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GaBI Scientific Meetings

ROUNDTABLE ON REGISTRIES
Practical Considerations for Registries – making them work

26 January 2017, Pullman London St Pancras, London, UK

Enhancing the role of routinely collected clinical data in a registry setting, and to support pharmacovigilance

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Enhancing the role of routinely collected clinical data in a registry setting, and to support pharmacovigilance

Professor John Williams
Director, Health Informatics Unit, RCP
January 2017

Royal College of Physicians

Setting higher standards

Overview

- Credentials
- Purpose of registries
- Challenges
- Opportunities
- Progress in the UK
- Conclusions

Credentials

- 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

What is a registry?

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?

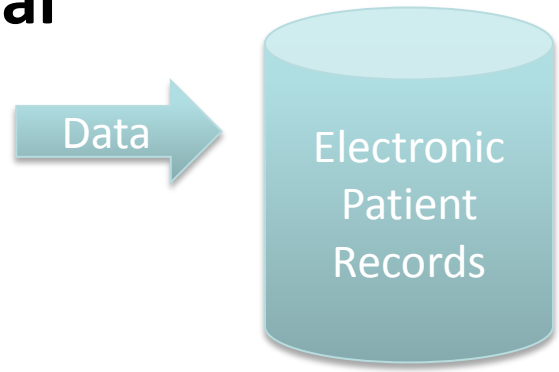
- Many disease or intervention specific registries
- 50 national audits
- Growing number of biobanks or bioresources
- eg Inflammatory Bowel Disease
  - IBD Registry
  - Biologics Registry
  - BioResource
  - National Audit
  - PANTS and other cohorts

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 – eg PEDW or HES
- Designed data – bespoke for audit or research and other specific purposes

Data collection

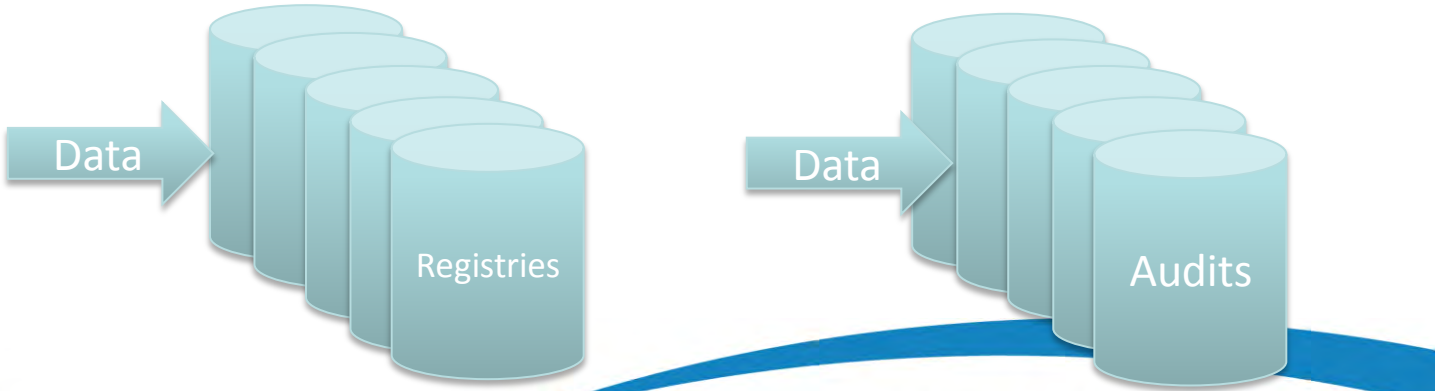
Operational data at point of care



Routine data in Central Returns (HES or PEDW)

Registries and audits use parallel processes to collect designed data

Records



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

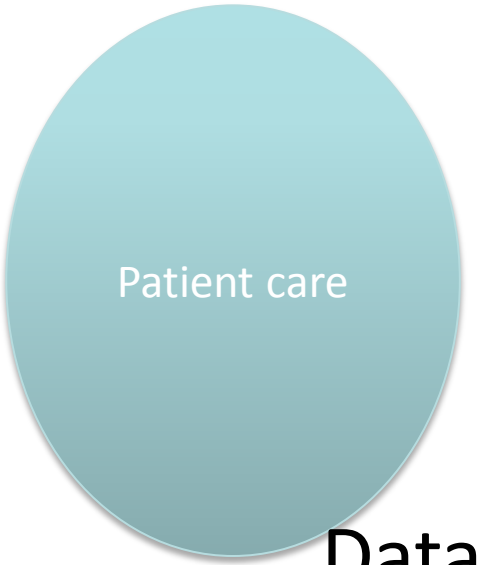
Weaknesses: Challenges

- 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

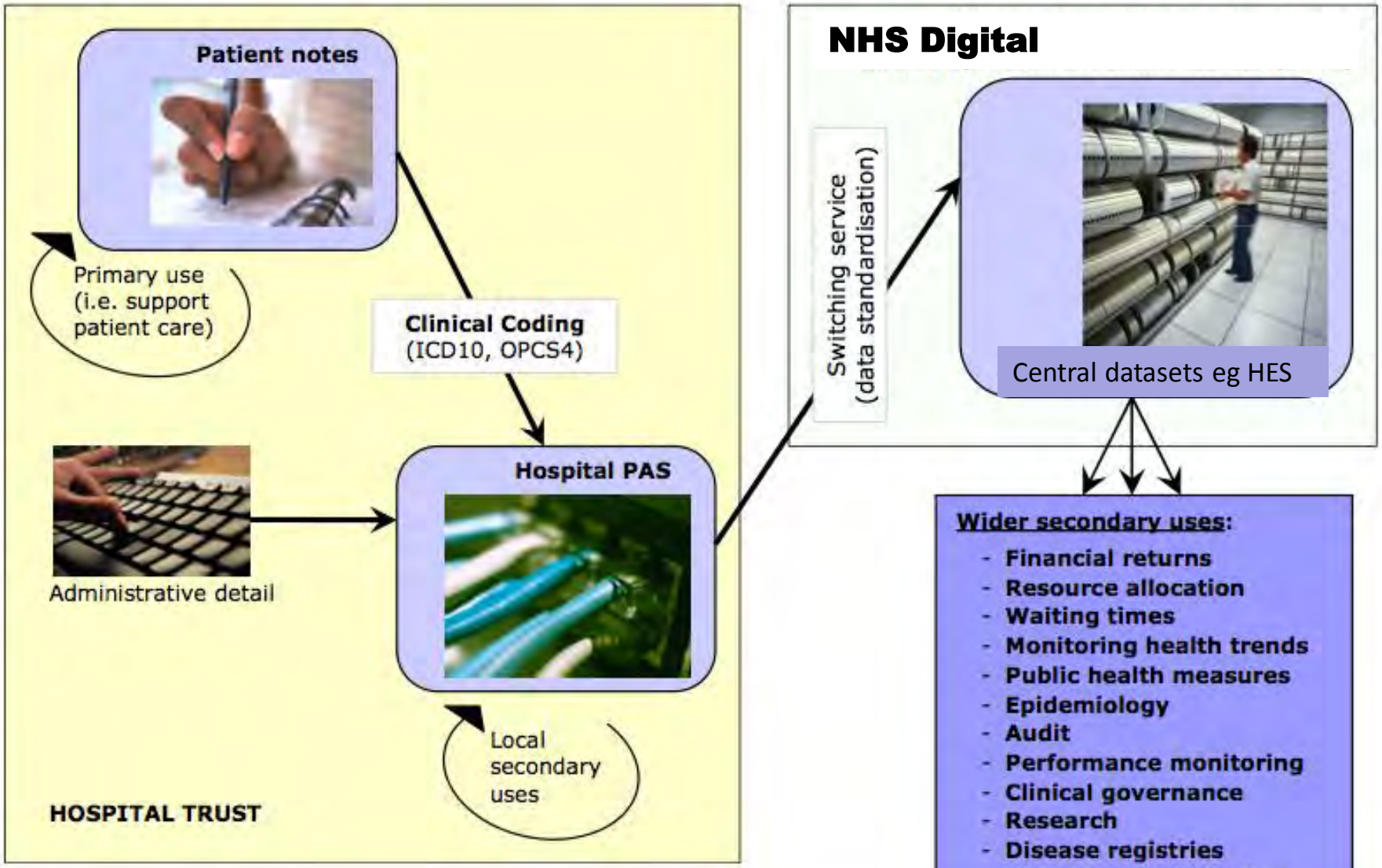


Data requirements

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



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

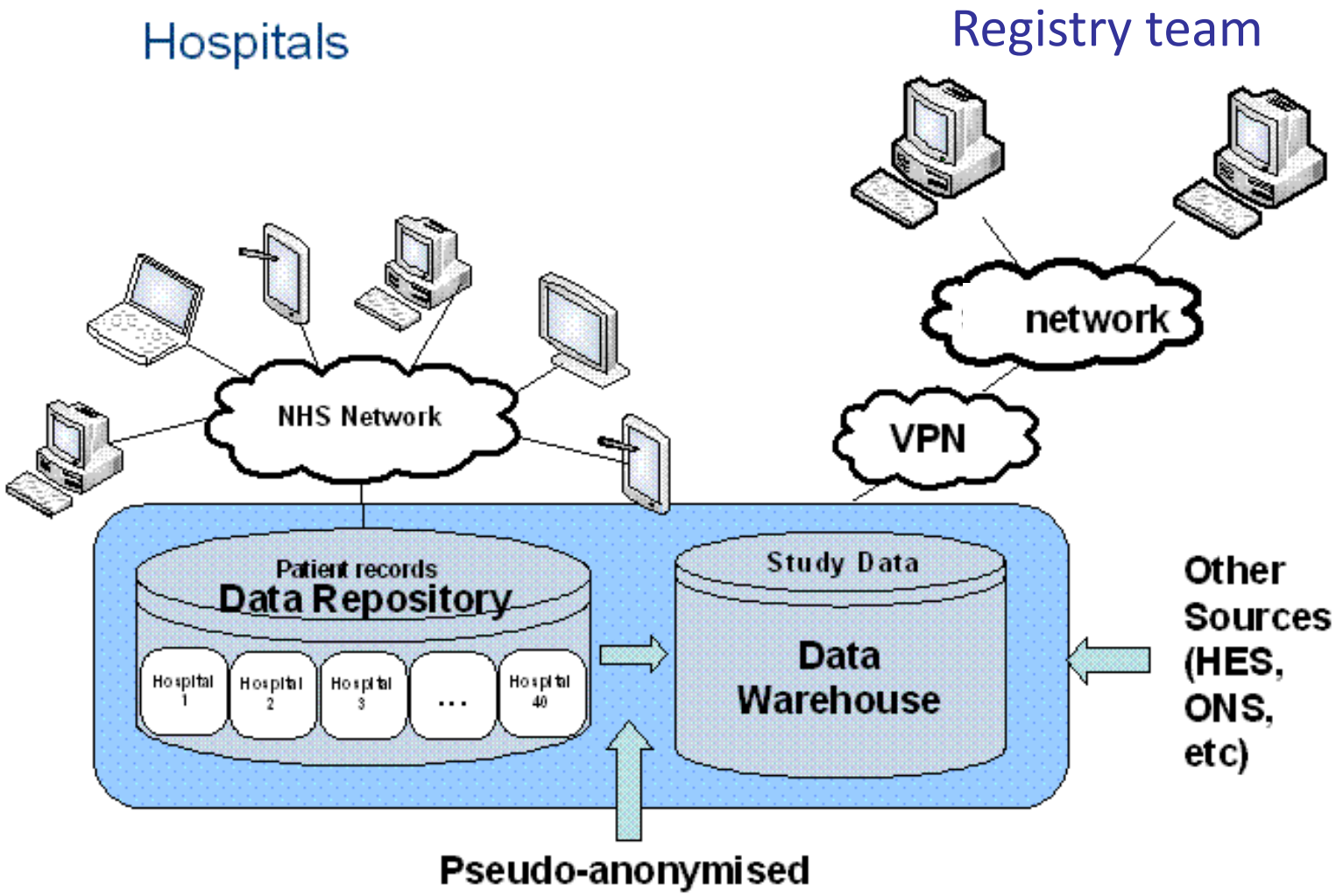
Medication – specific issues

- 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



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

http://volterra.co.uk/wp-content/uploads/2014/09/Final-EMC-Volterra-Healthcare-report-web-version.pdf

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

Data linkage studies
Stratified Medicine

Symptoms
Diagnoses
Tests/results
Treatment/procedures

Performance monitoring
Audit
Registries
Appraisal
Pharmaco-vigilance

Research data

Guidelines
Technology appraisals
Quality standards