Clinical Registries
Will impact on everyone's practice

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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

- Hospital 1
- Clinic 2
- Rooms 3
- Hospital 4
- ...etc

Central data collation

- Registry services provider
- High security
- Quality control*

Governance process*

identical outcome determination

Benchmarking

IDENTICAL
Minimum data-set
Operation of a registry
Typical data-entry screen
Provides data-spine

Ideally auto-populated

Incorporated into work-flow
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.

- 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
Registry output
Victorian Prostate Cancer 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

Evans et al   MJA 2016
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

Evans et al MJA 2016
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.

Source: Health Outcomes Australia Analysis. Registry data.
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
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

Clinical trials
- Efficacy
  - Selected individuals

Registries
- Safety & quality
  - Real world

Evidence synthesis
- Modelling risks & benefits
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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