal doses within six months. An intravenous bolus dose of cyclophosphamide is given six days after a “skin test” using M–VAX™ without bacille calmette–guerin (BCG). The vaccine is administered together with BCG to maximise immunogenicity.

### ***Recommendation***

The MSAC recommended that on the strength of evidence pertaining to M–VAX™, a treatment for patients with advanced Stage III melanoma, public funding should not be supported for this procedure.

### **Nuchal Translucency Measurement in the First Trimester of Pregnancy for Screening of Trisomy 21 and Other Autosomal Trisomies – October 2002**

Nuchal translucency screening (NTS) is undertaken as part of an obstetric ultrasound and involves the measurement of subcutaneous fluid seen in the neck of all late first trimester fetuses. When the nuchal translucency measurement is combined with information on other risk factors such as an expectant mother’s genetic history and age, advice can be provided on whether there is a relatively high or low risk of the fetus being affected by a major genetic abnormality.

The MSAC review considered both NTS alone and in association with first trimester maternal biochemical screening (T1MBS). These were compared with second trimester maternal biochemical screening (T2MBS) which is currently funded through Medicare.

### ***Recommendation***

The MSAC considers that nuchal translucency screening (NTS), and NTS in conjunction with first trimester maternal biochemical screening (T1MBS), are safe and effective where provided by individuals with appropriate expertise in NTS. Hence NTS providers need to be appropriately accredited. However, the MSAC recommends that public funding should not be supported for NTS or NTS in conjunction with T1MBS as stand–alone services, due to their poor cost–effectiveness.

Consideration should be given to public funding of NTS or NTS in conjunction with T1MBS by incorporating, as far as possible, provision of the services into existing services provided in early pregnancy.

### **Antenatal Screening for Heritable Thrombophilia – October 2002**

Thrombophilia is an inherited or acquired haematological disorder in which there is a predisposition for clots to form within blood vessels. It has been suggested that women should be screened for inherited thrombophilia during pregnancy because pregnancy itself poses an additional risk of thrombosis. This review looked at screening the whole pregnant population for these disorders and also looked at targeted antenatal screening in women with heritable thrombophilia.

Heparin prophylaxis during pregnancy in high-risk thrombophilic women will reduce foetal loss but was also associated with nearly four times the risk of increased blood loss during delivery and post partum anaemia.

#### ***Recommendation***

The MSAC recommended that, on the strength of the evidence pertaining to antenatal screening for heritable thrombophilia, public funding should not be supported for systematic screening of all pregnant women.

Since there is currently insufficient evidence pertaining to antenatal screening for heritable thrombophilia in high risk obstetric groups, the MSAC recommended that public funding should not be supported at this time for this procedure. However, this recommendation should be reviewed in two years' time.

### **Liquid Based Cytology for Cervical Screening – October 2002**

Liquid-based cytology (LBC) is an alternate system of processing cervical cell specimens. This involves either centrifugation or filtration of the specimen to remove any blood, mucus or other non-diagnostic debris before slide preparation. A key advantage

of LBC, according to its sponsor, was that the technology reduces the number of equivocal smear results and hence the need for repeat Pap smears.

The MSAC evaluation of this technology explored both filtration and centrifugation methods of LBC sampling. The comparator in each case was manual slide preparation following the conventional Pap smear.

#### ***Recommendation***

Since there is currently insufficient evidence pertaining to liquid-based cytology for cervical screening, the MSAC recommends that public funding should not be supported at this time for this screening test.

### **Human Papillomavirus Testing in Women with Cytological Prediction of Low-Grade Abnormality – October 2002**

The human papillomavirus (HPV) test is a DNA test that detects strains of the virus that are associated with the development of cancerous lesions if they persist in cervical cells. This involves the use of nucleic acid amplification technology.

#### ***Recommendation***

Since there is insufficient evidence pertaining to the use of the human papillomavirus Hybrid Capture-II test for triaging of women with equivocal cervical screening results, the MSAC recommends that public funding should not be supported at this time for the use of this diagnostic procedure.

### **Multifocal Multichannel Objective Perimetry – December 2002**

Multifocal Multichannel Objective Perimetry is a modification of multifocal visually evoked potentials. It is an objective electrophysiological technique used to detect visual field defects. It examines the response of the occipital cortex to light, allowing the clinician to examine components of the visual field. The visual field is the area where peripheral vision is mapped while fixating the eye on a central point.

### *Recommendation*

Since there is currently insufficient evidence pertaining to Multifocal Multichannel Objective Perimetry, the MSAC recommended that public funding should not be supported at this time for this procedure.

# REVIEWS IN PROGRESS

The MSAC commenced reviews on the following applications and references in 2002–2003, with the majority of assessments to be completed in 2003–2004:

- Treatment of heart failure by permanent tri-chamber resynchronisation
- Specific mass measurement of bone alkaline phosphatase by immunoassay
- Optical biometry
- Radio frequency ablation of liver tumours
- Acticon neosphincter (artificial bowel sphincter)
- Hyperbaric oxygen therapy
- Hysteroscopic sterilisation by tubal cannulation and placement of intrafallopian implant
- LeukoScan®
- Capsule endoscopy
- QuantiFERON–TB Testing
- Endovenous laser treatment for varicose veins
- Bone mineral densitometry
- Implantation of an insertable loop recorder for the diagnosis of recurrent unexplained syncope
- A scan for imaging recurrence and / or metastases in patients with histologically demonstrated carcinoma of the colon or rectum
- Photodynamic therapy
- 3–Dimensional magnetic electroanatomical radiofrequency ablation for the treatment of cardiac arrhythmias
- Sentinel node biopsy for breast cancer
- Intracytoplasmic sperm injection
- Nucleic acid amplification testing for haematological malignancy
- Laparoscopic gastric banding for morbid obesity
- Transanal endoscopic microsurgery
- Positron emission tomography
- Neonatal hearing screening
- Faecal occult blood testing
- Carotid stenting
- Drug (Sirolimus) eluting stents

# CONTRIBUTORS TO THE MSAC PROCESS

The MSAC would like to acknowledge and thank the following organisations and their members for contributing to the MSAC process through Supporting Committee membership. The Committee regularly calls on the Medical Colleges and associated bodies to identify individuals with specialist expertise relevant to technologies being reviewed. The MSAC's reviews would not be possible without the efforts of these experts whose knowledge is critical to ensuring that the MSAC's evidence based assessments reflect Australian clinical reality.

Arthritis Australia

Australian and New Zealand Association of Physicians in Nuclear Medicine

Australian and New Zealand College of Anaesthetists

Australian and New Zealand Hyperbaric Medicine Group

Australian and New Zealand Society of Nephrology

Australian Association of Clinical Biochemists

Australian Association of Neurologists

Australian College of Physical Scientists and Engineers in Medicine

Australian Orthopaedic Association

Australian Rheumatology Association

Australian Society of Cytology

Australian Society of Infectious Diseases

Australian Society of Thrombosis and Haemostasis

Cardiac Society of Australia and New Zealand

Colorectal Surgical Society of Australia

Consumers' Health Forum of Australia

Endocrine Society of Australia

Fertility Society of Australia

Gastroenterological Society of Australia

Haematology Society of Australia and New Zealand

Medical Oncology Group of Australia

Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Royal Australian and New Zealand College of Ophthalmology

Royal Australian and New Zealand College of Radiologists

Royal Australian College of General Practitioners

Royal Australian College of Surgeons

Royal Australasian College of Physicians

Royal College of Pathologists of Australasia

Thoracic Society of Australia and New Zealand

Urological Society of Australasia

The MSAC would also like to acknowledge the large number of co-opted experts who have generously contributed their time and expertise to assist the Committee throughout the year.

# MAKING AN MSAC APPLICATION

## Who can apply?

Applications can be made by the medical profession, medical industry and others with an interest in seeking Australian government funding for a new medical technology or procedure.

## How to apply?

Applicants should refer to the application form and guidelines to assemble and submit their information in the appropriate format, and ensure the application meets the eligibility criteria. All parts of the application form should be completed to the fullest extent possible before forwarding it, along with any supporting documents, to the MSAC Secretariat.

Pre-lodgement consultations are available through the MSAC Secretariat. While not compulsory, this is a helpful step in the successful lodgement of an application.

The format of both the MSAC application form and the guidelines will continue to evolve based on experience and feedback from applicants and the MSAC members. Applicants should refer to the MSAC website for the latest version of the form and guidelines.

## How long will it take?

The time taken for an application to be assessed depends on a number of factors, such as the completeness of an application, the quality of available evidence and the complexity of the service. As a general guide, the more complete the application and the more robust the evidence available, the easier it will be to progress. Based on past experience it should take approximately 14–16 months from the time of submission to the completion of an MSAC assessment report.

## Can I get help in lodging an application?

A Departmental Medical Advisor and the MSAC Secretariat are happy to meet and provide advice to those who are considering making an application to the MSAC. Feedback from stakeholders suggests that the pre-lodgement consultation service assists in providing applicants with a better understanding of the MSAC assessment process as well as the Committee's information requirements.

It is recommended that prospective MSAC applicants avail themselves of the pre-lodgement consultation service in the early stages of preparing their application. Further information on this service can be obtained by calling the MSAC Secretariat on (02) 6289 6811.

## HOW TO CONTACT THE MSAC

All MSAC enquiries should be directed to:

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