

Clinical Registries

Will impact on everyone's practice

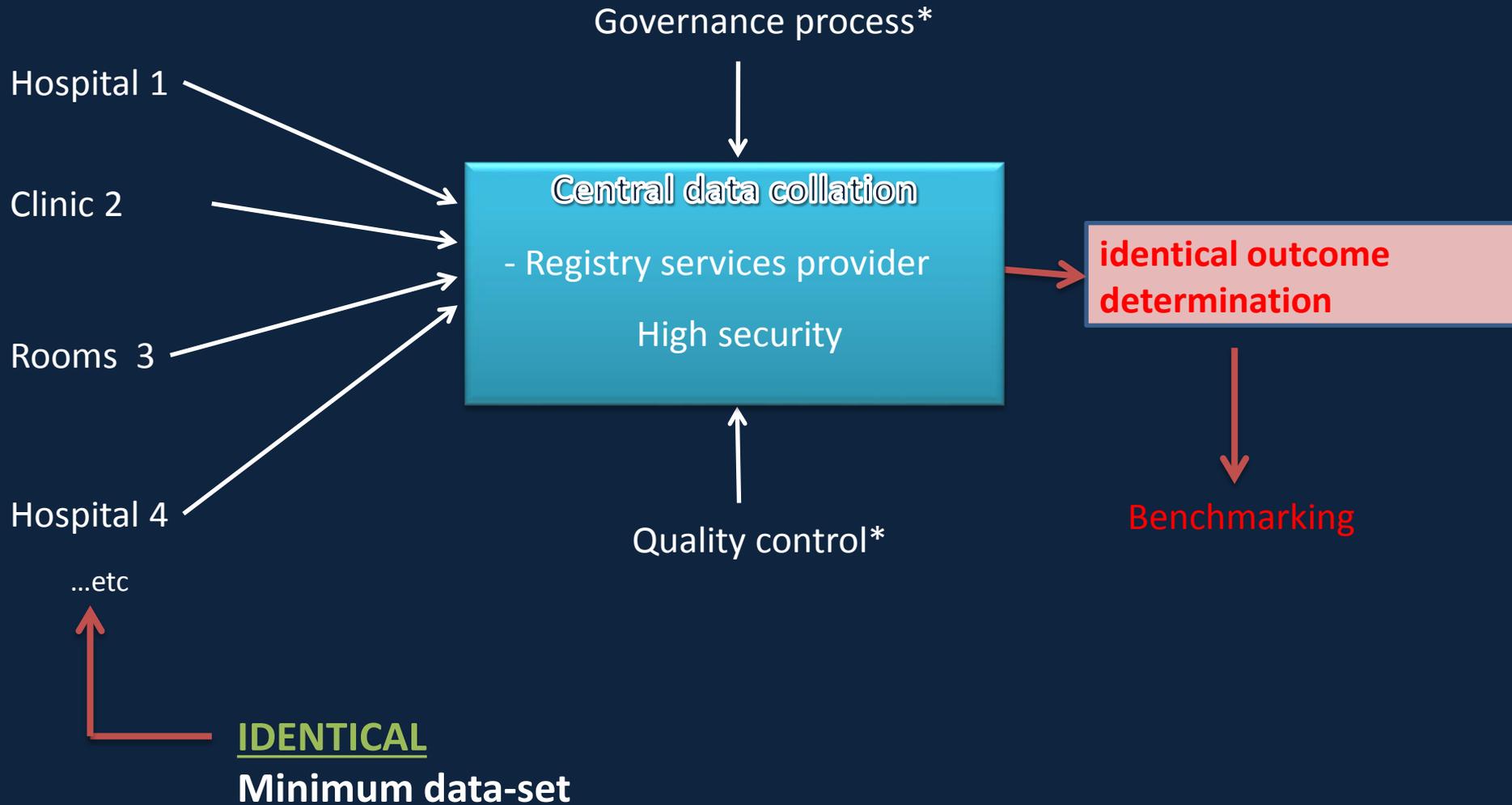
John McNeil MSc PhD FRACP FFPAHM

South Australian Impact

- ANZDATA (Renal dialysis & transplantation)
 - Steve McDonald, Alex Disney, Tim Mathew
- AOANJRR (Joint replacement)
 - Steve Graves, Phil Ryan
- Breast Device
 - Rod Cooter
- National Prostate Cancer Registry
 - Kim Moretti , David Roder

What is a registry

Typical clinical registry



Operation of a registry

Opting in for opt-out consent

A place for opt-out consent in the *National statement on ethical conduct in human research*

In most human research, potential participants are provided with detailed information so that they can make a fully informed choice about whether to participate in the project. The requirement for explicit consent reflects the value that our society places on individual autonomy.

Ian N Olver
MD, PhD, FRACP,
Chief Executive Officer

Cancer Council Australia,
Sydney, NSW.
ian.olver@cancer.org.au

- Governance delays still a major cause of delay

Systematic outcome measurement :

The most difficult challenge

- Personal contact with standard script
 - Eg letters or SMS x 2, then phone
- ‘Systematic’ clinical review
- Record linkage for longer term surveillance
- **Information sought**
 - Disease specific questions
 - Quality of life
 - Flags for further follow-up

Epidemiological principles

Applicable to registries

No “cherry picking”

report all or report none

report before outcomes have occurred

Near complete follow-up

incomplete follow-up risks bias

Statistical risk adjustment

Distinguishing operator vs device

Accounting for factors beyond control

Contrasts

within the registry eg different devices

or across similar registries



MONASH
University

Monash
Public Health

Registry output



Victorian Prostate Cancer RRegistry



FIVE YEAR REPORT



Victorian Prostate Cancer
Clinical Registry

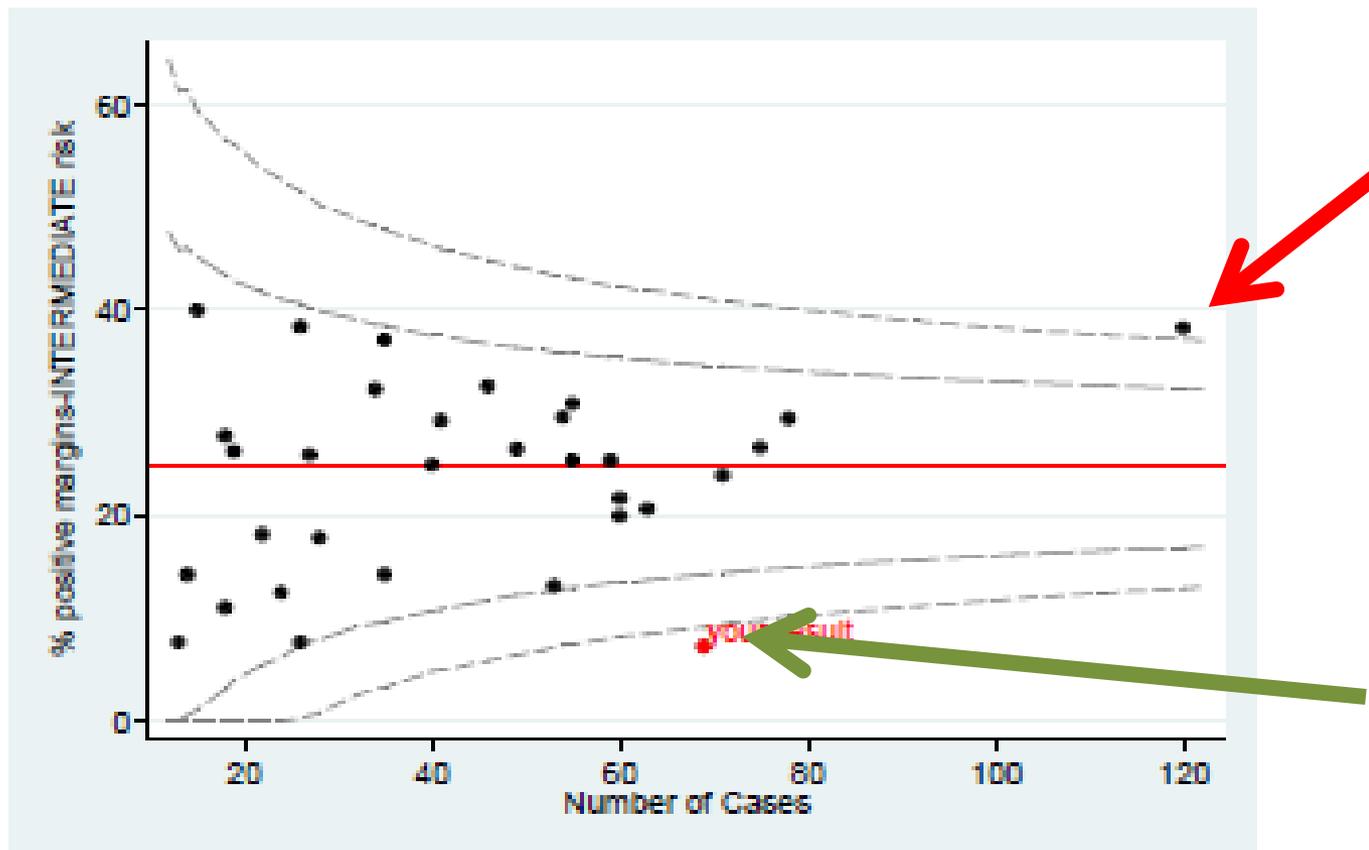


- From 2009
- Covers ~80% Victoria, includes >12 000 men
- Linked to private clinicians and health services
- Opt-out consent (2% opt-off)
- Small dataset, from data-managers not clinicians
- Regular feedback reports
- Includes Delphi derived quality indicators
- Indicators: include proportion of very low-risk men (“PRIAS-eligible”) having no active treatment and risk-adjusted positive surgical margin rate

Outcome benchmarking reports

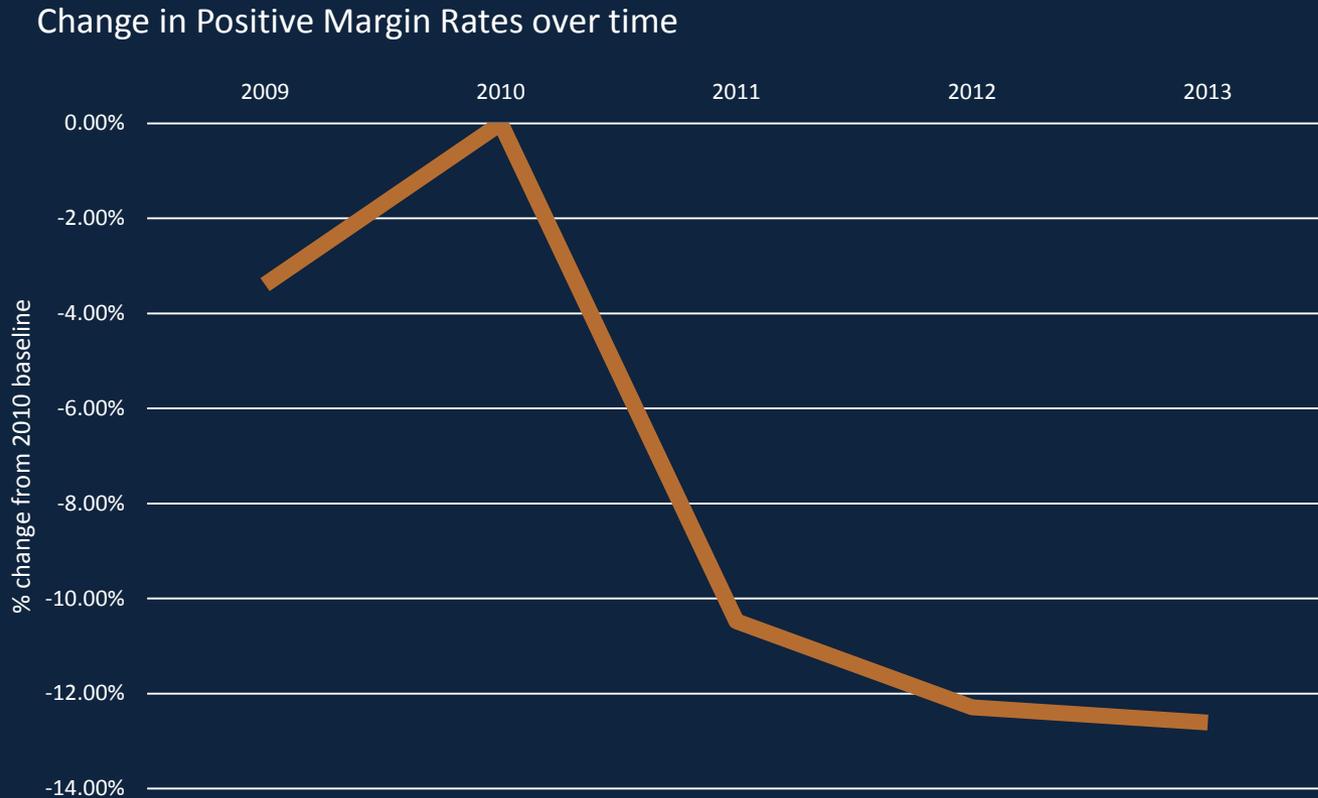
(Risk adjusted)

Figure 5: Registry reporting - example of a funnel plot showing percentage positive margins following cancer surgery



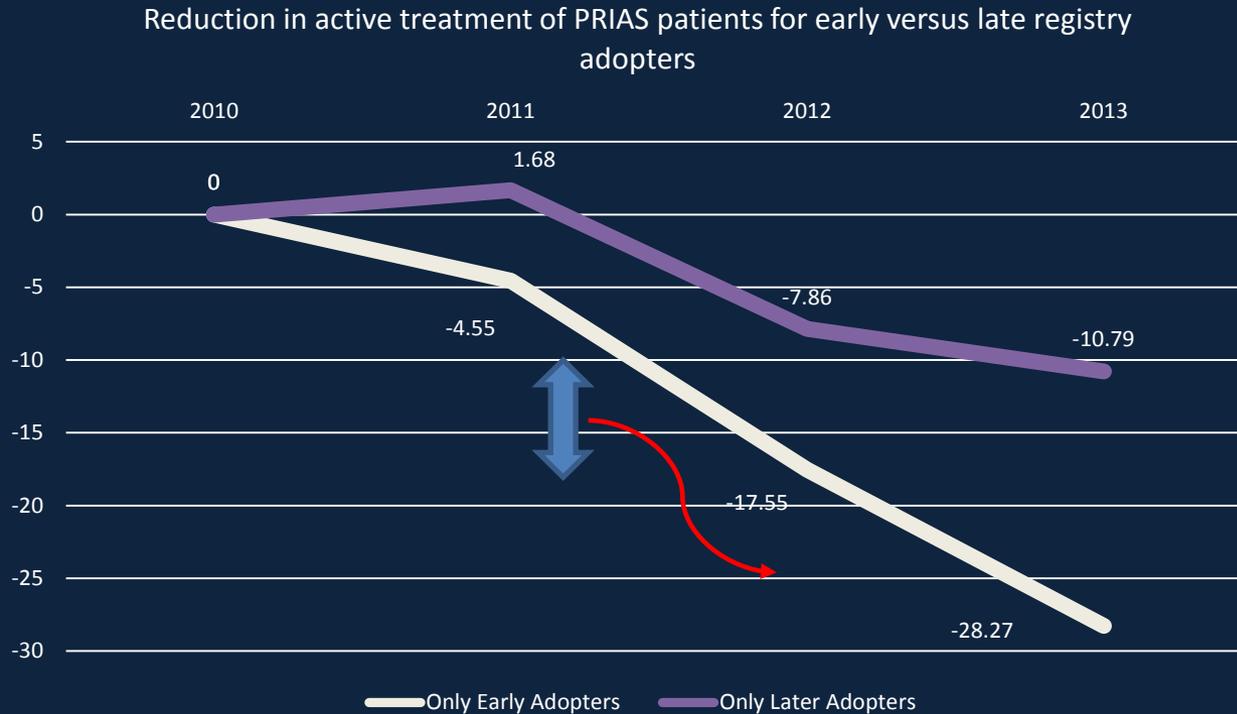
NOTE: EARLY RECOGNITION OF PROBLEMS

Positive Surgical Margins



12% reduction in rate of positive surgical margins (pT2 organ confined) since 2010

Reduction in Low Risk Men having active Treatment



Rates of change in compliance with PRIAS guidelines are greater in hospitals that are early contributors to the registry compared to later adopters.

Who values the information?

Clinical Registries:

Who values the information? And for what?

- Benchmarking
- Appropriateness of care/accountability
- Variation**
- Planning, trend analysis
- Access to care
- Credentialing
- Drug & device safety
- Clinical research

Who values the information?

Government

Hospitals (public & private)

Clinicians

Insurers

Professional societies

Drug & device manufacturers

Lack of data: Breast Implants

➤ Dow Corning 1984-1992

- Implant brand erroneously linked to chronic disease
- 132 law suits costing Dow Corning \$3.2 billion resulting in bankruptcy



➤ PIP April 2010

- Non medical grade silicone
- Total Australian sales ~13,000



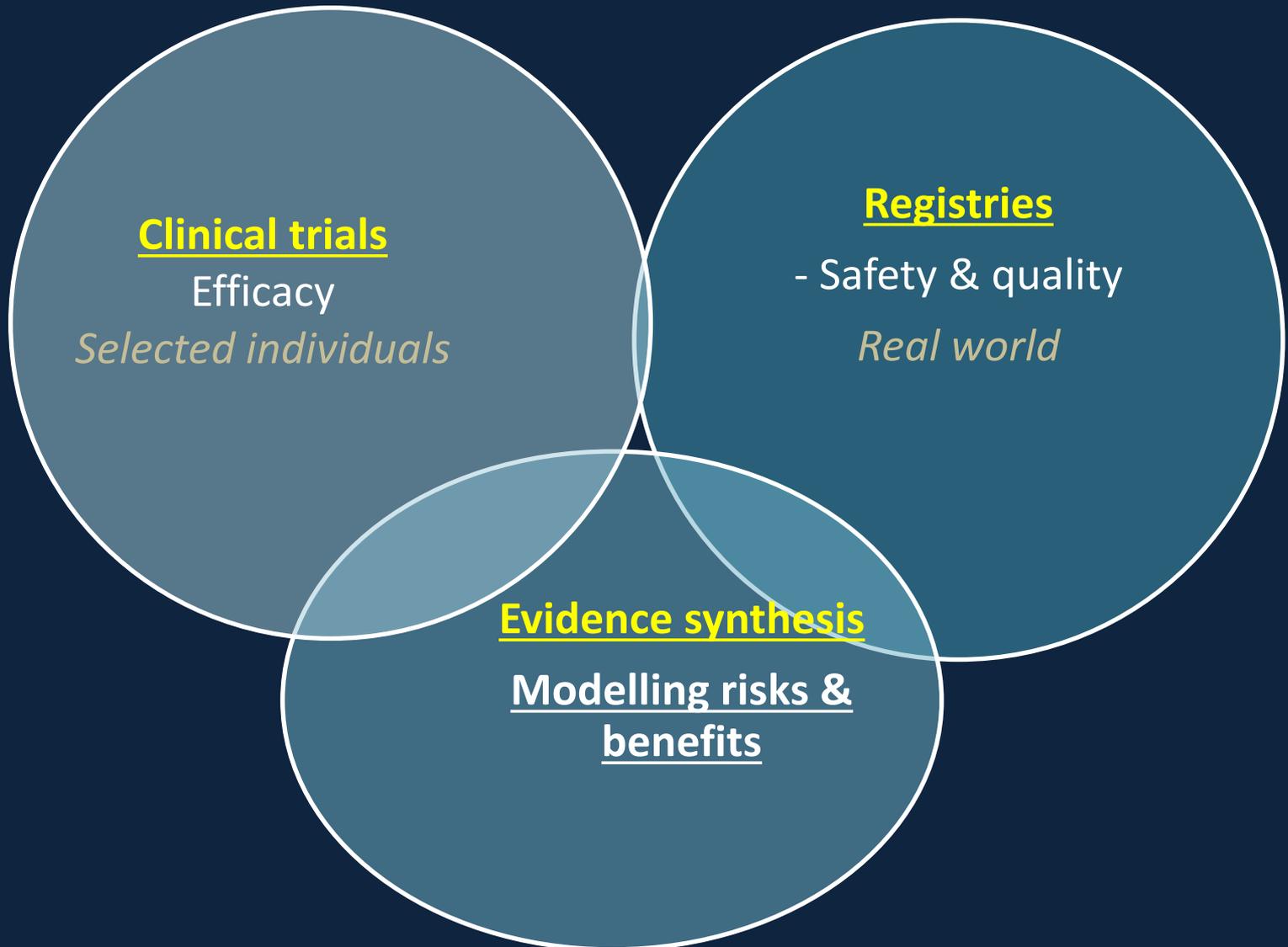
➤ Anaplastic Large Cell Lymphoma 2010

- a low but increased risk of ALCL



Registries, clinical trials, evidence synthesis and modelling

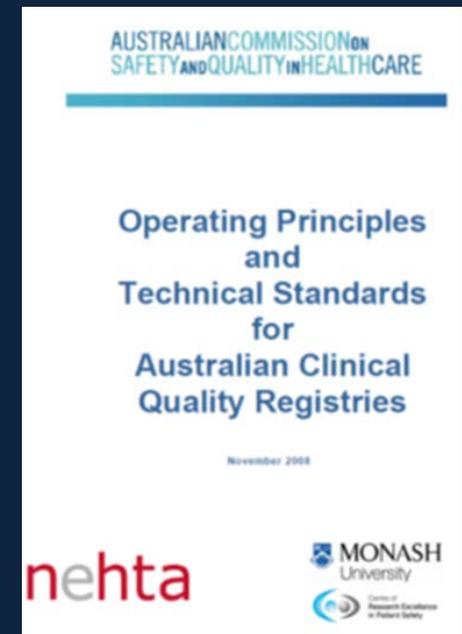
Trials, registries & modelling



Challenges ahead

Future challenges

- More complex than appreciated
- Participation largely voluntary
- Require substantial infrastructure
- Data & ethics burdens
- No personal & device identifiers
- No systematic approach to:
 - Governance
 - Resourcing
 - Data
 - Legal
- Potential multiplicity (rail gauge issue)



What is happening in Australia?

Australian developments

- ACSQHC ‘ Operating Principles for Clinical Quality Registries’ & “Framework for Australian Clinical Quality Registries
- NHMRC endorsement of opt-out consent in certain settings
- Industry or charity funding of key registries in cancer, trauma & heart disease. Industry funding of AOANJRR
- Commonwealth funding for breast, cardiac and bariatric registries. State funding for others
- Consulting for **cost-effectiveness & prioritisation**

Summary

- Provide clinically credible benchmarking
- Priority is: **high impact, high cost defined episodes**
- Data of value for multiple stakeholders
- Challenges in ethics, governance, funding models
- Rapid developments overseas, especially Europe & US
- Increasing levers to encourage participation



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Prof Chris Reid

Prof Rowan Walker

Cancer Clinical Quality Registry Program

Transfusion & Blood Product Registries

Trauma & Burns Registry program

Bariatric Registry Program

Victorian Cardiac Arrest Registry

Victorian Cardiac Procedures Registry

Victorian Prostate Cancer Registry

Australian Cardiac Surgery Database

Victorian Renal Diseases Registry

Major Funders: Victorian Department of Health, Victorian Transport Accident Commission, Commonwealth Department of Health, Movember, Medibank Private.