



Australian
Clinical
Trials
Alliance

A pilot national perioperative outcomes registry

Dr Jennifer Reilly MBBS (Hons) FANZCA

Specialist Anaesthetist, Alfred Hospital, Melbourne

Adjunct Research Fellow, Monash University, Melbourne

jennifer.reilly@monash.edu

Knowing the Risk

Measuring the Risk – a single centre surgical outcomes study

A pilot national surgical outcomes study

A pilot national perioperative registry

Surgery in Australia

- 23% of all hospital separations (AIHW, 2017)
- 2.7 million hospital admissions per year (AIHW, 2017)
- 1 in 4 inpatients experience an avoidable complication (Duckett, 2018)
- Existing surgical sub-specialty registries – cardiothoracic, transplant, bariatric, joint replacement surgery, hip fracture

“Knowing the Risk” (NCEPOD, 2011) (UK)

- 80% of perioperative deaths occurred in 20% of patients
- Key recommendations on **identifying and caring for** high-risk surgical patients
 - Before surgery
 - Documented **mortality risk assessment** (risk prediction)
 - Discussing risk prediction as part of surgical **consent process**
 - After surgery
 - Providing appropriate postoperative care **based on risk**
 - Basic ward care, **enhanced ward care**, HDU, ICU

“Knowing the Risk” (Australia)

- **Elderly patients** in Australia and New Zealand (REASON study, 2010)
 - 20% experience a major complication after surgery
 - 5% die within 30 days
- **Alfred Hospital perioperative team (2015 – 2017)**
 - High-risk surgical patients managed on the ward
 - Adults inpatient noncardiac surgery
 - 10.9% went to critical care post-op (excluded from our study)
 - 500/25,000 patients (2%) were referred to perioperative team for daily follow-up by an anaesthetist and/or physician

“Knowing the Risk” (Alfred Perioperative Team)

Outcome	Emergency	Elective	Overall
MET Call	25%	17%	21%
NSQIP major complication	56%	34%	44%
30-day mortality	5.2%	0.7%	2.7%
1-year mortality	20%	5.6%	12%

“Knowing the Risk” (Australia)

- **Risk minimisation** – elective critical care admission (ICU, HDU)
 - Expensive; no evidence this practice improves outcomes
 - Critical care beds and staff needed by patients on life support
- **Enhanced ward care** – extended recovery, surgical HDU, co-managed ward care
 - Opportunity to generate evidence across the healthcare system
 - To do this, we need to objectively identify high-risk patients
- **No systematic process or outcomes measurement or feedback**
 - Sub-specialty surgical registries (managed independently)
 - ANZICS CORE registries (managed by ANZICS)

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Towards a national perioperative clinical quality registry: the diagnostic accuracy of administrative data in identifying major postoperative complications


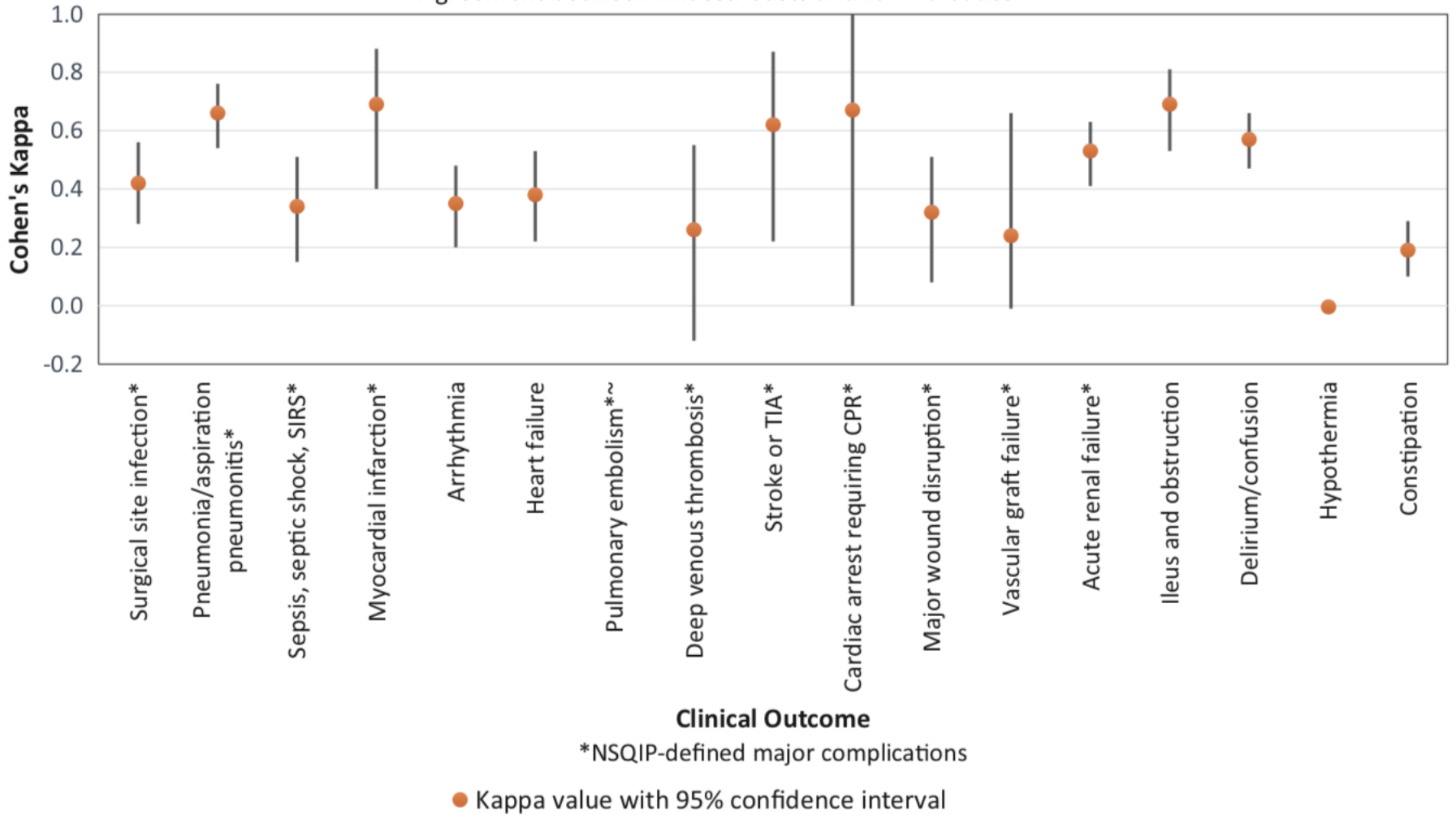
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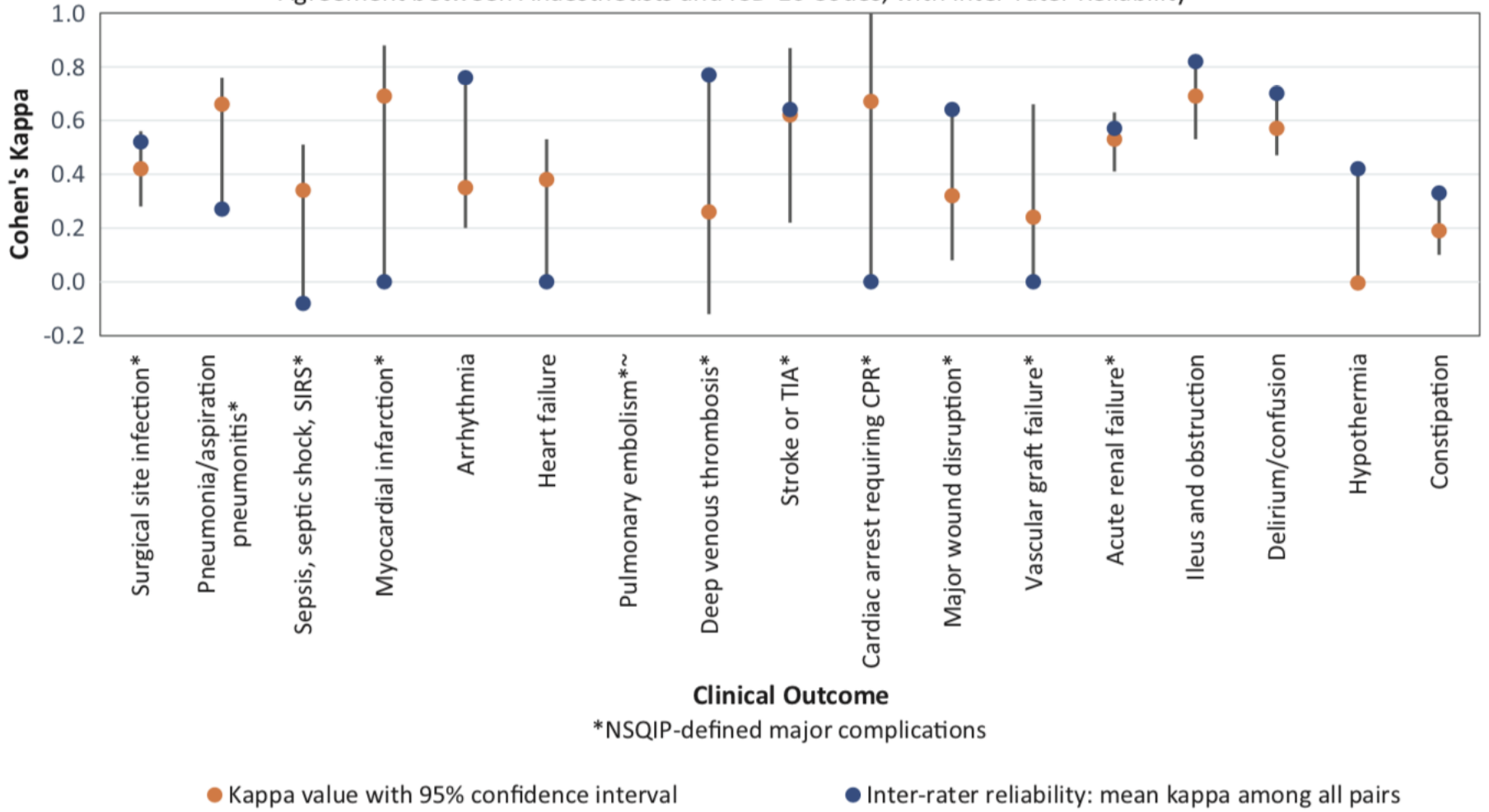
Table 2. In-hospital major complications and 30-day mortality.

Major complications	Total (<i>n</i> = 482)
Infectious complications	
Surgical site infection ^a	34/477 (7.1%)
Pneumonia/aspiration pneumonitis ^a	52/476 (10.9%)
Sepsis, septic shock, SIRS ^a	19/475 (4.0%)
Cardiovascular complications	
Myocardial infarction ^a	13/480 (2.7%)
Arrhythmia	29/480 (6.0%)
Heart failure	22/480 (4.6%)
Pulmonary embolism ^a	0/476 (0%)
Deep venous thrombosis ^a	10/478 (2.1%)
Stroke or TIA ^a	8/479 (1.7%)
Cardiac arrest requiring CPR ^a	1/480 (0.2%)
Surgical complications	
Major wound disruption ^a	15/477 (3.1%)
Vascular graft failure ^a	3/477 (0.6%)
Other complications	
Acute renal failure ^a	50/473 (10.6%)
Ileus and obstruction	31/478 (6.5%)
Delirium/confusion	84/477 (17.6%)
Hypothermia	58/464 (12.5%)
Constipation	116/478 (24.3%)
Mortality	
Death within 30 days	13/482 (2.7%)

Agreement between Anaesthetists and ICD-10 Codes



Agreement between Anaesthetists and ICD-10 Codes, with Inter-rater Reliability



*“Our study has **highlighted the limitations of both administrative data and retrospective clinical audit** in identifying major postoperative complications, leading us to conclude that the **most accurate method** will be a **clinical quality registry** with prospectively collected baseline and outcomes data, using explicit definitions, specifically trained staff and systematic data-quality controls.”*

*“We believe a perioperative clinical quality registry is necessary to **validly and reliably measure** major post-operative complications in Australia for **benchmarking** of hospital performance and **before public reporting of outcomes should be considered.**”*

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A pilot national surgical outcomes study (2019)

Aims

- Trial E+G, data collection & management processes in every state/territory
- Project the recruitment rate and required study duration

Objectives

- Obtain E+G approval for collection, use & disclosure of **identifiable data (for linkage to NDI)** with **waiver of consent**
- Trial and optimise CRF; determine time for CRF completion by anaesthetists
- Optimise Redcap study database and determine data entry time (costing)
- Determine mean number of eligible patients per month at pilot sites
- Obtain site feedback to inform the final study protocol and conduct

Days to HREC and SSA Approval: The COMPASS Pilot Study (20 patients per site)

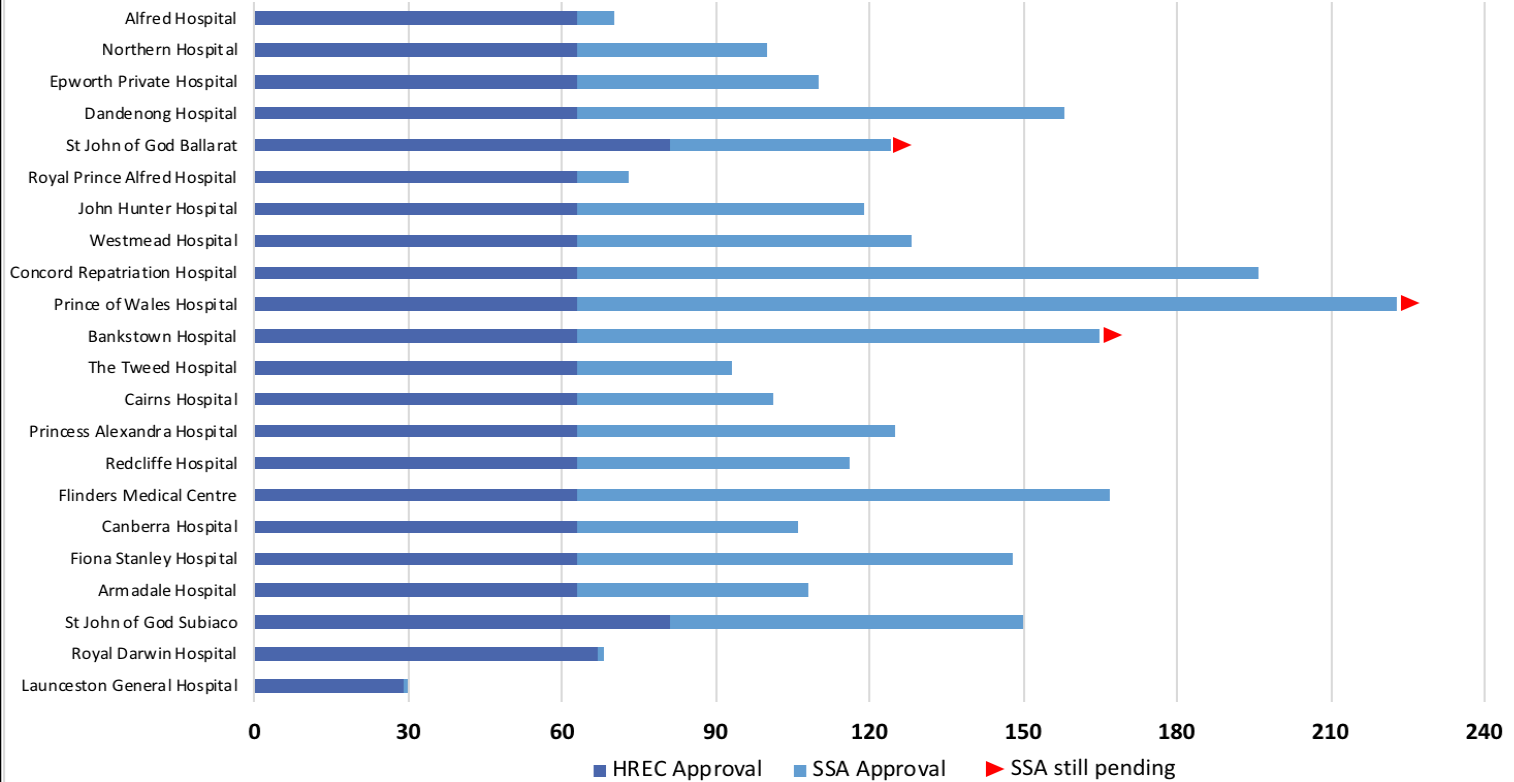


Table 1. Predicted number of eligible patients at COMPASS Pilot Study sites.

State or Territory (% of Australian population)	Participating Hospital	Number of Eligible Patients June 2018	Number of Eligible Patients February 2019	Mean number of eligible patients per month	Mean (SD) time to complete CRF (mins)	Mean (SD) time to enter CRF into REDCap (seconds)
New South Wales (32%)	John Hunter Hospital	1028	963	996	3.7 (2.1)	241 (91)
	Prince of Wales Hospital	621	474	548		
	Royal Prince Alfred Hospital	488	547	518		
	Westmead Hospital	667	898	783		
	Concord Repatriation Hospital	608	588	598		
	Bankstown Hospital	407	394	401		
	The Tweed Hospital	417	440	429		
Victoria (26%)	Alfred Hospital	1,111 [^]	987	1,049	2.9 (1.5)	118 (30)
	Epworth Private Hospital	1,724	1,634	1,679	2.2 (1.3)	125 (41)
	Northern Hospital*	610	607	609	5.6 (3.9)	316 (109)
	St John of God Ballarat [^]	80	100	90		
	Dandenong Hospital	520	515	518		
Queensland (20%)	Princess Alexandra Hospital	1,384	1,183	1,284		
	Redcliffe Hospital	204	202	203		
	Cairns Hospital	679	661	670		
Western Australia (10%)	St John of God Subiaco	1,397	1,328	1,363		
	Fiona Stanley Hospital	862	744	803		
South Australia (7%)	Flinders Medical Centre	769	852	811		
Tasmania (2%)	Launceston Hospital	533	531	532		
ACT (2%)	The Canberra Hospital [^]	685	685	685		
Northern Territory (1%)	Royal Darwin Hospital [^]	800	800	800	2.9 (1.4)	128 (45)
Australia – total (100%)		15,594	15,133	15,364		

* Eligible patient numbers are from July and August 2018.

[^] Approximate number of eligible patients.

A national perioperative outcomes registry will facilitate quality assurance and research in Australia.

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Manuscript ID	AIC-20-0068.R2
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Our feasibility study was coordinated by the ANZCA Clinical Trials Network at Monash University and was approved by the Alfred Health HREC (reference 47931) under the national mutual acceptance scheme, with a waiver of consent for the collection, storage and transmission of identifiable personal and health data. Separate ethics approval was obtained in the Northern Territory and Tasmania and at the St John of God Health Care private hospital network. Of the 22 hospitals recruited (19 public and 3 private), representing each state and territory of Australia, 18 gained site-specific approval under the national mutual acceptance scheme and three obtained site-specific approval under the separate ethics approvals. One private hospital was unable to gain site-specific approval. Site-specific approval required protocol variations at 5 of 21 hospitals, including additional privacy requirements at four hospitals and a requirement for full informed consent at one hospital. All 20/20 patients invited to participate at that hospital agreed to do so. Site-specific approval by local Research Governance Offices (RGOs) was the rate-limiting step, with half of all RGOs taking over 56 days to approve an observational pilot study gathering routinely collected data on 20 patients that already had HREC approval, the slowest taking 196 days and imposing no additional requirements.

Barriers to conducting a national surgical outcomes study in Australia include ethics and governance delays; privacy regulations relating to identifiable data; differing approaches to consent between the public and private sectors; ensuring that regional and rural hospitals are adequately represented; and ensuring the balance of public and private hospitals reflects the proportion of surgery performed in each sector.

An alternative source of national surgical outcomes data would be a national perioperative outcomes registry, modelled on international examples such as the Swedish Perioperative Outcomes Registry, the Multicentre Perioperative Outcomes Group or the National Surgery Quality Improvement Program.^{7,8,9} The Australian Commission for Safety and Quality in Health Care has published a framework for the development of clinical quality registries in Australia, whereby initial ethics and governance approval allows ongoing collection of data to monitor the quality and safety of care provided by hospitals.¹⁰ A national perioperative outcomes registry would facilitate risk prediction model development and updating, as well as population-based cohort studies, national audits, benchmarking of hospital performance, registry randomized-controlled clinical trials and real-world monitoring of the translation of research into practice. These benefits should be attractive to regional, rural, remote and private hospitals, and their participation would ensure registry data accurately represent the Australian population.

We have subsequently established a pilot national perioperative outcomes registry, *ANZCA Perioperative Clinical Outcomes Registry (PCORE): Pilot*, with ethics approval under the national mutual acceptance scheme for three years (including a waiver of consent for the collection of identifiable data) and seed funding from an ANZCA Pilot Grant. We invite interested hospitals to contact the ANZCA Clinical Trials Network office to join the pilot registry.

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ANZCA PCORE: Pilot

Australian and New Zealand College of Anaesthetists (ANZCA)

Perioperative Clinical Outcomes Registry

- Seed funding – ANZCA Pilot Grant (\$20,000 – late 2019)
- Sub-study funding – mortality risk prediction model development (\$145,000)
- Ethics approval for 3 years under NMA obtained 5 February 2020
- Includes a **waiver of consent** for the collection, use and transmission of **identifiable data**, data **hosting at AIHW**, data **linkage with NDI** and **other data sets held by AIHW**, data linkage with **ANZICS CORE registries**
- 25 hospitals (3 private) currently in process of joining (SSAs/ethics)

Justification for waiver of consent

- Hospitals are required to monitor the quality and safety of the care they provide (ACSQHC)
- Patients and the general public expect that hospitals are monitoring the quality and safety of the care they provide
- Large volume of surgical procedures performed per annum
- Impracticality of obtaining consent during clinical care in theatre
- Need for near-complete coverage of target population to avoid bias

Consent and privacy

- Sites can only see their own data within the registry
- Patient name fields will appear blank to Monash administrator users
- Dual authentication required for login to registry (eg. Google authenticate)
- A waiver of consent (not opt-out consent) has been granted by the Alfred Health HREC as per the study protocol

Study population

Inclusion criteria

- Adults aged 18 and over
- Inpatient surgery
- All types of surgery (including endoscopy and interventional neuroradiology), except cardiac surgery or any procedure combined with cardiac surgery

Exclusion criteria

- Day case/outpatient surgery
- Cardiac surgery, any other operation combined with cardiac surgery; transplant surgery; coronary angiography or coronary electrophysiology procedures

Registry enrolment and data collection

Baseline Data Set

- Enrolment initiated by the anaesthetist on the day of surgery
- Patients identified by anaesthetists from daily operating theatre lists
- Data collected from medical record during routine care
- Anaesthetists submit baseline data set either by direct data entry into the registry or via paper CRF (1-page tick box form)

Outcomes Data Set

- Obtained from the medical record by research coordinators after day 90
- Matched with National Death Index for mortality at 30 days, 1 year, 2 years
- **No patient contact**/follow-up required for minimum data set
- Protocol includes **ethics approval for sub-studies requiring patient contact**/follow-up and for **PROMS**

Proposed minimum data set

Demographic Data Set

- First, middle + surnames
- Date of birth
- Sex*
- Postcode
- ATSI status*
- Date of surgery

Core Data Set

- Indication for surgery*
(NCD/infection/trauma/cancer/pregnancy)
- Urgency*
- Type of surgery* (body system)
- Procedure name*
- ASA Physical Status*
- Clinical Frailty Scale*
- Critical care bed request*
(no/planned/unplanned)
- Direct critical care admission* (Y/N)
- Cancer in previous 5 years*
(no/local spread/metastatic)

Discharge Data Set

- MET call date, time, reason*
- Date of discharge
- Date of death
- ANZICS Adult Patient Database identifier

* Categorical data, selected from a menu of options

Surgical mortality risk prediction modelling

The Clinical Outcomes Measurement in Peroperative Medicine, Anaesthesia and Surgery Study (COMPASS)

Development of a perioperative mortality risk prediction model
for adults undergoing inpatient noncardiac surgery in Australia

The Surgical Outcome Risk Tool (SORT) (UK)



Procedure: Appendicectomy

Surgical Severity (auto-populated):
 Minor Intermediate
 Major Xmajor/Complex

ASA-PS (scroll down for definitions):
 1 2 3 4 5

Urgency (scroll down for definitions):
 Elective Expedited
 Urgent Immediate

Thoracics, gastrointestinal or vascular surgery:
 Yes No

Cancer (active malignancy within past 5 years):
 Yes No

Age:
 <65 65-79 ≥80

Mortality risk within 30 days of surgery: **Fields incomplete**

Procedure: Appendicectomy

Surgical Severity (auto-populated):
 Minor Intermediate
 Major Xmajor/Complex

ASA-PS (scroll down for definitions):
 1 2 3 4 5

Urgency (scroll down for definitions):
 Elective Expedited
 Urgent Immediate

Thoracics, gastrointestinal or vascular surgery:
 Yes No

Cancer (active malignancy within past 5 years):
 Yes No

Age:
 <65 65-79 ≥80

Mortality risk within 30 days of surgery: **6.57%**

Adapted as NZRISK (New Zealand)

The screenshot shows the nzRISK web application interface. At the top, there is a navigation bar with the nzRISK logo and links for Home, About, Calculate, and Contact. Below the navigation bar, a red banner contains text about the development of the tool. The main content area is titled 'Calculate' and is divided into several sections:

- User notes:** A blue box containing text about ASA-PS (American Society of Anaesthesiology - Physical Status) Score and Active malignancy.
- Warning:** A pink box stating 'Currently in test mode. The result will be accurate, but not all operation codes are currently loaded.'
- Input fields:** A series of form elements for patient data: Age (in years, 18 or above), Gender (Male/Female), Ethnicity (dropdown), ASA (radio buttons 1-5), Acuity (checkbox 'Tick if acute'), Cancer (checkbox 'Tick if cancer present'), Specialty (dropdown), Sub (dropdown), Procedure (dropdown), and a reCAPTCHA 'I'm not a robot' checkbox.
- Calculate button:** A green button at the bottom right of the form.

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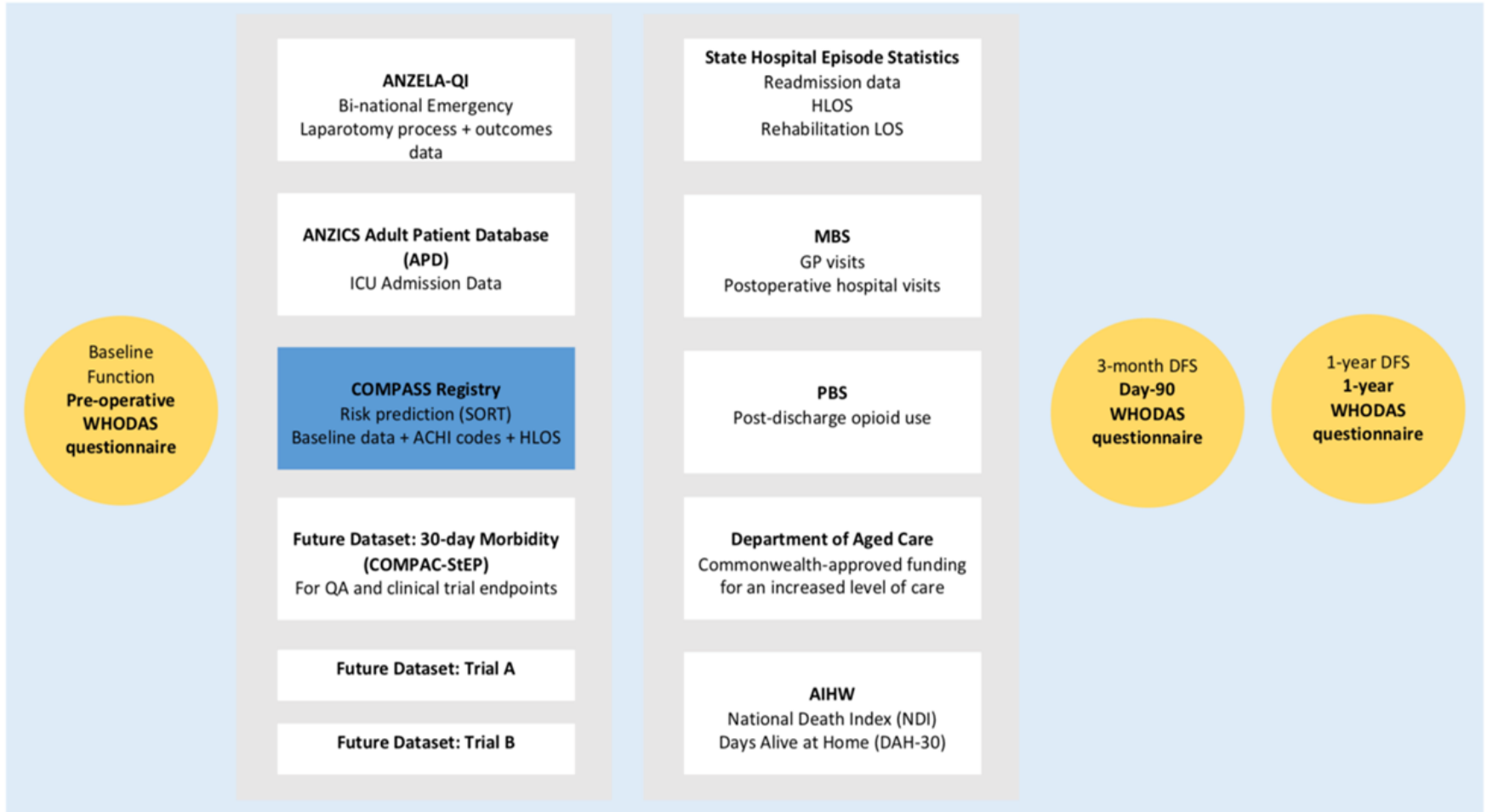
Next steps

- COMPASS will fund 1 month of data collection at participating sites (\$10 per patient) for risk prediction model development
- Major funding to be sought for registry
- Business case to be written – ACSQHC

Proposed studies

- Population-based cohort studies
- National audits in anaesthesia and surgery
- Benchmarking of surgical outcomes (internal and external)
- Registry randomised controlled trials

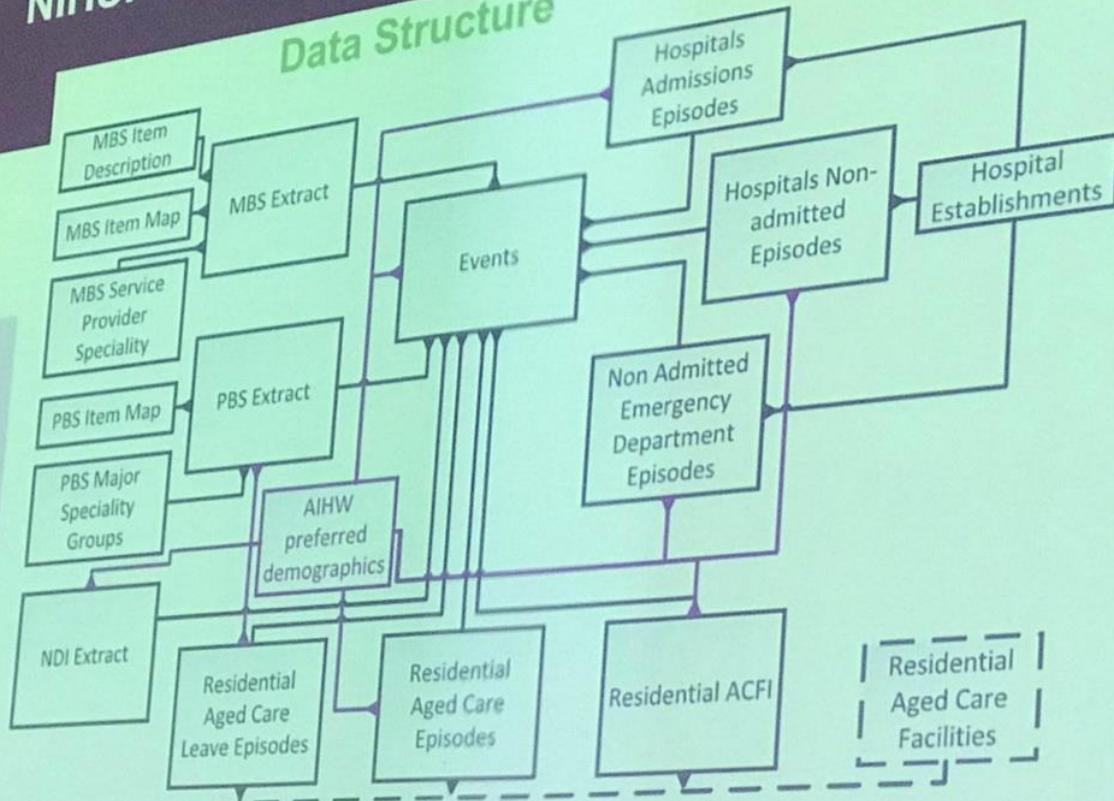
Sample framework for a national perioperative registry



NIHSI Data Structure

Data Structure

v0.5
MBS, PBS,
NDI, RAC,
hospital and
ED data from
4 states



v1.0
Planned two
year update
with 7
jurisdictions



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