Universal drug coverage: Perspectives from another federated health system

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Medicines Intelligence
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Disclosure of interests

I receive funding support and/or sitting fees from:

- National Health and Medical Research Council (NHMRC)
- Department of Industry, Innovation and Science
- *Australian Government Department of Health and Aged Care*
  - *Member, Drug Utilization Sub-Committee of the Pharmaceutical Benefits Advisory Committee*
  - *Expert Panel, Health Technology Assessment and Methods Review*
- Australian Commission on Safety and Quality in Health Care
- National Data Advisory Council
- NSW Bureau of Health Information

Overview

- Australia's Pharmaceutical Benefits Scheme (PBS) in context
- Is the PBS still fit-for-purpose?
- Future proofing the PBS

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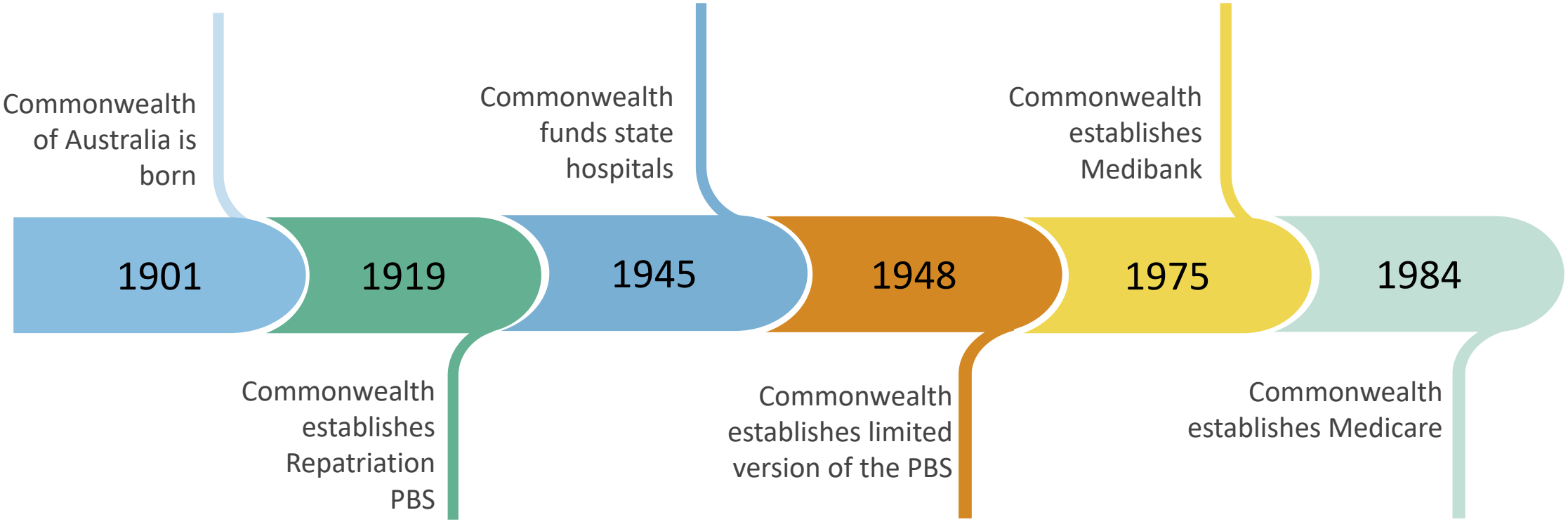
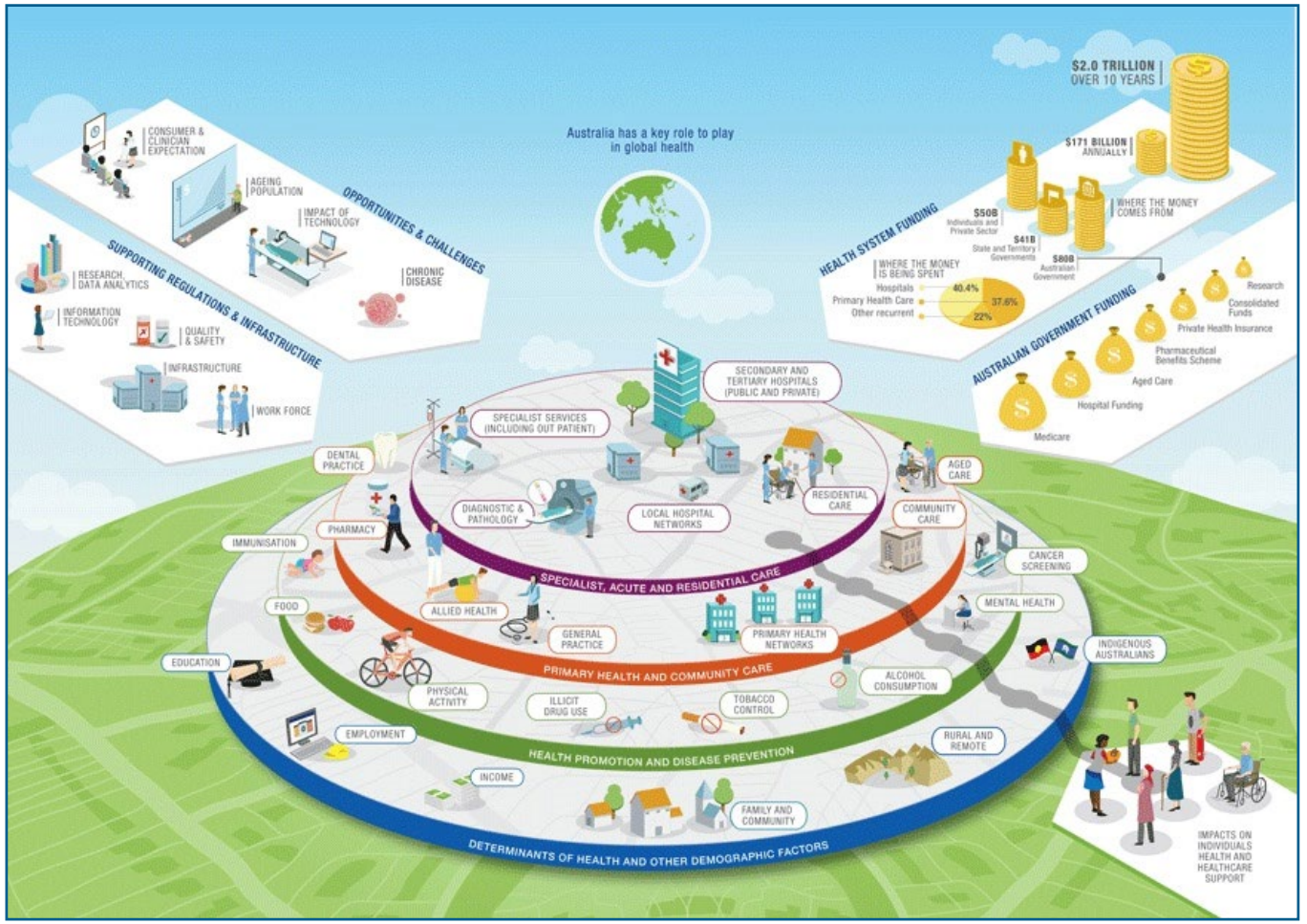
Aussie health system snapshot

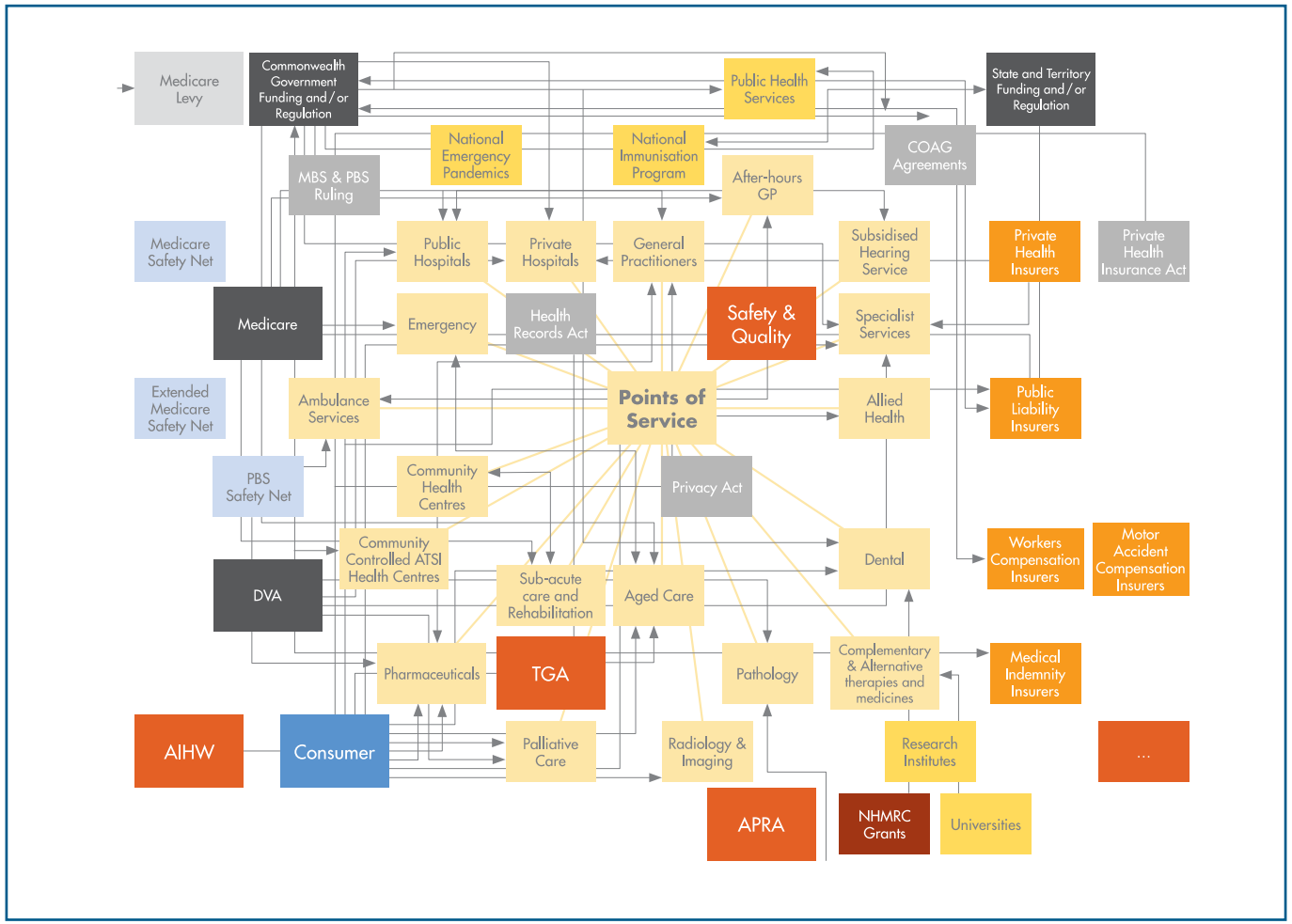


Australia's contemporary health system



www.health.gov.au

Australia's contemporary health system



https://apo.org.au/node/69020

Australia's health spend

- Financial year 2021-2022
  - $241.3 billion on health goods and services
  - Governments funded 72.9%, non-government sources fund remainder
  - Average $9,365/person
  - 10.5% of GDP
  - PBS 0.7% of GDP

- Medicare levy funds public health care: 2% taxable income

https://www.aihw.gov.au/reports/health-welfare-expenditure/health-expenditure

Australia's health spend

Financial year 2020-2021

- Australian Government: $94.336 million
- State/Territory Governments: $61.601 million
- Individuals: $33.156 million
- Private Health Insurance: $18.039 million
- Other: $13.712 million

https://www.aihw.gov.au/reports/health-welfare-expenditure/health-expenditure

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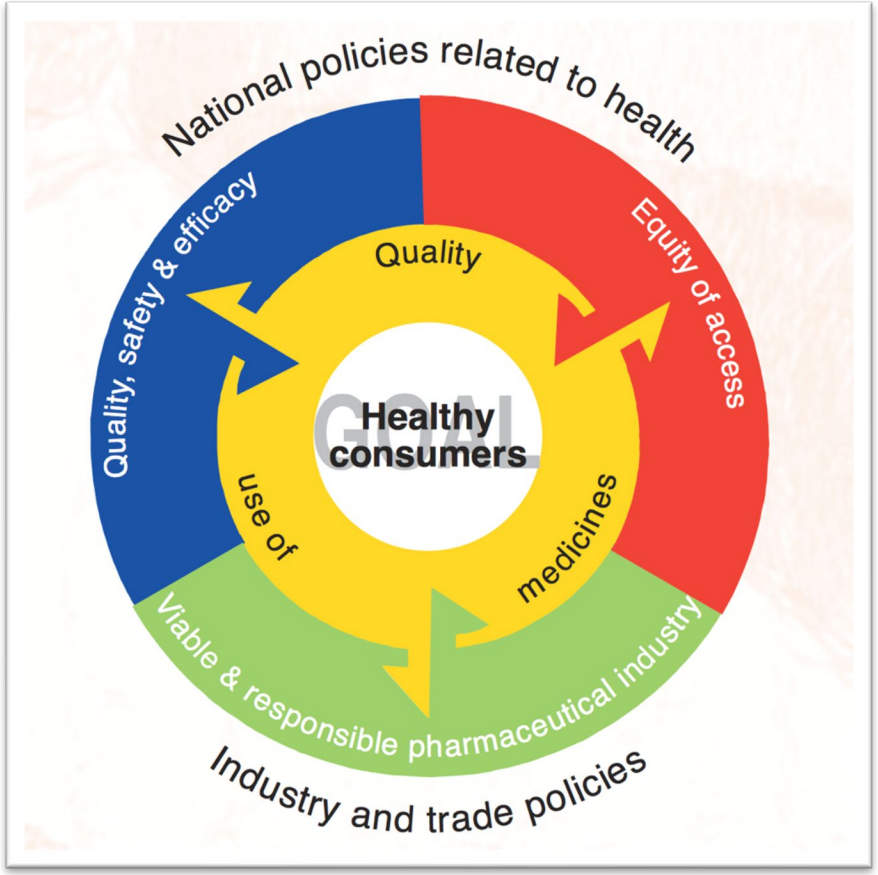
Australia's National Medicine Policy (2000)

- Meet medicine and related health service needs
- Achieve optimal health and economic outcomes
- Prescription, non-prescription and complementary medicines
- Centrality of quality use of medicines (QUM)
  - Selecting management options wisely
  - Choosing suitable medicines, if a medicine is considered necessary
  - Using medicines safely and effectively



QUM initiatives

1998
- National Prescribing Service launched

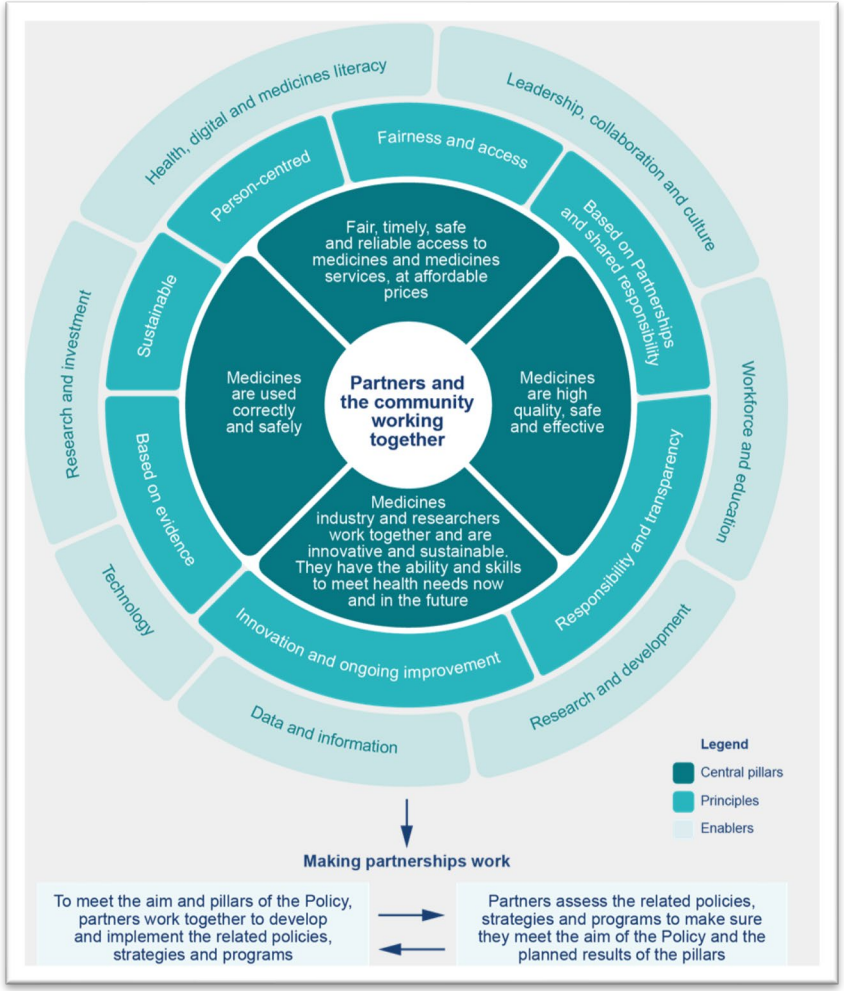
2004
- Veterans' Medicines Advice and Therapeutics Education Services (MATES) launched

2019
- QUM and medicines safety becomes Australia's 10th National Health Priority

Australia's National Medicine Policy (2022)

Pillars

- equitable, timely, safe and reliable access to medicines and medicines-related services, at a cost individuals and the community can afford
- medicines meet the required standards of quality, safety and efficacy
- quality use of medicines and medicines safety
- collaborative, innovative and sustainable medicines industry and research sector with capacity and expertise to respond to current and future health needs



Australia's National Medicine Policy

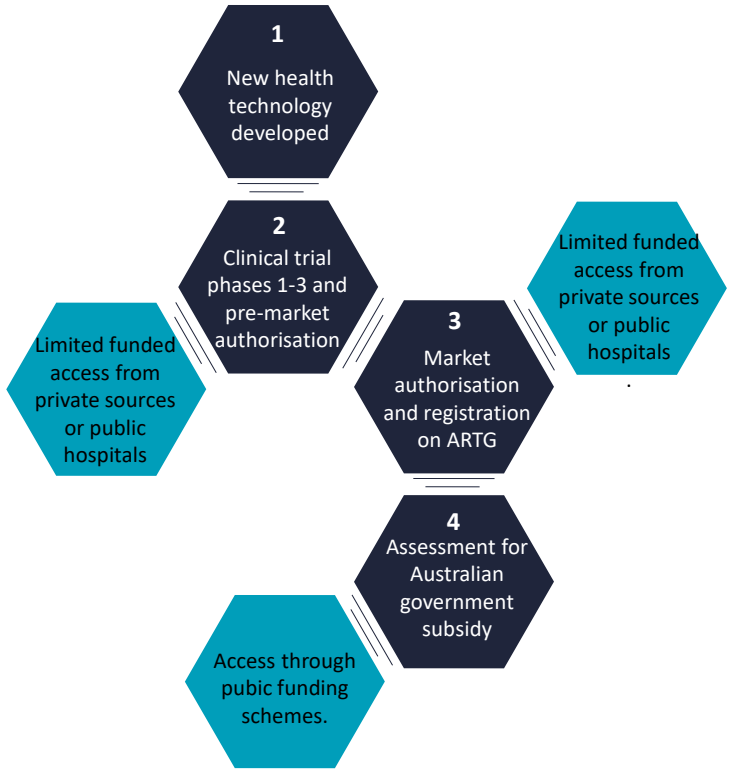
Therapies/products used to treat disease or health condition

- *prescription medicines*
- *gene therapies*
- *vaccines*
- *devices used to administer and monitor medicines or used together with medicines*
- non-prescription medicines
- complementary and traditional medicines

Australia's Pharmaceutical Benefits Scheme

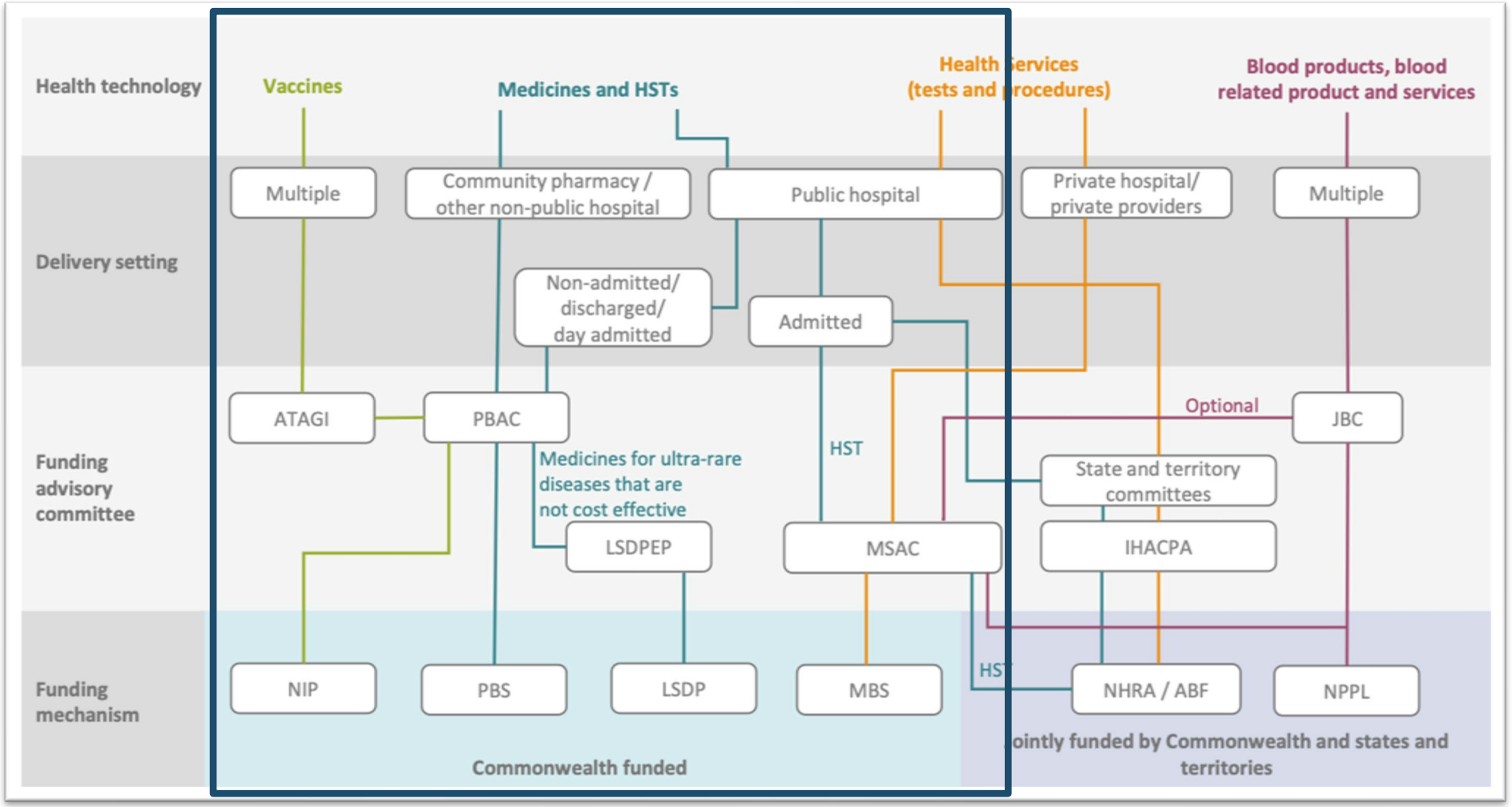
- Universal, single public payer prescription medicines program for all Australians and permanent residents
- PBS as we know it today, established under *National Health Act 1953*
- Uncapped budget
- June 2023: 928 different medicines, 5,261 brands
- More than 200 million PBS scripts dispensed annually

PBS listing process



- Medicine assessed for quality, efficacy and safety by the Therapeutic Goods Administration (TGA)
- Must be listed on the Australian Register for Therapeutic Goods
- Assessed by Pharmaceutical Benefits Advisory Committee (PBAC): independent expert body recommending new listings based on
  - clinical efficacy
  - safety
  - cost-effectiveness, relative to other available treatments

Funding pathways



Approval times (months)

New Drugs (all)	Min	Median	Average	Max
First EMA/FDA approval to PBS listing	11	37	47	205
PBAC submission to PBS listing	9	17	22	75
ARTG registration to PBS listing	2	21	25	84

Schedule of Pharmaceutical Benefits

- Subsidises medicines at point of dispensing
- Community pharmacies *plus public and private hospitals*
- Most medicines dispensed on ‘General Schedule’ or ‘Section 85’ by community pharmacies
- Commonly 28-day supply

A-Z medicine listing – Viewing by Drug (View by Brand)

A | B | C | D | E | F | G | H | I | K | L | **M** | N | O | P | Q | R | S | T | U | V | W | Y | Z |

MACITENTAN
S100 HSD Private

MACITENTAN
S100 HSD Public

MACROGOL-3350
General Schedule

MACROGOL-3350
Palliative Care

MACROGOL-3350 + SODIUM CHLORIDE + BICARBONATE + POTASSIUM CHLORIDE
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General Schedule

MAGNESIUM
Repatriation Pharmaceutical Benefits

MAGNESIUM
General Schedule

MANNITOL
S100 HSD Private

MANNITOL
S100 HSD Public

MARAVIROC
S100 HSD Community Access

Schedule of Pharmaceutical Benefits

- Some PBS medicines supplied through ‘Section 100’ where normal supply arrangements are not suitable:
  - **Highly Specialised Drugs Program:** prescribed by or under the guidance of a treating specialist, and dispensed by a hospital pharmacy
  - **Efficient Funding of Chemotherapy:** PBS cancer medicines administered through infusion or injection
  - **Opiate Dependence Treatment Program**
  - Supply to remote area **Aboriginal Health Services:** no charge or need for PBS prescription
  - Other programs: e.g. **supply of IVF medicines**

Managing uncertainty

- Deed of agreement between Australian Government and 'Responsible Parties' to maintain appropriateness and cost-effectiveness of PBS-listed medicines
- Two broad arrangements covered by the Deed and managed through rebates
  - **Special pricing arrangements**: the difference between the 'published price' on the *Schedule of Pharmaceutical Benefits* and the price actually paid by the Commonwealth (the 'effective' price)
  - **Risk share arrangements**: developed to address common uncertainties
    - Overall PBS costs
    - Cost-effectiveness
    - Overall gain in health outcomes
    - PBS utilisation
- Some experience with **Managed Entry Schemes** since 2011

PBS co-payments and safety net (2022)

- Patients pay co-payment towards the cost of each PBS medicine dispensed
- Patients may pay additional fees e.g. brand premium
- Co-payments adjusted to CPI each year

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Beneficiary Type	Co-payment	Safety Net Threshold	Safety Net Co-payment
General	$42.50 (max.)	$1,542.10	$6.80
Concessional	$ 6.80	$ 326.40	$0.00

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Beneficiary Type	Co-payment
DVA	$6.80
Closing the Gap - General	$6.80
Closing the Gap - Concessional	$0.00

PBS co-payments and safety net (2022)

- Patients pay co-payment towards the cost of each PBS medicine dispensed
- Patients may pay additional fees e.g. brand premium
- Co-payments adjusted for CPI each year
- Patient contributions
  - From co-payments >$1.5 billion
  - Under general beneficiary co-payment > $1.4 billion

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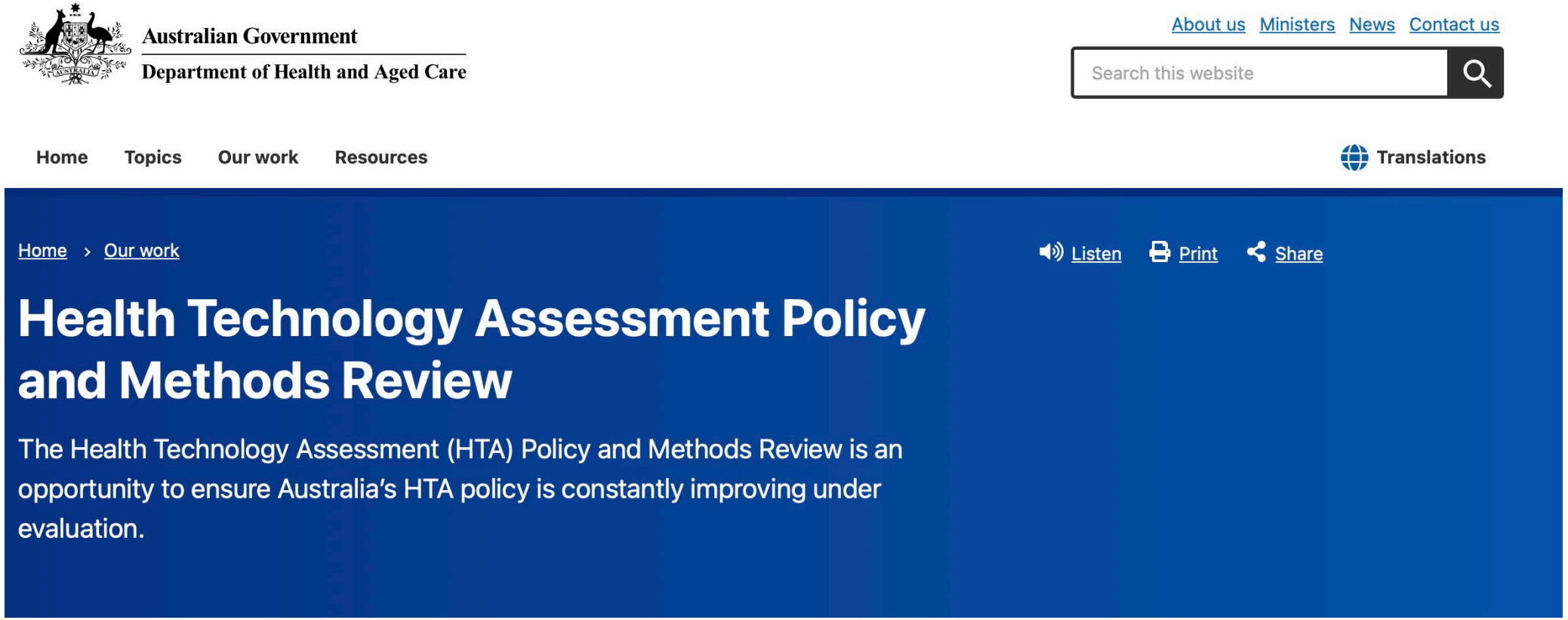
HTA Review



www.health.gov.au/our-work/health-technology-assessment-policy-and-methods-review

Challenges

- More medicines marketed each year
- More challenges in assessment for listing
  - Increased complexity
  - Lower quality evidence base
- Greater need for evidence development after medicines are listed
- Increased expectation from patients, consumers, clinicians and others to be informed and involved in decision-making

Australia has a world class system but…….

- Reactive not proactive: no mechanism to seek submissions
- Assessment and funding pathways convoluted and not timely
  - Co-dependent technologies
  - Emerging technologies used across multiple settings
- Gaps in continuity of care for people receiving some treatment as inpatient and some as outpatient
- Concerns about funding treatments currently delivered in inpatient setting becoming outpatient treatment
- Emerging therapies require more resource intensive implementation than previous therapies

Australia has a world class system but…….

- Lack of transparency
  - Unequal knowledge
  - Lots of information but not targeted to specific audiences
  - Many misconceptions
- Untapped potential of community engagement
  - Consumers: patients, families/carers, consumer organisations
  - First Nations people
- Lost opportunities
  - Data availability and use in listing and post-listing setting
  - Lack of transparency around use of RWD in submissions
  - No systematic approach to performance assessment post-listing (also reactive)

Equity of access (2020-21)

- Over half a million Australians faced prescription affordability issues, leading to deferred or unfilled prescriptions
- Nearly half a million Australians decided not to see a specialist because of cost
- Younger people, particularly women, forgoing health care due costs
    - Prescriptions, GP visits, specialist visits

Australian stories

I am unable to afford my ADHD medication and I have been off it for 3 months due to the cost
Jacqueline

I am on a disability pension and as a diabetic with chronic depression and heart problems I am always juggling food, bills and the cost of medicines
Peter

My husband is diabetic and we don't have a health care card so we have to decide between his meds or feeding our family
Pat

January 2023

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Cheaper scripts for millions

For the first time in its 75-year history, the maximum cost of general scripts under the Pharmaceutical Benefits Scheme (PBS) will fall. Joint media release with Prime Minister Anthony Albanese.

The Hon Mark Butler MP
Minister for Health and Aged Care

September 2023

Home › The Hon Mark Butler MP › Minister Butler's media

Cheaper medicines from 60-day dispensing

From September 1, Australians with a chronic condition will benefit from cheaper medicines on around 100 common medicines listed on the Pharmaceutical Benefits Scheme (PBS) under the first stage of the Albanese Government's new 60-day dispensing policy.

The Hon Mark Butler MP
Minister for Health and Aged Care

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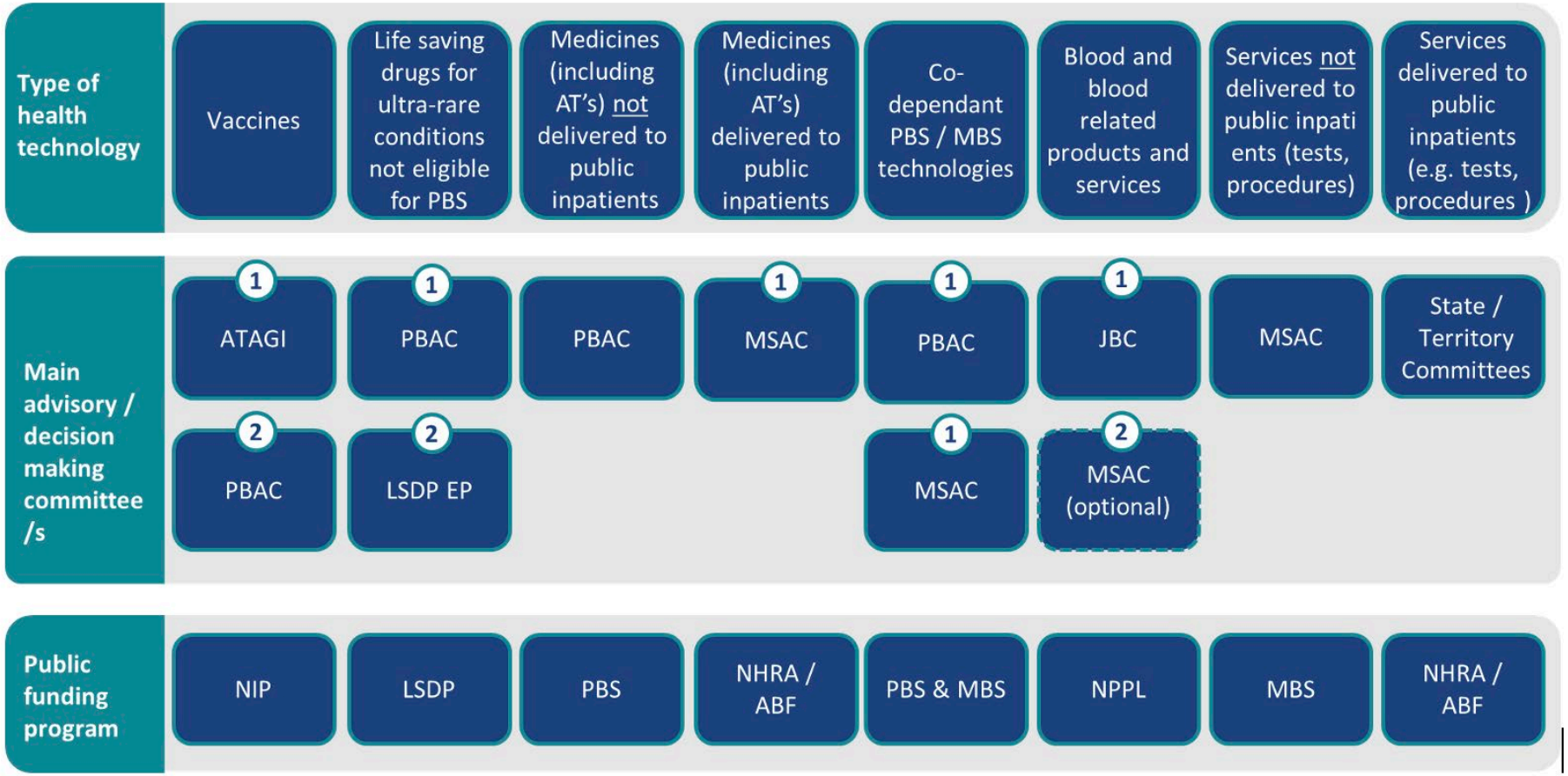
Sustainability and flexibility

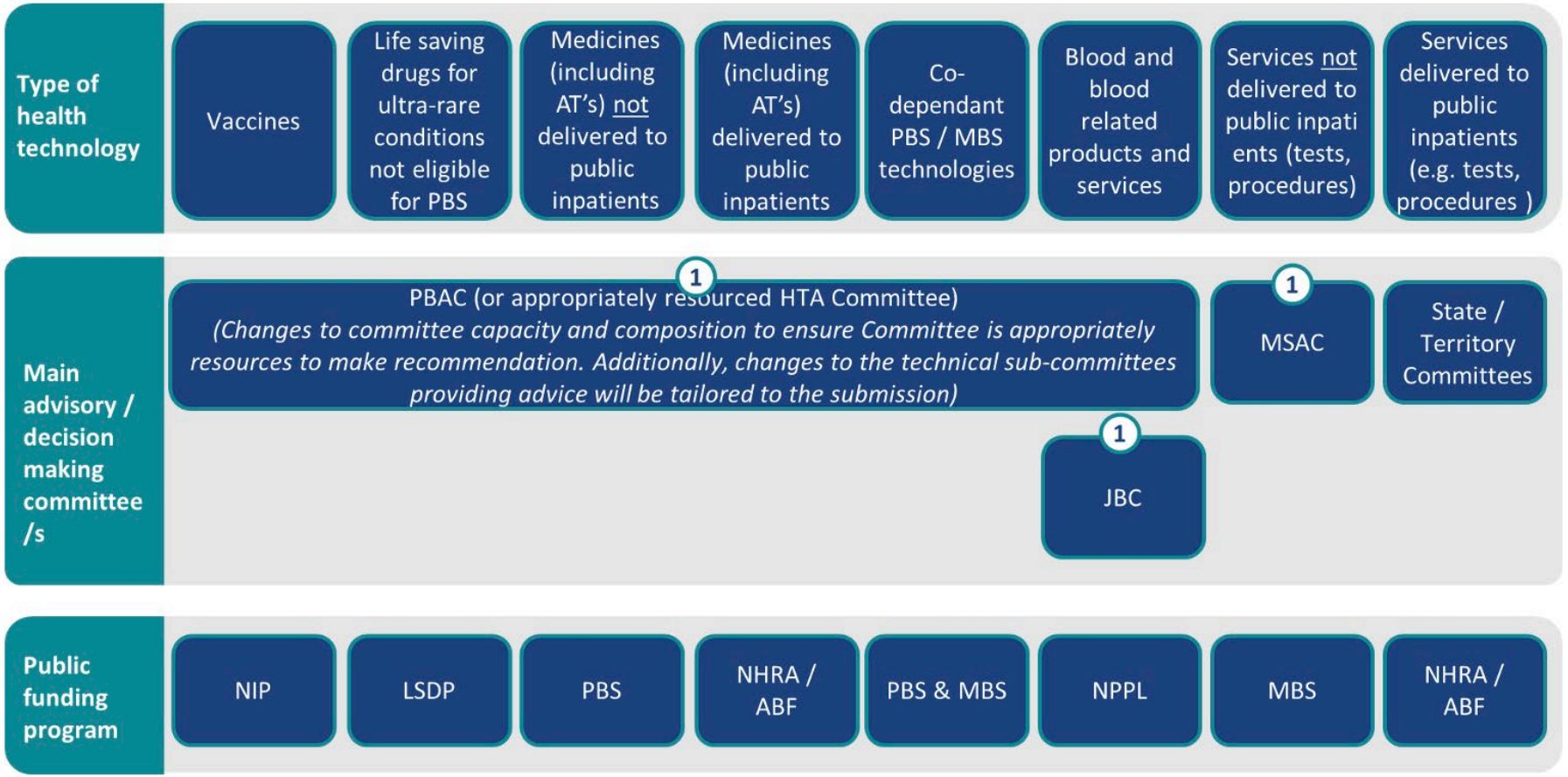
Increase transparency, communication, stakeholder involvement

- Include consumers, clinicians earlier and more consistently in process
- Develop fit-for-purpose communication to all stakeholders
- Establish First Nations Advisory Committee
- Increase collaboration with State/Territory governments for jointly funded medicines
    - Hight cost therapies delivered in inpatient settings

Streamline processes and pathways



Unify HTA pathway

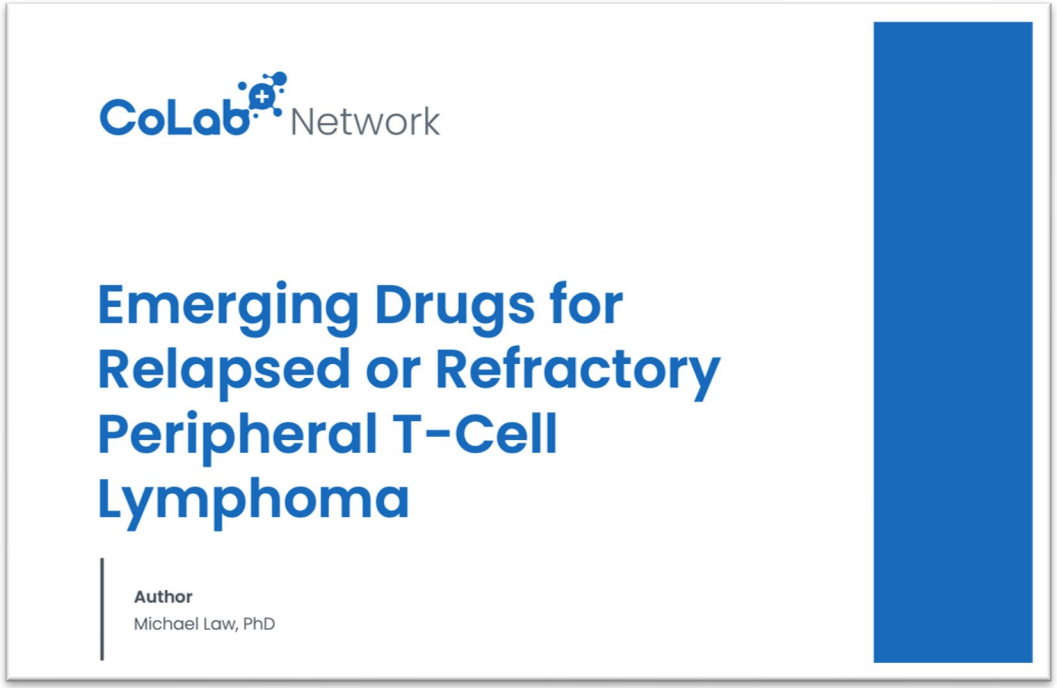


Apply best practice assessment methods

- Methods for assessing non-randomised and real-world evidence
  - Indirect comparisons
  - Creation of control groups
  - Adjustment of treatment effects due to switching
  - Bias and confounding on observational studies
  - Assessment of surrogate end-points
  - Understanding the value of qualitative evidence

Proactively assess areas of unmet clinical need

- Develop priority list of areas of high unmet clinical need
- Identify therapies to meet priority list (horizon scan)
  - International work sharing
- Proactively request sponsor submission, with incentives



Continuously review and improve

- More frequent reviews of HTA processes and guidelines required given speed of evidence evolution
- Greater need for systematic post-market approach to:
  - monitor medicines throughout their lifecycle
  - improve quality use of medicines, patient safety and education for patients and prescribers
  - ensure PBS viability by tracking medicines use, mimimise preventable wastage and/or inappropriate prescribing
  - review intended clinical benefit and ongoing cost-effectiveness

Maximise value of RWD and RWE

Optimising the availability and use of real world data and real world evidence to support health technology assessment in Australia

Paper 7, 11 October 2023

This paper has been developed by members of the NHMRC Medicines Intelligence Centre of Research Excellence (MI-CRE).

Maximise value of RWD and RWE

International Journal of *Environmental Research and Public Health*

MDPI

Review

Generating Real-World Evidence on the Quality Use, Benefits and Safety of Medicines in Australia: History, Challenges and a Roadmap for the Future

Sallie-Anne Pearson [1,*], Nicole Pratt [2], Juliana de Oliveira Costa [1], Helga Zoega [1,3], Tracey-Lea Laba [4], Christopher Etherton-Beer [5], Frank M. Sanfilippo [5], Alice Morgan [6], Lisa Kalisch Ellett [2], Claudia Bruno [1], Erin Kelty [5], Maarten IJzerman [7], David B. Preen [5], Claire M. Vajdic [1] and David Henry [8]

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Citation: Pearson, S.-A.; Pratt, N.; de Oliveira Costa, J.; Zoega, H.; Laba, T.-L.; Etherton-Beer, C.; Sanfilippo, F.M.; Morgan, A.; Kalisch Ellett, L.; Bruno, C.; et al. Generating Real-World Evidence on the Quality Use, Benefits and Safety of Medicines in Australia: History, Challenges and a Roadmap for the Future. *Int. J. Environ. Res. Public Health* **2021**, *18*, 13345. https://doi.org/10.3390/ijerph182413345

Academic Editor: Richard Madden

Received: 13 September 2021
Accepted: 14 December 2021
Published: 18 December 2021

Publisher's Note: MDPI stays neutral with regard to jurisdictional claims in published maps and institutional affiliations.

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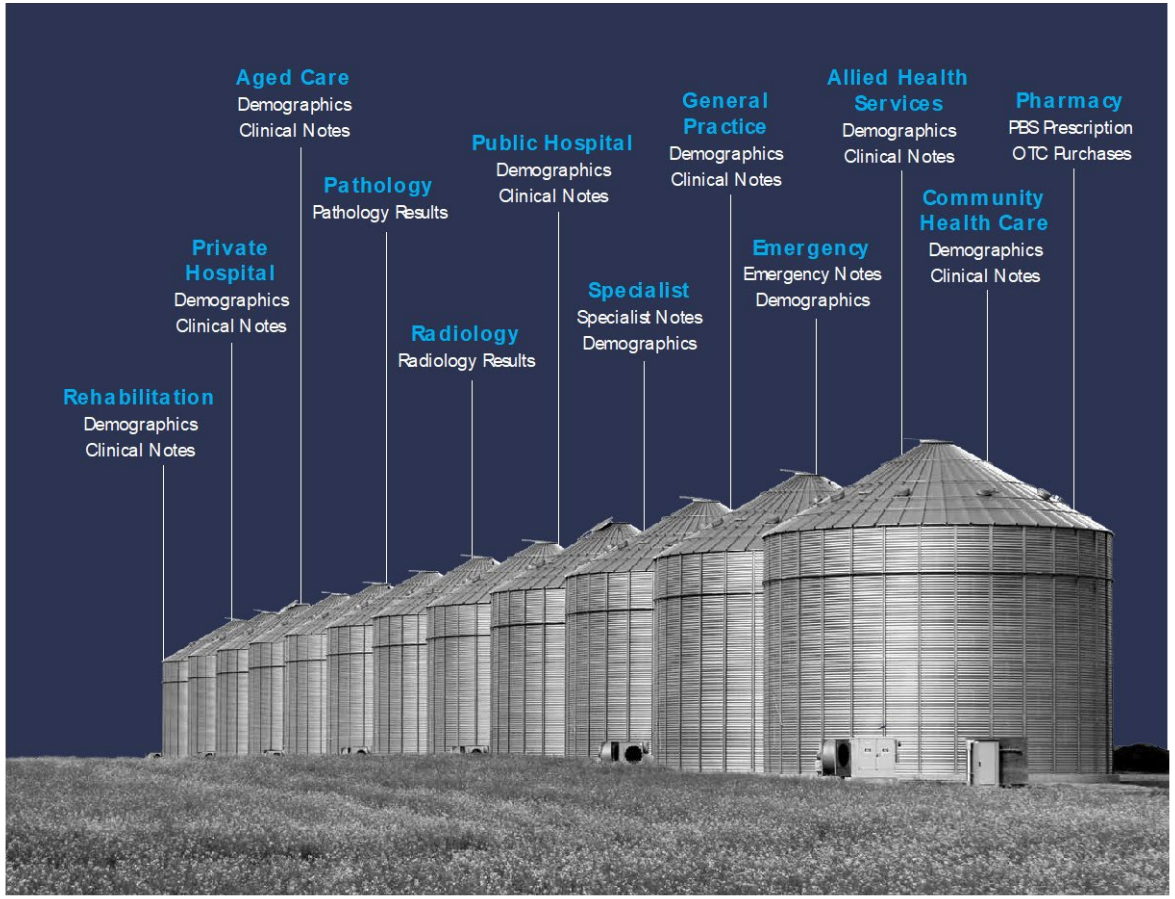
Abstract: Australia spends more than $20 billion annually on medicines, delivering significant health benefits for the population. However, inappropriate prescribing and medicine use also result in harm to individuals and populations, and waste of precious health resources. Medication data linked with other routine collections enable evidence generation in pharmacoepidemiology; the science of quantifying the use, effectiveness and safety of medicines in real-world clinical practice. This review details the history of medicines policy and data access in Australia, the strengths of existing data sources, and the infrastructure and governance enabling and impeding evidence generation in the field. Currently, substantial gaps persist with respect to cohesive, contemporary linked data sources supporting quality use of medicines, effectiveness and safety research; exemplified by Australia's limited capacity to contribute to the global effort in real-world studies of vaccine and disease-modifying treatments for COVID-19. We propose a roadmap to bolster the discipline, and population health more broadly, underpinned by a distinct capability governing and streamlining access to linked data assets for accredited researchers. Robust real-world evidence generation requires current data roadblocks to be remedied as a matter of urgency to deliver efficient and equitable health care and improve the health and well-being of all Australians.

Keywords: prescribing; quality use of medicines; medication safety; pharmacoepidemiology; medication data; data linkage; health outcomes; real-world data; real-world evidence

1. Introduction

Prescribing medicines is the most common health intervention globally [1]. Modern medicines have changed the course of major diseases including coronary atherosclerosis, heart failure, stroke, HIV/AIDS and several cancers. However, these major advances have come with costs, both human and financial. Medicines are approved by regulators and



Thank you!

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