Health Technology Assessment in Australia

OSTEBA 25th Anniversary
Bilbao October 24th – 25th 2017

Prof Brendon Kearney, Chair Health PACT
Adoption and diffusion

Technology → Adoption → Technology use → Diffusion → Impact

Diffusion %

0 100

EuroScan International Network
Horizon scanning and HTA

- Basic biomedical research
- Translational research
- Safety and efficacy
- Effectiveness and cost-effectiveness
- General clinical use

Primary data collection
- Horizon scanning (early awareness and alert activities)
- Reviews and early assessments
- Pragmatic trials
- Licensing

Full HTAs and Cochrane style reviews
Australia is a Federation

National Government

State Government
- New South Wales
- Queensland
- South Australia
- Tasmania
- Victoria
- Western Australia

Territory Government
- Australian Capital Territory
- Northern Territory
Australian Health Ministers Conference

Represented by National, State and Territory Health Ministers
And the New Zealand Health Minister
Australian Health System

Universal Health Care

All citizens have a right to
- free hospital care
- subsidised medical services
- subsidised pharmaceutical services
Australian Government

Responsible for

Medical Benefits
- Approx. 85% of the medical schedule
- Varies - low income people no cost
- Others out of pocket costs 15% plus

Pharmaceuticals
- Low income approx. $6 per prescription
- Others approx. $38 per prescription

Approves Private Health Insurance fees
State and Territory Governments

- Operate Public Hospitals
  - Receives part funding from national government
  - Provides own financing

Public Health Services
Health Technology Agencies in Australia

- Therapeutic Goods Administration
- Pharmaceutical Benefits Advisory Committee
- Medical Services Advisory Committee
- Health Policy Advisory Committee on Technology
- Prosthesis List Advisory Committee
TGA

Regulator of therapeutic goods

- Therapeutic goods must be on the Australian Register of Therapeutic Goods to be legally supplied in Australia
- Applicant based information is considered
- Risk benefit approach

Priorities built into application process with risk classification structures for drugs, devices, invitro diagnostics
An Agency of the Australian Department of Health

CEO – Prof. John Skerritt
Deputy Secretary of Health
Review of TGA in 2016 accepted by Government
  - Generics
  - Biosimilars
  - SAS and CTN
  - Classification of medical devices
  - Recognition of international agencies

TGA funded by industry charges
Committees of TGA

Medicines Committee
- complimentary medicines
- medicine scheduling
- non prescription medicine
- prescription medicine
- safety of medicine
- safety of vaccines
TGA committees

Medical Devices

- Medical devices
- Safety of medical devices

BiologicaIs

Other

- Chemical scheduling
- Therapeutic goods
## Classification of Medical Devices

<table>
<thead>
<tr>
<th>Classification</th>
<th>Level of Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class 1</td>
<td>low</td>
</tr>
<tr>
<td>Class 1 - supplied sterile</td>
<td>low to medium</td>
</tr>
<tr>
<td>- incorporating a measurement function</td>
<td></td>
</tr>
<tr>
<td>Class 11a</td>
<td>medium - high</td>
</tr>
<tr>
<td>Class 11b</td>
<td>high</td>
</tr>
<tr>
<td>Class 111</td>
<td>high</td>
</tr>
<tr>
<td>Active implantable medical devices</td>
<td>high</td>
</tr>
</tbody>
</table>
PBAC

Recommends drugs to be funded on the National Pharmaceutical Benefits Scheme.

Application based submissions.

Recommendation of consideration of

- Safety
- Effectiveness
- Cost effectiveness

Priority setting
- Cost effectiveness
  - QALY
  - ICER

Some exceptions
Pharmaceutical Benefits scheme started 1948.

PBAC early in cost effectiveness.

Charges per prescription
- $AUD 38.30
- $AUD 6.20 concession

Safety Net
- $AUD 1475.70
- $AUD 372 concession
- applies to a family

Section 100
- highly specialised drugs
- special authority program
- other
New Drugs

Introduced on a clinical trials basis.

Funding or reimbursement by PBS only after recommendation by PBAC.

Considering

- safety
- effectiveness
- cost effectiveness
PBS Costs

↑ by 13% from 1994 to 2005

2005 2.7%
2006 4.3%
2007 9.4%
2008 9.2%
2009 9.3%
2010 5.7%

Reduced since then by use of
- generics
- biosimilars
- but funding new high cost drugs
QALY

Used in PBAC assessments

No set amount

Can vary widely
PBAC

HPV Vaccine

High Qualy

Population Health approach
  - reduction in cervical cancer and precursor lesions
  - changes to cervical cancer screening programme
PBAC

Hepatitis C

- Industry submitted to PBAC for listing
- Request for approx $3 billion dollars
- PBAC looks at Population Health approach to eliminate Hepatitis C from Australia
- Currently 230,000 patients
- PBAC Qualy assessed at $15000
- PBAC/Health negotiates with industry to fund all drugs and genotypes
- 10 year agreement for approx. $1 billion
  - Volume vs. price
  - risk for Government and Industry
- 30,000 treated in first six months
- Generic scheme ceased
- Associated public health programme
<table>
<thead>
<tr>
<th>Genotype</th>
<th>No Previous Treatment (naïve)</th>
<th>Previously Received Treatment (experienced)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No cirrhosis</td>
<td>With cirrhosis</td>
</tr>
<tr>
<td>1 a/b</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ledipasvir/sofosbuvir (8 or 12 Weeks)</td>
<td>Ledipasvir/sofosbuvir (12 Weeks)</td>
</tr>
<tr>
<td></td>
<td>or Sofosbuvir and Peg-Interferon alfa-2a/ribavirin (12 weeks)</td>
<td>or Sofosbuvir and Peg-Interferon alfa-2a/ribavirin (12 weeks)</td>
</tr>
<tr>
<td>1 a/b</td>
<td>Daclatasvir and sofosbuvir (12 weeks)</td>
<td>Daclatasvir and sofosbuvir and ribavirin (12 weeks)</td>
</tr>
<tr>
<td></td>
<td>or Daclatasvir and sofosbuvir (24 weeks)</td>
<td>or Daclatasvir and sofosbuvir (24 weeks)</td>
</tr>
<tr>
<td>1 a</td>
<td>Paritaprevir-ritonavir, ombitasvir, dasabuvir and ribavirin (12 weeks)</td>
<td>Paritaprevir-ritonavir, ombitasvir, dasabuvir and ribavirin (12 weeks)</td>
</tr>
<tr>
<td>1b*</td>
<td>Paritaprevir-ritonavir, ombitasvir and dasabuvir (12 weeks)</td>
<td>Paritaprevir-ritonavir, ombitasvir and dasabuvir (12 weeks)</td>
</tr>
<tr>
<td>2</td>
<td>Sofosbuvir and ribavirin (12 weeks)</td>
<td>Sofosbuvir and ribavirin (12 weeks)</td>
</tr>
<tr>
<td>3</td>
<td>Daclatasvir and sofosbuvir (12 weeks)</td>
<td>Daclatasvir and sofosbuvir (24 weeks)</td>
</tr>
<tr>
<td></td>
<td>or Sofosbuvir and ribavirin (24 weeks)</td>
<td>or Sofosbuvir and ribavirin (24 weeks)</td>
</tr>
</tbody>
</table>
MSAC

Recommends non drug technologies for funding on the National Medical Benefits Scheme

Application based submissions

Recommendation on consideration of
  • Safety
  • Effectiveness
  • Cost effectiveness

Priority setting
  • Cost effectiveness
  • QALY
  • ICER

Some exceptions
MSAC

All non drug technologies associated with a medical service devices, prostheses, procedures, diagnostics, hybrid technologies etc.

- safety, effectiveness, cost effectiveness
- public funding
- description of service

Established 1998
MSAC

Subcommittees

- Evaluation (ESC)
  Reviews evidence including economic and financial, clinical comparators, expert opinion and assumptions summary to MSAC

- Protocol (PASC)
  Develop a decision analytical protocol to consult.
MSAC

Use of QALY
No set amount
Varies according to circumstance

Other references
Including population health and screening services
Industry plus individual reference
HealthPACT

emerging health technology

Health Policy Advisory Committee on Technology – HealthPACT

Professor Brendon Kearney
Chair, HealthPACT
Health care cost continue to increase

30-40% of the annual increase in health care costs are due to new and emerging technologies
HealthPACT
emerging health technology

HealthPACT Membership consists of representatives of:

- Australian States and Territories
- New Zealand Ministry of Health
- Medical Services Advisory Committee
- Hospitals Principal Committee
- Department of Veteran Affairs
- Therapeutic Goods Administration
HealthPACT

emerging health technology

HealthPACT

Reports to Australian Health Ministers

Conference on new and emerging technologies

Uses technique of horizon scanning
Priority Setting

Results of Horizon Scanning to members every three months.

Members can nominate technologies.

State committees and hospital HTA committees can nominate.

Decision is based on the following criteria.
HealthPACT
emerging health technology

Priority Setting:
- Jurisdictional strategies
- Volume and cost
- Clinical need
- Rate and pattern of diffusion
- Estimated cost impact
- Efficacy and safety issues
- Ethical issues
- Cultural or religious issues
Identification
Scan data sources to identify emerging health technologies

Apply Priority Threshold Criteria
Is the technology:
- Associated with obvious safety or ethical issues?
- Rapidly diffusing throughout the Australian health system and yet to be assessed?
- Applicable to a large proportion of the Australian population, with considerable clinical or cost impact?
- Applicable to a small proportion of the population but with obvious and far-reaching benefits?

Fails to meet criteria

Meets criteria

Technology Brief developed

HealthPACT consideration

Full HTA
NEHTR
Monitor
Watching Briefs

MSAC

HealthPACT consideration

Outcomes inform jurisdictions
HealthPACT
emerging health technology

Recent issues identified by HealthPACT:

- Trans-catheter aortic valve implantation (TAVI)
  - First identified and assessed by HealthPACT in 2007
  - For the treatment of symptomatic aortic stenosis
  - At the time TAVI device not approved by the regulator TGA
  - Diffusing rapidly throughout the jurisdictions
  - High cost device ($25-30,000 for the device alone)
  - Highly controversial – limited data on the long term durability and cost effectiveness of the device
  - Patient selection critically important: should only be performed in patients with inoperable aortic valve disease
  - Potential to significantly impact on health budgets if performed in patients with operable aortic valve disease
  - March 2016: MSAC supported MBS listing of the TAVI procedure
HealthPACT
emerging health technology

Recent issues identified by HealthPACT:
- Renal denervation
  - Identified and assessed by HealthPACT in March 2010
  - For the treatment of refractory hypertension
  - Several devises approved by the regulator TGA
  - Diffusing rapidly throughout the jurisdictions
  - High cost device (in excess of $10,000 per patient)
  - Potential to significantly impact on health budgets due to large number of patients
- Highly controversial –
  - Initial results from RCTs showed a reduction in BP on up to 30 mmHg
  - No long-term data effectiveness data, especially on outcomes such as morbidity and mortality from stroke and cardiovascular disease
  - Some patients have undergone multiple procedures
  - Some patients remain on medication
HealthPACT

emerging health technology

Both of these technologies highlight the need for:

- Clinical trials with defined patient criteria and appropriate data collection to allow determination of the long-term clinical effectiveness and cost-effectiveness of the device.

- A well funded, national device registry.
Other cardiovascular technologies identified by HS:

- Endovascular clot retrieval with thrombolysis for ischaemic stroke.
- Mitral valve using the transapical approach.
- Bioresorbable vascular scaffolds for coronary artery disease.
- Leadless Pacemakers.
- CT calcium scoring for coronary artery diseased screening in asymptomatic population.
- Zio patch for diagnosis of cardiac arrhythmias.
- ROX Coupler for Treatment-resistant Hypertension.
- Drug eluting stents with CED34 antibodies for the treatment of coronary artery disease.
Prostheses List Advisory Committee

Advises on the list of prostheses that Private Health Insurers pay benefits for.

Application based.
PLAC

Private Health Insurance under financial pressure.

Review of PLAC and PHI packages
Conclusions

- Australia spends 10% GDP on health
- A number of HTA committees work to oversight the role of HTA in health care.
- New drugs are introduced on a clinical trials basis
- Non drugs technologies are assessed by HealthPACT to oversight diffusion of new and emerging technologies
- Once technologies have diffused or are mature they are assessed for reimbursement by PBAC and MSAC
- PLAC oversights non drug technologies covered by Private Health Insurance – PHI increases are under significant pressure.
Conclusions (continued)

Australia has an active disinvestment programme

- Choosing wisely Australia.
- Review of the Medicare Benefits Schedule.
- HealthPACT is working with Safety and Quality to reduce variation.