Implementing guidelines for reimbursement in Australia
How the PBAC & MSAC use comparative cost-effectiveness

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Access to medicines, devices and procedures in Australia

- Two stage system
  - Access
  - Subsidised access
1) Registration (licensing approval) by Therapeutic Goods Administration (TGA)
   - Efficacy, safety, quality
2) Subsidised access to listed drugs through the Pharmaceutical Benefits Scheme (PBS);
   Subsidised access to devices and procedures through the Medical Benefits Scheme (MBS).
About the Pharmaceutical Benefits Scheme

- National scheme in operation since 1948
- Open-ended funding
- Subsidised access to pharmaceuticals
  - 665 different drugs (June 2006)
  - 168 million scripts (05/06)
  - AUD $6.2 billion cost to government (05/06)
    - 17% of government health budget
    - 7.8% of Australian health expenditure
- PBAC “recommends”
  - comparative effectiveness, comparative safety, comparative costs

Who pays for medicines?

- Australian Government
- State/Territory Governments
- Consumers (Copay/NonPBS)
- Community Pharmacies
- Private Hospitals
- Public Hospitals
- PHARMACEUTICAL BENEFITS SCHEME (PBS)
  - Section 85
  - Highly Specialised Drugs (Section 100) (some other smaller programs)
Role of the PBAC

- Consider and evaluate submissions (requests for listing)
  - Drugs can only be listed on the PBS following positive recommendation by PBAC
- Legislative requirement for consideration of comparative costs and effectiveness in recommending drugs (since 1987)
- A new drug may be recommended for listing if:
  - Needed for prevention or treatment of significant medical conditions not already covered or inadequately covered, and is of acceptable cost-effectiveness
  - More effective and/or less toxic than a listed drug, and is of acceptable cost-effectiveness
  - At least as effective and safe as a listed drug, and is of similar or better cost-effectiveness
- Make recommendations about pricing matters referred by PBPA
- Since 2005-6 PBAC can also initiate reviews of drugs or classes of drugs
- Since 2006 PBAC processes apply to vaccines, including for the National Immunisation Program

Economic evaluation and PBAC

- Pharmaceutical Benefits Advisory Committee (PBAC)
  - makes recommendations about allocation of resources to and between medicines
- Economic evaluation (formal requirement since 1993)
  - Informs decisions about “acceptable cost-effectiveness”
  - Answers questions of technical and (to some extent) allocative efficiency
  - Does not address issues of equity
- PBAC is concerned with efficiency and equity
  - Committee judgment
  - Other relevant factors
Economic Sub-Committee of PBAC

- ESC is a technical committee
- Comprises clinicians, epidemiologists, pharmacologists, biostatisticians and economists
- Undertakes prior technical assessment of the submission and the commentary
  - Uses advice from independent groups of academic evaluators
- Provide ESC advice to PBAC on clinical and economic aspects
  - Particularly on the nature of the evidence and on key areas of clinical and economic uncertainty
- ESC does not make recommendations about listing,
  - Identify all issues that are relevant to the decision
  - Aiming to ensure all relevant information is available by PBAC meeting
- Also provides advice about other issues
  - Particularly guidelines, methodological developments

Economic Evaluation

- Stepped economic evaluation
  - From the clinical trial results to the model
  - Designed to make explicit the impact of the assumptions made in the pre-modelling studies
- Explicit preference for CUA in most cases
  - where there is a claim of life-years gained to assess the impact of QOL for the survival gain
  - where there is a claim of improvement in QOL
  - where relevant direct randomised trials report results using a MAUI
- CUA not mandated
  - Where there is a high degree of uncertainty about the translation to QALYs may be less informative
PBAC recommendations

- Recommend:
  - Cost-minimisation (no price advantage)
  - Acceptable cost-effectiveness (price advantage)
  - Other factors (eg, rule of rescue)

- Reject
  - Incremental cost-effectiveness ratio unacceptably high
  - Poor quality of evidence
  - High level of uncertainty
  - Concerns about total cost
  - Concerns about leakage
  - Other concerns

- Deferral

Relevant factors in PBAC decisions

- Quantifiable
  - comparative health gain
  - comparative cost effectiveness
  - total cost to government
  - affordability
  - financial implications for PBS
  - financial implications for government

- Less readily quantifiable
  - severity of condition treated
  - presence of effective alternatives
  - ability to target therapy to those likely to benefit most
  - non-health related benefits
  - uncertainty
  - equity
  - development of resistance
Descriptive data on decision to list drug on PBS and cost per QALY (uncontrolled for other factors)

PBAC recommendations of list at price proposed 1994-2004 Cost per QALY

Transparency of the PBAC

- A difficult issue
  - Submissions are commercial-in-confidence
  - Evaluation documents are commercial-in-confidence

- Decisions published on the Web
  - Both positive and negative

- Public summary documents made available
  - 14 weeks after decision

Medical Services Advisory Committee

- MSAC provides recommendations to the Australian Minister for Health and Ageing regarding evidence relating to:
  - Safety
  - Effectiveness
  - Cost-effectiveness
  - Budgetary impact

- MSAC recommendations are used to decide whether public funding, via MBS is granted
  - Directly – MBS fee payable to medical practitioner
  - Indirectly – determines other costs associated with procedure e.g. theatre, bed-days, equipment and prosthesis
The place of MSAC

Australian Government

- Therapeutic Goods Administration (TGA)
- Medical Services Advisory Committee (MSAC)
- Health Minister
- Medical Benefits Scheme (MBS)

State/hospital

- State/hospital Committee
- Hospital procedures

MSAC composition

- 3 Executive members
  - 1 chair
  - 2 deputy chairs
- 17 Members (mainly specialists), consumer representative (CHF), health economists (2), epidemiologist
- Recently introduced economics sub-committee
Current MSAC process

- $250,000 per application
- Slow appraisal process - up to 2 years
  - Creating an advisory panel
  - Balance b/w clinician engagement – process consultation and timely process
  - Balance between evidence and expert opinion
- Standard treatment not always an MBS listed item
- Evidence of Effectiveness
  - Not nearly as robust data as presented to PBAC
  - Sponsor often has markedly less funds to invest in studies generating high level data
  - Culture of surgical innovations historically occurring behind “closed doors”

MSAC - Uptake and diffusion

- Established or intermediate technologies, but not “cutting edge technologies.”
- Technological imperative
  - Once MBS listed the cap is loose - strong economic incentives to use a technology once capital equipment is paid for, marginal cost is very low
- Incentive for the over provision of expensive technologies
  - Financial reward for doctors in a fee for service system
  - Facilitator of the uptake of new technologies not primary driver
Challenges for MSAC

- Clarify role of advisory committee
  - Needs to be more advisory, not make recommendations
  - AC provides technical advice; advice reviewed by ESC; advice comes to MSAC, who make decision
- Cost-effectiveness evaluation compromised
  - MBS sets floor price + safety net = no ceiling
    - Price in CEA not what patient pays (dr’s fees)
    - Price in CEA not what govt pays (safety net)

Procedural fairness -1

- Daniels et al, …"deliberate process is transparent and encourages relevant stakeholders to deliberate on relevant reasons as well as providing room for revising decisions”.
- MSAC process is generally fair and transparent, and has been increasingly so over time
- Minutes are published and made publicly available, draft reports are sent to applicants for critiquing.
- Reports are available on the website
Procedural fairness -2

• Decision making process is not consistent
  – Unlike PBAC – less looking back to previous decisions to see whether or not they are consistent
  – No consistent evidence across the reports
    • not using the same evidence, not using the same outcome measures, costed differently, across technologies (diagnostics, devices)

• Ultimately decisions are value judgements
  – other considerations in MSAC reports

Summary

PBAC
• Companies conduct research; PBAC commissions evaluations
• COI more readily avoided
• Cost-effectiveness
• Gate keeper re access

MSAC
• MSAC-appointed group conducts evaluation
• COI difficult – need experts for process; they also stand to gain from decision
• Cost-effectiveness
• About price, not access