

Registry of Registries

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Research Excellence
in Patient Safety



Background

- There is no national database identifying what registries exist in Australia
- Compare this with clinical trials
 - Helsinki Declaration states that “Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.” (Para 19)



Policy

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53th WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008





Background

- Do the same ethical principles apply for clinical registries as for clinical trials?
 - Is there the ability for registries to exploit patients? (Observational NOT interventional)
 - vulnerable groups recruited
 - data linkage increases amount of information accessible to registry custodians
 - What accountability should registries have to have
 - Report their governance structure/processes?
 - Report how data are being collected?
 - Assess and report their outcomes?





Why develop a registry of registries?

- To prevent unnecessary duplication of registries
- To facilitate development of national databases with identical definitions
- To identify gaps in research/data
- To provide a checklist for those wishing to establish a registry (much like CONSORT)
- To enable researchers to understand the quality of data within registries (unlike BioGrid)
- To assist efforts to link databases for QI purposes





Aim

- To assess the feasibility and utility of an Australian registry of registries
- To assess the ability of clinical registries currently in existence to monitor quality of care





Methods

ORIGINAL ARTICLE

Directory of clinical databases: improving and promoting their use

N Black, M Payne, on behalf of the DoCDat Development Group

See editorial commentary, pp 327–8

Qual Saf Health Care 2003;12:348–352



0845 300 6016 enquiries@ic.nhs.uk
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Welcome

List of Databases

Supporting Documents

Search

Feedback

- [Send us your comments](#)
- [Notify us of a new data collection](#)

Enquiries

0845 300 6016
➤ enquiries@ic.nhs.uk

DoCDat is an information resource for all those involved in clinical audit, clinical governance, health services management and health services research. It provides information about databases containing patient level and administrative data concerned with clinical care in the UK

To access the listings, use the **List of Databases** or **Search** links above.

In the Directory you can find information concerning:

- which clinical databases exist in the UK
- a brief description of the area each one covers and how it is managed
- a simple, at-a-glance review of the quality of their data
- contact details of the custodian of each database.





Methods



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Welcom

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Results summary

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- 4
 - 4Child - Four Counties Database of Cerebral Palsy, Vision Loss and Hearing Loss in Children, formerly Oxford Register of Early Childhood Impairments
- A
 - A Health Informatics Programme for Coronary Heart Disease
 - All Wales Audit of Critically Ill Children
 - All Wales Injury Surveillance System
 - Anglia Childhood Diabetes Register
 - Assessment of Stomach and Oesophageal Cancer
 - Association of Upper Gastrointestinal Surgeons - National Oesophago-Gastric Cancer Surgery Registry
 - Avon Longitudinal Study of Parents and Children
- B
 - Bristol Royal Infirmary Cardiac Surgery Audit
 - British Association of Cardiac Rehabilitation - Register of Rehabilitation Programmes
 - British Association of Head and Neck Oncologists' National Minimum Head and Neck Cancer Data Set
 - British Association of Perinatal Medicine Data Network
 - British Association of Surgical Oncology - Breast Unit Database
 - British Association of Urological Surgeons Cancer Registry
 - British Cohort Study 1970
 - British Society of Blood and Marrow Transplantation Registry
- C
 - CAMS Outcome Research Consortium
 - Canterbury Carpal Tunnel Database
 - Cardiac Ablation Procedures
 - Cardiac Rehabilitation Minimum Data set
 - Carers and Users Expectations of Mental Health Services
 - Chronic Obstructive Pulmonary Disease 2001 Audit
 - Confidential Enquiry into Maternal and Child Health - Diabetes

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Clinical and Health Outcomes Knowledge Base

Managed for The Information Centre for health and social care by the
National Centre for Health Outcomes Development
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Bristol Royal Infirmary Cardiac Surgery Audit

Centralised individual level database. DoCDat has not yet fully assessed this database. Details are provided to enable you to investigate the database yourself.

GENERAL ASPECTS:

Background information

Acronym:	BRICSA
Date last updated:	21/07/2003
Background Information	ACSA submits data to the National Adult Cardiac Surgical Database. Additional fields have been added to the NACSD dataset for local audit purposes and to enable automated processing of discharge summaries.

Reference population

Common circumstance that determines inclusion in database:	Patients aged 16 and over undergoing cardiac surgery at Bristol Royal Infirmary.
Does the database trace the individuals through more than one episode of care?	Yes. Patients are traced through subsequent episodes of cardiac surgery.
Geographical area covered by the database:	Patients resident and/or treated in Avon and Somerset Health Authorities; some cases drawn from Gloucestershire, Wiltshire Devon, Dorset, and Cornwall.

CONTACT DETAILS

Contact name:	David Finch
Address:	
Phone number:	
Email address:	David.Finch@ubht.nhs.uk
Website:	

DATABASE CLASSIFICATION

Body system:	Cardiovascular, Pulmonary
Pathogenesis:	Congenital/Genetic, Degenerative, Infections, Injury
Intervention:	Surgery
Age group:	Older People
Country:	England



Methods

- Inclusion/exclusion criteria
 - Patient level health-related data was continuously collected;
 - Outcome data was collected by the registry and not primarily through linkage with outcome databases;
 - Data were collected across more than one site or healthcare institution.
- Did not include product registries e.g. medication/blood





Methods

- Face and content validity of survey assessed
- Additional questions identified
 - Governance structures
- Search strategy identified
 - Peer reviewed journals
 - Consultation
 - Grey literature





Results

- Good buy-in
- 28 eligible registries; all completed survey
- Approach taken to complete the survey varied





- Victorian Infection Control Nosocomial Infection Surveillance System (VICNISS)
- Australian and New Zealand Cardiothoracic Organ Transplantation Registry
- Victorian State Trauma Registry (VSTORM)
- Australian and New Zealand Liver Transplantation Registry
- Australian Bone Marrow Transplant Recipient Registry
- Australian Corneal Graft Registry,
- Australian Orthopaedic Association Joint Replacement Registry
- Australian Society of Cardiothoracic Surgeons Database Project
- Centre for Healthcare Related Infection Surveillance and Prevention (CHRISP)
- Cervical Cytology Registry- Victoria
- NSW Concord Colorectal Cancer Clinical Registry
- Queensland Trauma Registry- CONROD
- Trauma Registry, Royal Perth Hospital
- ACCORD Comprehensive Cancer Patient Database
- Australian and New Zealand Burns Association (ANZBA) national burns registry
- Australian and New Zealand Intensive Care Unit Society (ANZICS) Adult Patient Database
- Australian Bleeding Disorder Registry
- Australian and New Zealand Dialysis and Transplantation Registry
- Australian Creutzfeldt-Jakob Disease (CJD) Registry
- Breastscreen Australia y
- Australian Rheumatology Association Database Project
- Melbourne Interventional Group Interventional Cardiology Registry
- Melbourne Vascular Surgeons Association Audit
- Australian Motor Neuron Disease Registry
- South Australian Infection Control Surveillance database,
- South Australian Trauma Registry
- Victorian Cardiac Arrest Registry
- Victorian Orthopaedic Trauma Registry (VOTOR)





General attributes of registries

N=28

Classification of body system

All body systems	11 (39)
Cardiovascular	5 (18)
Musculoskeletal	3 (11)
Neurological	2 (7)
Haematological	2 (7)
Reproductive	2 (7)
Other (Ophthalmological, gastrointestinal, Urological)	3 (11)

Intervention being monitored by the registry

Multiple interventions	14 (50)
Surgery	7 (25)
Medicines	2 (7)
Primary care	2 (7)
Intensive care/coronary care/dialysis	2 (7)
Psychiatric/psychological care	1 (4)

Length of Operation

Less than 5 years	6 (21)
6 to 10 years	10 (36)
11 to 20 years	7 (25)
More than 20 years	5 (18)

States/territories represented

State-based	13 (42)
Australia - all states	10 (39)
Australia + New Zealand	4 (19)
Aust – NT/Tas	1 (4)

Follow up

Until discharge	10
For less than 1 year	4
Until stopped being seen	1
Until death	13





Data collection and output

	Freq
<i>Variables collected</i>	<i>N=28</i>
<i>Identifier, condition, intervention, short term outcome</i>	5 (18)
<i>Identifier, condition, intervention, short term outcome + major confounders</i>	7 (25)
<i>Identifier, condition, intervention, short term outcome, major confounders + long term outcome</i>	16 (57)
<i>Primary outcomes collected</i>	<i>N=46</i>
Mortality/survival	28 (61)
Morbidity/complications	6 (12)
Procedural success	5 (11)
Cancer	4 (9)
Discharge status, service utilisation, exposure	3 (6)
<i>How are data collected?</i>	<i>N=28</i>
Paper-based reporting	18 (64)
Web-based reporting	4 (14)
Combination of paper and web-based	3 (11)
Electronically via administrative database	1(4)
Not answered	2 (7)
<i>How are records stored on the data base?</i>	<i>N=28</i>
Identifiable	17 (61)
Reversibly anonymised	7 (25)
Irreversibly anonymised	4 (14)
<i>Data linkage</i>	<i>N=28</i>
No data linkage	11 (39)
Linkage to a hospital administrative database	6 (21)
To another registry	5 (18)
To National Death Index or state equivalent	4 (14)
Not stated	2 (7)





Data collection and output

Freq[#]

Frequency of audit reports

N=28

Annually	9 (32)
Monthly to quarterly	8 (29)
Not produced	5 (18)
6-monthly	3 (11)
On request	1 (4)
Not applicable/not answered	2 (7)

Frequency of provider-specific reports

N=28

Annually	6 (21)
Monthly to quarterly	6 (21)
On request only	6 (21)
6 monthly	4 (14)
Not produced	4 (14)
Not applicable / not answered*	2 (7)





3 Registry governance and ethics

Freq (n=28)*

What is the level to which potential participants have consented?

Participants individually informed	15 (54)
Not informed	8 (29)
Participants informed collectively	4 (14)
Not answered	1 (4)

What level of consent was provided by registry participants

Opt off	21 (75)
Opt in	6 (21)
Consent not required (legislated data collection)	1(4)

A steering committee was involved in the establishment of the registry

Yes	22 (79)
No	6 (21)

The database has the support of relevant clinical or professional association

Yes	15 (54)
No	13 (46)

A management group oversees the activities of the registry

Yes	25 (89)
No	2 (7)
Not answered	1 (4)

How often do management group meet to discuss aspects of the registry?

Weekly to monthly	12 (43)
>Monthly to 3 monthly	5 (18)
> 3 monthly to 6 monthly	5 (18)
>6 monthly to 1 year	3 (11)
No meeting	2 (7)
Not answered	1 (4)





4. Data quality

<i>Completeness of recruitment of eligible population</i>	28 (100%)
Unknown or few (<80%)	13 (46)
All or almost all (>97%)	7 (25)
Most (90-97%)	5 (18)
Many (80-89%)	2 (7)
Not representative	1 (4)
<i>Use of explicit definitions for variables</i>	
All or almost all (>97%)	26 (93)
Many (50-79%)	2 (7%)
<i>Use of explicit rules for deciding how variables are recorded</i>	
All or almost all (>97%)	22 (79)
Many (50-79%)	3 (11)
None	2 (7)
Not answered	1 (4)
<i>Reliability of coding of conditions and interventions</i>	
No inter-rater reliability undertaken	23 (82)
Good (kappa > 0.8)	4 (14)
Fair reliability (kappa 0.5-0.8)	1 (4)
<i>Extent to which data are validated</i>	
Range and consistency checks	13 (48)
Range and consistency checks + external validation	10 (37)
10% of all data is audited by a CRO	1 (4)
No audit	1 (4)
Not answered	3 (11)
<i>Completeness (% of variables at least 95% complete)</i>	
Most/ many (80-97%)	13 (46)
All or almost all (>97%)	9 (32)
Unknown or few (<80%)	6 (21)
Not answered	1 (4)
<i>Independence of observations of primary outcome*</i>	n=48
Independent observer blinded to the intervention or not necessary as objective outcome e.g. death	44 (92)
Independent observer not blinded to the intervention	3 (6)
Observer neither independent nor blinded to the intervention	1 (2)





Limitations

- Pragmatic about the definition of a registry
- Data search strategy not extensive. Many local registries might exist which we have not captured.
 - Would not capture registries which (1) do not publish in peer-reviewed journals or (2) do not have a webpage (3) do not use terms register, registry, database
- Relied on self-reporting





Conclusions

- Need better operational definition of what is a clinical registry
- Need to consider how to recruit registries to the Registry of registries ? like clinical trials
- Need to collect information on process of care measures as well as outcomes collected by registries





- Need to identify the quality of the underlying data source. ? Independent audit and scoring system

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Patients not given the full picture

April 3, 2009

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NUMEROUS concerns have been raised over the integrity of public hospital performance data. AMA Victoria's Bendigo and district subdivision did so in a submission to an upper house inquiry that was the culmination of feedback from patients, GPs, specialists and family experience. Our concerns relate to the integrity of performance data across the state, not just in Bendigo.

Hospital audits tipped amid claims of waiting list fraud

Rick Wallace, Victorian political reporter | *April 01, 2009*

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Article from:  **THE AUSTRALIAN**

VICTORIAN Health Minister Daniel Andrews has been forced to order audits of all of the state's major hospitals in the wake of a growing scandal over manipulation of waiting lists.

It is believed an audit into waiting list data to be released today will make a number of criticisms of the hospital system, increasing pressure on the minister to act.





Conclusions. Some sobering thoughts....

- When using registries to measure quality of care, need to:
 - Collect data from close to entire eligible population
 - 45% don't or can't demonstrate it
 - The fact that 75% have opt off consent provides greater assurance of high capture rate
 - Have good governance structures
 - 11% don't have regular management meetings
 - Provide information back to providers
 - 18% don't provide any audit reports and 4% only provide them on request
 - 14% don't provide any reports back to providers and 21% only provide them on request
 - Capture quality of care issues
 - Is mortality a good marker of quality of care?
 - Need to consider what process measures are collected by registries





Thank you

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