

# Future Directions for HTA - VPACT

Stephen Blamey



# Australia – Introducing New Technology/Clinical Practice

HTA linked to Healthcare Policy

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- TGA
- PBAC
- MSAC
- PDC

# Australia

HTA linked to Healthcare Policy

- **TGA – ANZTPA**
  - **Drugs and Devices**
  - **Not Procedures**
  - **World Harmonisation**
  - **Classification based on Risk**
    - **Class 1** low
    - **Class 2A 2B** medium
    - **Class 3** high
    - **AIMD** very high
  - **MDEC**

# Australia

HTA linked to Healthcare Policy

- **PBAC - Therapeutic Pharmaceuticals (drugs) Statutory Body**
  - Application with Information
  - Assessment of Application
  - Funding Decisions
  - Price “Negotiation”

# Australia

HTA linked to Healthcare Policy

- **PDC – PHIMDEC**
  - Ministerial Advisory
  - Devices
  - Private Health Funds
  - Link with procedures

# Australia

HTA linked to Healthcare Policy

- **MSAC – Medical Services**
  - **Devices**
    - **Combination**
  - **Procedures**
  - **Diagnostics**
    - **Imaging**
    - **Pathology**
    - **Pharmaceuticals**

# Australia

HTA linked to Healthcare Policy

- **HealthPACT**
  - **Horizon Scanning MSAC 2003**
  - **Subcommittee of MSAC**
    - **Jurisdictions and MSAC**
  - **Agencies**
    - **AHTA**
    - **ASERNIP-S**
    - **EuroScan**
  - **Output**
    - **Archive Monitor or full HTA**

# HEALTH PACT

- 155 Prioritising Summaries

- 20 Horizon Scanning reports

Molecular adsorbents recirculating system® - MARS. March 2006

The Meniett™ device for the treatment of Ménière's disease. February 2005

The detection of diabetic retinopathy utilising retinal photography in rural and remote areas in Australia. October 2004

Computer aided detection systems in mammography. July 2004

Left Ventricular Assist Devices as destination therapy. March 2004

Elecsys ProBNO immunoassay for the diagnosis of congestive heart failure. June 2004

**MRI for breast cancer in genetically high risk women. May 2004**

Glucowatch G2 Biographer for the non-invasive monitoring of glucose levels. May 2004

Combined PET and CT Scanner for the diagnosis of cancer. February 2004

Enterra® Therapy Gastric Electrical Stimulation (GES) System for the treatment of the symptoms of medically refractory gastroparesis. March 2006

OP-1 Putty® for posterolateral lumbar fusion. March 2006

Injectable silicone biomaterial implants. November 2005

Endokeratoplasty for decompensated corneal endothelium. October 2004

The Tan-Bianchi procedure and modifications. August 2004

Minimally invasive oesophagectomy. August 2004

Collagen meniscal implants. July 2004

Intraoperative radiation therapy. April 2004

Continuous Glucose Monitoring Devices. March 2006

SonoPrep ultrasonic skin permeation system. May 2005

Virtual bronchoscopy. July 2004



Medical Services Advisory Committee

Strengthening evidence-based health care in Australia

# Banks Report – Review of HTA

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- **Review the processes of TGA MSAC & PDC to identify opportunities for enhancing efficiency and transparency of current systems for regulation and approval of medical procedures and devices.**
- **Industry Concern**
  - Short Life of Technology
  - High Costs of Development
  - Delays to Market

# The World – Introducing New Technology/Clinical Practice

## HTA linked to Healthcare Policy

- **NIHCE**
  - HTA
  - CPG
  - Clinical Service Guidelines
  - Policy Guidance
- **FDA**
  - Drugs Devices
  - Safety and Efficacy
  - No cost considerations
- **VA**
  - HTA
  - Policy Guidance

# MSAC:

## The Processes and the Outlook



The image shows the logo for the Medical Services Advisory Committee (MSAC). The logo consists of the lowercase letters 'msac' in a white, rounded, sans-serif font, set against a dark grey background. Below the logo is a purple horizontal bar with the text 'Medical Services Advisory Committee' in white. At the bottom is a white horizontal bar with the text 'Strengthening evidence-based health care in Australia' in black.

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**Medical Services Advisory Committee**

Strengthening evidence-based health care in Australia

# MSAC

- Brief History
- Membership
- Terms of Reference
- MSAC Process
- Examples

# Medical Services Advisory Committee

**MSAC, originally Medicare Services Advisory Committee, was established in 1998 (1998-2001, 2001-2006) to strengthen arrangements for assessing new technologies and procedures before they are considered for reimbursement under the Medicare Benefits Schedule (MBS).**

# Medical Services Advisory Committee

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- Replaced NTAP and AHTAC
- Supported through DoHA
- 22 members

# MSAC Membership

**22 members consisting of:**

- specialist practitioners**
- general practitioner**
- 2 health economists**
- 1 health consumer representative**
- 2 health planning and administration experts**
- 2 epidemiologists**

# MSAC - Terms of Reference

- Advise the Minister for Health and Ageing (MHA) on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their **safety, clinical and cost effectiveness** and under what circumstances public funding should be supported
- Advise the MHA 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
- Advise the MHA on references related either to new and/or existing medical technologies and procedures
- Undertake health technology assessment work referred by AHMAC

# MSAC Process (1)

- Pre-lodgement Teleconference
  - **With prospective applicant**
  
- Application or Referral Received
  - **Eligibility assessed**
    - **Medical service**
    - **Registered Device – TGA**
    - **Clinical need**

# MSAC Process

- Applications and References
  - Diagnostics
  - Therapy
    - Procedures
    - Combination Therapies eg DES
- AHMAC
  - NFCs
    - Low volume
    - Complex
    - Resource intensive
      - Panc Tx
      - PTE
      - Peritonectomy
      - PLT
      - PHT

# MSAC Process (2)

- Application or Referral Accepted
  - Evaluator appointed;
  - Advisory Panel (AP) convened;
  - AP with evaluator develops research protocol;
  - Research protocol sent to applicant (or in the case of a referral to the profession or industry) to comment;
  - A literature review is undertaken and a draft report is developed;
  - The draft report is sent to the applicant (or in the case of a referral to the profession or industry) to comment;

# MSAC Process (3)

- A report is provided to MSAC with conclusions on safety, effectiveness and economic considerations (such as cost-effectiveness) along with the applicants comments and the evaluators response;
  - MSAC considers the report and makes a recommendation to the Minister for Health and Ageing.
- Decision
  - The Department implements the Minister's decision

# ASSESSMENT:

## Who is involved in an assessment?

- **MSAC Committee**
- **Advisory Panels**
  - MSAC member/s
  - Clinical experts
  - Economists
  - Consumers
- **Evaluators - assessments are contracted to organisations with expertise in Health Technology Assessment**
- **Support by DHA**

# Important elements of the assessment

- Search Strategy
  - **Safety – Wide including case reports**
  - **Effectiveness - RCTs if available**
  - **Cost effectiveness – Australian Health Care Context**
- Expert Opinion
- Develop Report
- Executive Summary
  - **Safety (all evidence)**
  - **Effectiveness (best evidence)**
  - **Cost Effectiveness (Australian evidence and whole of health care costs)**

# Issues for MSAC

- Diagnostic Technologies
- Funding in Uncertainty
- Approach to Economic Analysis

# MSAC Considerations

- **Evidence – HTA**
  - Safety
  - Effectiveness
  - Cost Effectiveness
    - True CE eg QALYS
    - Cost minimisation etc
- **Context**
  - Clinical Need
  - Australian context
  - Consistency
  - Fairness
  - Access
  - Equity and ethics
  - Costs
  - Funding

# Dimensions of Evidence (NHMRC)

- **Strength of Evidence**
  - Levels I - IV
  - Quality
  - Statistical Precision
- **Size of Effect**
- **Relevance of Evidence**

# Recommendations to the Minister for Health and Ageing

- **Public Funding Supported**
  - Full support
  - Interim Funding
    - With data collection
    - Awaiting trials
  - Restricted Funding
    - Specify Patient groups
    - Specify Indications MRI PET etc
    - Specify Providers
- **Public Funding Not Supported**

# Examples: Outcomes of MSAC assessments

- Carotid Stenting
  - Issue of patient preference
- Sentinel Lymph Node Biopsy in Breast Cancer
- MRCP
  - Issue of Substitution
- Artificial Anal Sphincter for Faecal Incontinence
  - Complication - reoperation
- Lung Reduction Surgery
  - Safety and disinvestment

# Some Issues for VPACT

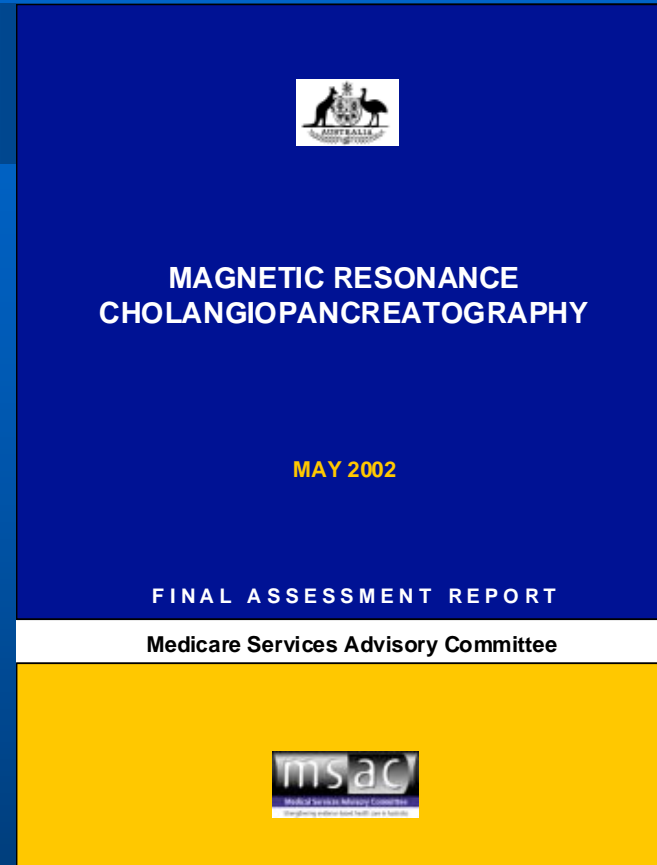
- **ToR**
  - **Identification of NT**
    - Health Service Network
    - HealthPACT
  - **Assessment of ClinE & CostE**
  - **Prioritise**
  - **Best Practice for Introduction**
  - **Policy on Health Service Delivery**
  - **Monitoring of NT**
  - **Dissemination of Info on NT**
- **Funding of NT**

# Some Issues for VPACT

- **Other Issues**
  - **Disinvestment**
  - **New uses of Existing Services**
    - **LVRS, TOE**
  - **Reevaluation of Existing Services**
    - **High Cost**
    - **Low Volume**
    - **High Risk**
  - **PET/Oesophagectomy/Transplant**

# Conclusions

- Achievements
- Future



<http://www.msac.gov.au>

# Promoting Clinically Relevant Innovation and Managing Uncertainty: The role of the HTA process

- **Healthcare Perspective**
  - **Consumers Providers Funders**

# Questions

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- **Clinically Relevant**
- **Innovative**

# OUTLOOK (1)

- Prosthesis Schedule
- Reviews
  - MSAC review
  - Productivity Commission Study into “The impact of advances in medical technology on healthcare expenditures in Australia”.

# OUTLOOK (2)

- Guidelines
  - Application and Assessment Guidelines
  - Guidelines for the assessment of diagnostic technologies
  - Guidelines relating to economic evaluation of health technologies
- Challenges
  - Gene technology
  - Tests/drugs eg osteoporosis

# MSAC Review (1)

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**The review aimed to identify areas where the MSAC could improve its capacity to fulfil its terms of reference.**

**The review is complete and is currently being considered by the Minister for Health and Ageing.**

# MSAC Review (2)

- **Submissions**
- **Main Themes**
  - **Clear reasons for decisions**
  - **Timely decisions**
  - **Consistent use of evidence**
  - **Including others in the MSAC process**
  - **Information and communication**

# MSAC Review (3)

- **Actions**

- **Some actions have been implemented in advance of the review being made public**

- **Examples**

- **Applicant feedback on evaluation protocols and draft assessment reports**
- **Inviting MIAA and AMA to comment on the evaluation protocol and assessment report for technologies referred to MSAC for review**
- **Minutes of MSAC meetings to be made available on the website**

# Productivity Commission Study (1)

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**The Australian Government asked the Productivity Commission to undertake a research study detailing the impact of advances in medical technology on healthcare expenditure, and the associated costs and benefits for the community.**

**A progress report was published in April 2005 and the final report is expected to be presented to Government late August.**

# Productivity Commission Study (2)

Key points from the progress report:

- **Over the past ten years, advances in medical technology have brought large benefits but have also been a major driver of increased health spending.**
- **Increased expenditure reflects a significant increase in the number of people treated, not simply higher prices.**
- **Establishing the precise impact of advances in medical technology on the overall cost effectiveness of the health system is not possible.**

# Productivity Commission Study (3)

- **The cost effectiveness of individual technologies is also difficult to determine and varies widely.**
- **There are numerous procedural and coverage gaps in health technology assessment (HTA) processes and considerable scope for better coordination of HTA processes, especially for devices and some medicines.**
- **Improved HTA processes could help to target new technologies to patient groups likely to benefit most and improve overall cost effectiveness of healthcare.**

# Productivity Commission Study (4)

## Next Steps

- **MSAC and the Department will be considering the findings of the study and implications for how it conducts health technology assessments.**

# Clinically Relevant

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- **Improve Healthcare**
  - **Real Endpoints**
  - **Avoid Surrogate Measures**

**Treating cancer**

**survival**

**QOL**

**Not regression of metastases (Sirtex)**

# Clinically Relevant – How?

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- **Advisory Panels – Clinical Experts**
- **Pathways of Care**
  - **Clinical Usage**
  - **Economic Modelling**

# Innovation

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- **New Technology**
- **New Roles for established Technology**
  - **Drugs ( Glivec for GIST) c-KIT**
  - **Lung Reduction Surgery**

# Problems for New Technology

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**Insufficient Data**

**Safety**

**Effectiveness**

**Cost Effectiveness**

**Lack of evidence of effectiveness does not imply ineffectiveness**

# Funding in Uncertainty

- **Interim Funding (may be conditional)**
  - **Awaiting further Information**
    - **Clinical trials**
    - **Other Studies**
- **Restricted Funding**
  - **Specify Patient groups**
  - **Specify Indications**
  - **Specify Providers**
    - **Credentialing**
    - **Craft Groups**

# Understanding Context

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- **Need**
- **Alternatives (Rule of Rescue)**
- **Utilisation**
- **Costs (CE, Total, Opportunity)**
- **Future Evidence**
- **Ethics**
- **Access**
- **Healthcare System / Funding**

# Examples

- TOE
- Nuchal Translucency
- DXA
- Liquid Based Cx Cytology
- ICSI
- Utilisation
- Ethics
- Real Improvement
- Australian System
- Ethics

# Components of the Assessment of a diagnostic test

- Define scope of assessment
  - **research question/s**
- Clinical need
  - **burden of disease/current treatment/tests**
- Systematic review of clinical evidence
- Economic evaluation

# Assessments of diagnostic technology

## Outcomes:

### Diagnostic accuracy

- **Sensitivity:** ability to detect people with the disease
- **Specificity:** ability to exclude people who don't have the disease
- **Accuracy:** proportion of all test results that are correct

### Downstream outcomes

- **Clinical management**
- **Clinical patient-outcomes**

# Define the Scope of the Assessment – PPICO (1)

## Patients & Prior tests

That requested by sponsor/referrer

May consider narrower or broader indications

## Index test

Specific components

## Determine 'Comparator'

“current test most likely to be replaced by the new technology”

OR

“supplementary test”

(all tests still done, none replaced)

comparator = current clinical practice

# Define the Scope of the Assessment – PPICO (2)

- Determine ‘reference standard’ measure of true disease status
- Define most appropriate Outcome measure
- Build PPICO to define research question

# Clinical need/burden of disease/current treatment

## Epidemiology:

- **Incidence & prevalence**
- **include estimates for “sub-indications” if necessary (often sourced from clinicians)**

## Mortality and morbidity

## Review current treatment practice

- **National statistics and clinical opinion**
- **Medicare-funded and other health sectors**
- **include estimates for “sub-indications” if necessary**
- **Implications for down-stream resource use**

# Systematic review of evidence

- Relative to comparator treatment/test
- Literature search
  - **Inclusion/exclusion criteria**
  - **Assess quality of evidence**
  - **Data extraction** (intention-to-treat if possible)
  - **Pooling data if necessary/appropriate** (meta-analysis)
- Summarise results
  - **Incremental outcome** (proposed vs comparator)