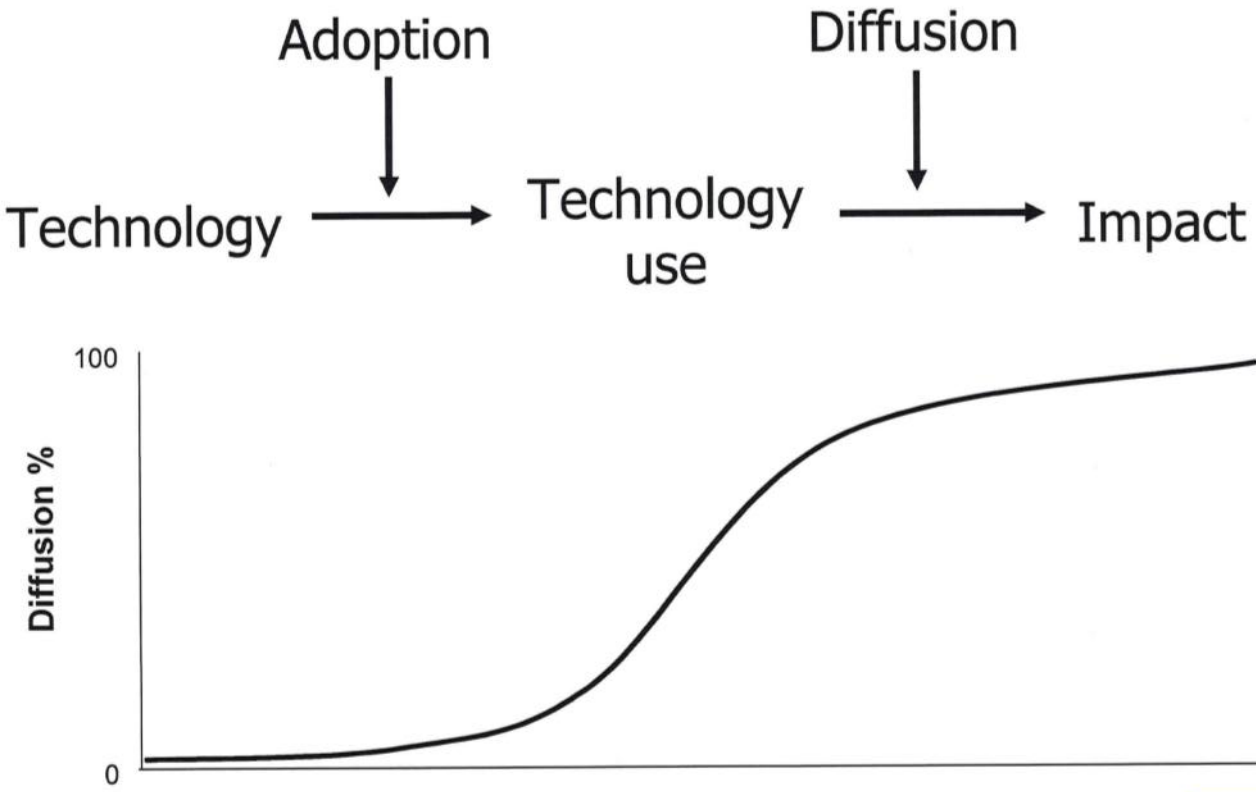
Health Technology Assessment in Australia

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

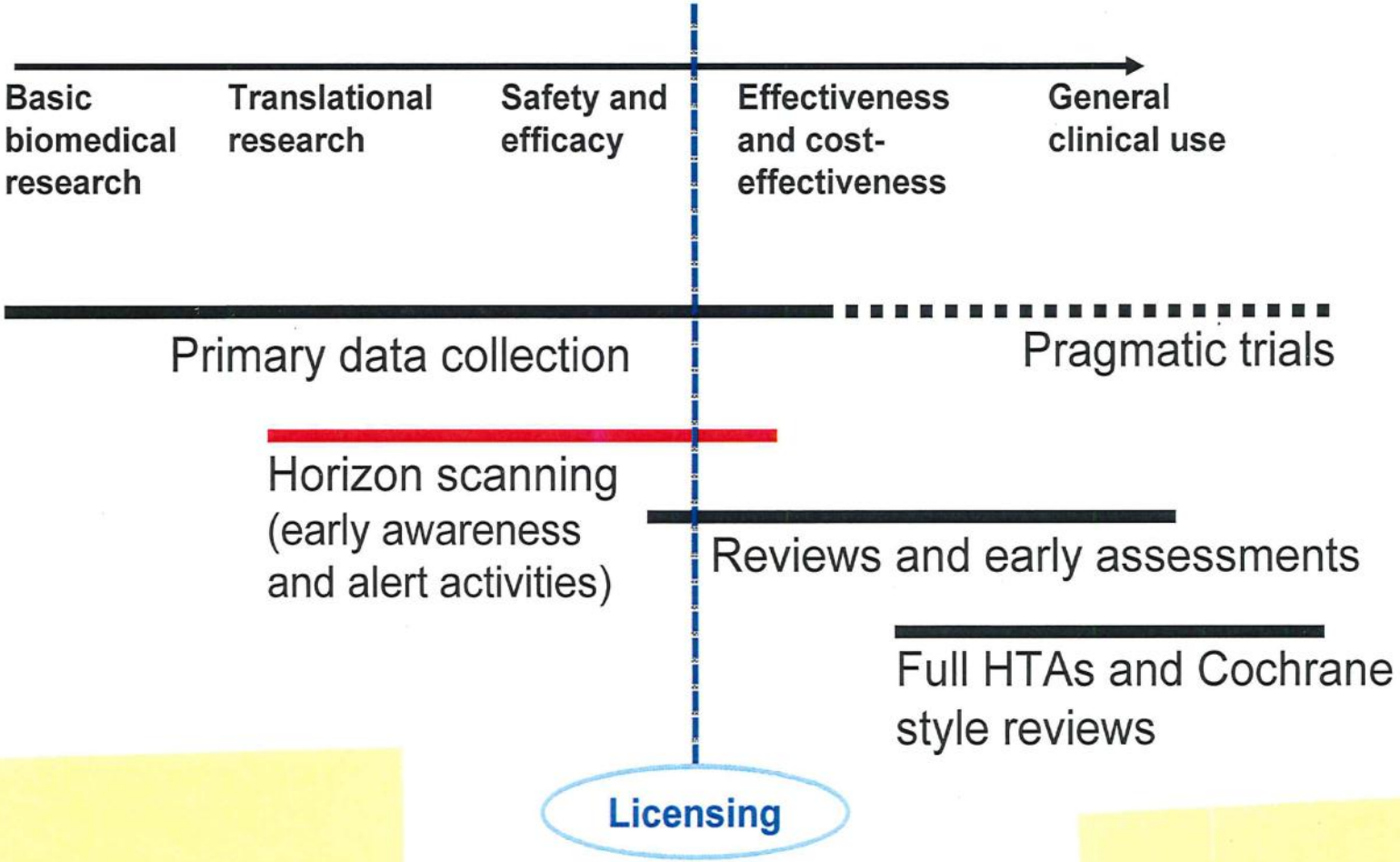
Prof Brendon Kearney, Chair Health PACT

Adoption and diffusion



EuroScan
International Network

Horizon scanning and HTA



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

Biologicals

Other

- Chemical scheduling
- Therapeutic goods

Classification of Medical Devices

Classification	Level of Risk
Class 1	low
Class 1 - supplied sterile	low to medium
- incorporating a measurement function	
Class 11a	
Class 11b	medium - high
Class 111	high
Active implantable medical devices	high

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

Genotype	No Previous Treatment (naïve)		Previously Received Treatment (experienced)	
	No cirrhosis	With cirrhosis	No cirrhosis	With cirrhosis
1 a/b	**Ledipasvir/sofosbuvir** (8 or 12 Weeks)	**Ledipasvir/sofosbuvir** (12 Weeks) or **Sofosbuvir** and **Peg-Interferon alfa-2a/ribavirin** (12 weeks)	**Ledipasvir/sofosbuvir** (12 Weeks) or **Sofosbuvir** and **Peg-Interferon alfa-2a/ribavirin** (12 weeks)	**Ledipasvir/sofosbuvir** (24 Weeks) or **Sofosbuvir** and **Peg-Interferon alfa-2a/ribavirin** (12 weeks)
1 a/b	**Daclatasvir** and **sofosbuvir** (12 weeks)	**Daclatasvir** and **sofosbuvir** and **ribavirin** (12 weeks) or Daclatasvir and sofosbuvir (24weeks)	**Daclatasvir** and **sofosbuvir** (12 or 24 weeks)	**Daclatasvir** and **sofosbuvir** and **ribavirin** (12 weeks) or Daclatasvir and sofosbuvir (24weeks)*
1a	**Paritaprevir-ritonavir, ombitasvir, dasabuvir** and **ribavirin** (12 weeks)	**Paritaprevir-ritonavir, ombitasvir, dasabuvir** and **ribavirin** (12 weeks)	**Paritaprevir-ritonavir, ombitasvir, dasabuvir** and **ribavirin** (12 weeks)	**Paritaprevir-ritonavir, ombitasvir, dasabuvir** and **ribavirin** (12 or 24 weeks)
1b*	**Paritaprevir-ritonavir, ombitasvir** and **dasabuvir** (12 weeks)	**Paritaprevir-ritonavir, ombitasvir** and **dasabuvir** (12 weeks)	**Paritaprevir-ritonavir, ombitasvir** and **dasabuvir** (12 weeks)	**Paritaprevir-ritonavir, ombitasvir** and **dasabuvir** (12 weeks)
2	**Sofosbuvir and ribavirin** (12 weeks)	**Sofosbuvir** and **ribavirin** (12 weeks)	**Sofosbuvir** and **ribavirin** (12 weeks)	**Sofosbuvir** and **ribavirin** (12 weeks)
3	**Daclatasvir** and **sofosbuvir** (12 weeks) or **Sofosbuvir** and **ribavirin** (24 weeks)	**Daclatasvir** and **sofosbuvir** (24weeks) or **Sofosbuvir** and **ribavirin** (24 weeks)	**Daclatasvir** and **sofosbuvir** (12 weeks) or **Sofosbuvir** and **ribavirin** (24 weeks)	**Daclatasvir** and **sofosbuvir** (24 weeks) or **Sofosbuvir** and **ribavirin** (24 weeks)

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

HealthPACT

emerging health technology

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

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emerging health technology

Priority Setting

Results of Horizon Scanning to members every three months.

Members can nominate technologies.

State committees and hospital HTA committees can nominate.

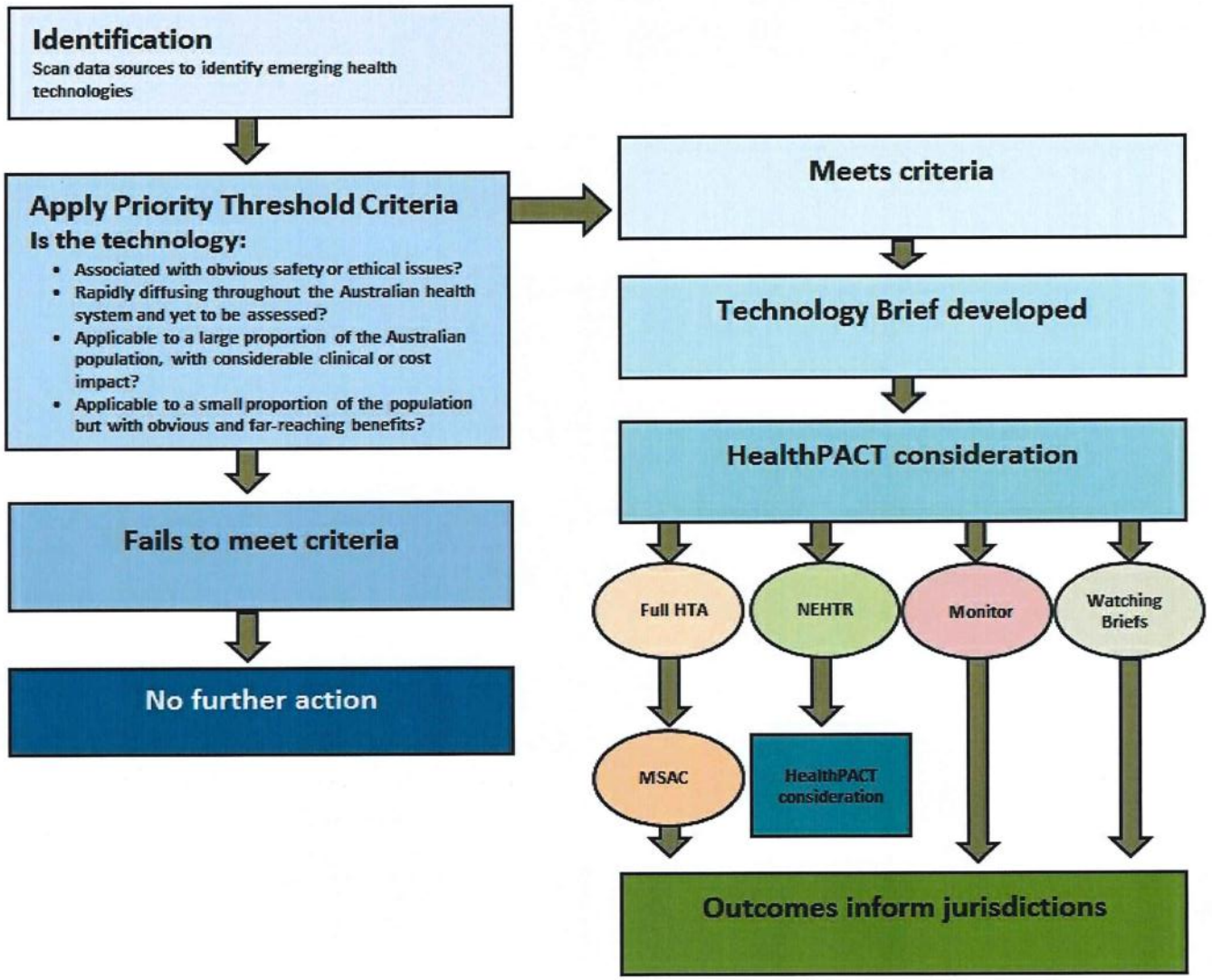
Decision is based on the following criteria.

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
No further action
Meets criteria
Technology Brief developed
HealthPACT consideration
Full HTA
NEHTR
Monitor
Watching Briefs
MSAC
HealthPACT consideration
Outcomes inform jurisdictions

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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.

HealthPACT

emerging health technology

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.