ROUNDTABLE ON REGISTRIES
Practical Considerations for Registries – making them work

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Professor John G Williams, CBE, FRCP, UK

• Professor of Health Services Research, Swansea University, Medical School, UK
• Consultant Gastroenterologist, Abertawe Bro Morgannwg University Health Board, UK
Enhancing the role of routinely collected clinical data in a registry setting, and to support pharmacovigilance

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Director, Health Informatics Unit, RCP
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Overview

• Credentials
• Purpose of registries
• Challenges
• Opportunities
• Progress in the UK
• Conclusions
Chair in Health Services Research, leading a team of ten in clinical research, service delivery, informatics and data linkage

Co-investigator, Farr Institute

Consultant Gastroenterologist

Director, Health Informatics Unit, Royal College of Physicians

Member, Strategic Clinical Advisory Group to the National Information Board
A **registry** is a collection of information about individuals, usually focused around a specific diagnosis or condition. *NIH 2016*

A **registry** is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. *Virginia Commonwealth University Office of Research & Innovation*
Purposes of a Registry

• To describe the natural history of a condition or disease
• To determine effectiveness or cost effectiveness of treatments/services and/or health care products
• To measure or monitor safety & harm
• To measure quality of care
Strengths: Potential benefits

• Pharmacovigilance
• Observational studies
• Precision Medicine
• Patient empowerment
• Professional empowerment
• Clinical efficiency
Where are we now in the UK?

- Many disease or intervention specific registries
- 50 national audits
- Growing number of biobanks or bioresources
- eg Inflammatory Bowel Disease
  - IBD Registry
  - Biologics Registry
  - BioResource
  - National Audit
  - PANTS and other cohorts
Analysable patient data

• **Operational** data captured at the point of care

• **Routine** data – collected continuously as a by-product of care, using a secondary extraction and coding process from (paper) records – e.g. PEDW or HES

• **Designed** data – bespoke for audit or research and other specific purposes
Data collection

Operational data at point of care

Registries and audits use parallel processes to collect designed data

Routine data in Central Returns (HES or PEDW)
## Examples of Registries in the UK

- Renal
- Diabetes - various
- IBD
- Industrial diseases
- Congenital anomalies
- Inflammatory arthritis
- Barretts Oesophagus
- Neuroendocrine disorders
- Cancer
- Interstitial lung disease
- Muscular dystrophy
- Rare disorders
- Cardiac surgery
- Bariatric surgery
- Joint
- Endocrine & Thyroid surgery
Weaknesses: Challenges

- Time
- Data
  - acquisition
  - integrity
  - quality
  - completeness
- Fitness for purpose
- Cost
- Maintenance
Where do we want to be?

This is now the explicit vision of NHS England and NHS Digital.

Point of care
Data requirements

- Patient care
- Audit
- Research
- Commissioning
But.... weaknesses of source data

- **Content** of clinical data in central returns from hospitals (HES in England, PEDW in Wales)
  - **Breadth**: no data on presenting complaint or medication; poor data on co-morbidities
  - **Depth**: Diagnosis terms and codes lack attributes such as disease extent; behaviour; severity
  - **Quality**: Diagnosis and procedures are inaccurate in up to 20% of cases

- **Timeliness**: Delay in availability of data
- **Operational systems** do not meet good practice requirements applicable to research systems
Information flows for routinely collected data

**Patient notes**
- Primary use (i.e. support patient care)

**Clinical Coding** (ICD10, OPCS4)

**Hospital PAS**
- Administrative detail
- Local secondary uses

**NHS Digital**
- Switching service (data standardisation)
- Central datasets eg HES
- Wider secondary uses:
  - Financial returns
  - Resource allocation
  - Waiting times
  - Monitoring health trends
  - Public health measures
  - Epidemiology
  - Audit
  - Performance monitoring
  - Clinical governance
  - Research
  - Disease registries
  - LHBs & commissioning
Pharmacovigilance

• ‘The practice of monitoring the effects of medical drugs after they have been licensed for use, especially in order to identify and evaluate previously unreported adverse reactions’

• Requires
  • accurate data on prescribing and medication changes
  • comprehensive clinical data at baseline and regular intervals
  • Expert interpretation
Pharmacovigilance systems

• Yellow card
• Clinical trials
• Post marketing surveillance
• Monitoring using routine data
• Registries
Medication – specific issues

- Not collected in Hospital Episode Statistics
- Not standardised: product vs dose based prescribing
- National terminology and coding (DM&D was stand alone, but is now a SNOMED extension)
- Causal relationship of events in long-term follow up requires manual assessment
- What to collect is not standardised
Context is important

- New drugs in a specialist setting, such as cancer
  - sophisticated, dedicated pharmacovigilance
- Drugs used widely in the community
  - post-marketing surveillance
  - serendipitous data capture
  - yellow card system
IT infrastructure to support patient care and pharmacovigilance

Hospitals

Registry team

NHS Network

VPN

Other Sources (HES, ONS, etc)

Data Repository

Study Data

Data Warehouse

Pseudo-anonymised
The future

• Cherish the vision for point of care data
• Take a pragmatic approach now, but
• Future-proof the interim solution by taking a standards based approach
Standards for electronic records

- **Technical** – operating systems, networking, application interfaces
- **Information** – terminology (SNOMED-CT), drugs (dm+d), communication (HL7), patient identification (NHS number)
- **Professional** – structure and content
National Standards

• We now have national standards for structure and content of electronic patient records and communications, and information models to facilitate their incorporation in clinical systems.

• They have been endorsed by the Academy of Medical Royal Colleges, Professional Record Standards Body and NHS Digital.

• The requirement to use them is explicit in national policy and NHS contracts.

https://www.rcplondon.ac.uk/projects/outputs/standards-clinical-structure-and-content-patient-records
Opportunities

• Standards for data now exist
• EPRs enable recording at the point of care
• Patients who wish to control their care should be offered responsibility for their data in PHRs
• Other drivers for better data include precision medicine and the evolution of national audits
Threats

- Lack of
  - Money
  - Time
  - Technology
- But
  - Digital capture and analytics will bring savings

Conclusions

- Registries are a challenging solution to the need for comprehensive data, including for pharmacovigilance.
- Until ‘point of care’ data recording improves there is a need for them.
- Incorporating national standards for clinical data structure and content will ensure transition in the future.