Potential for linkage in trials in England

Research Capability Programme

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Context of English Health System

- The size and scope of the English Health System:
  - 8000+ GP Practices
  - 150+ NHS Acute Trusts
  - 120+ NHS Mental Health Trusts
  - 10 Strategic Health Authorities
  - 110+ Primary Care Trusts (soon to be 500 to 600 GP consortia for commissioning)
- There are over 60 million patients registered with the NHS in England

The data scope for England

- E-Health records for England:
  - There are over 60 million health records in England
  - These records are stored on multiple systems in different organisations and unlinked
  - The Primary Care record differs from the secondary care record (Primary care is longitudinal whilst acute care will be episodic but with a great deal of depth)
  - These records cover a rich set of demographic, encounters, consultations, diagnostics, treatments, medicines etc.

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The linkage scope of e-Health records

- Linkage is vital to unlocking the potential for research of the rich set of data in English health system, as it provides:

  - the potential to bring together the full spectrum of data held in the NHS

  - the potential to augment health data with other data-sets to provide additional information to support both observational research and clinical trials

  - the potential to take English data and link it to the home countries data to give a UK view. This can then be extended beyond the UK

The potential of linked records to support clinical trials

NHS
National Institute for Health Research

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- Having access to a linked set of 60 M + health records will mean the following for clinical trials:
  - Feasibility of trials for patient identification and site selection become faster and cheaper to do
  - By linking records the selection process and criteria can be targeted and bring other factors, such as environmental etc
  - Trial data can be augmented by clinical events that may not be part of the trial protocol, thus giving contextual information regarding the patient, which otherwise would not have been captured

The potential of technology to support clinical trials

- What can technology do to support clinical trials?
    - Feasibility (patient numbers and sites)
    - Automate the process of site participation
    - Automate the process of patient recruitment via clinical consultations into current or new trials
    - Automate the consented data feeds to CI/PI (or team)
    - Identify data quality and completeness levels and if they are material to the trial
    - Reduce the burden of data collection by having access to the data that is part of the care process

What is happening in England to meet this potential for clinical trials?

Execution of the Research Capability Programme:

- Its primary objective is to enable research to achieve its full potential as a "core" activity for healthcare.
- The Research Capability Programmes vision is to:
  - Enable better health outcomes for the public and patients achieved at best value for the taxpayer; and
  - Support the ambition to make the UK the preferred place to carry out medical research, by building a nationwide health data and information platform that will enable research to achieve its maximum potential benefit.
- It will do this by developing and implementing the Health Research Support Service (HRSS)

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The Health Research Support Service (HRSS)

- The HRSS will link together data for researchers to use for research studies or clinical trials

- It will increase the data routinely available to health research

- Patient data and confidentiality will be protected by strict controls

- It will enable researchers to carry out studies that lead to more effective treatments and improved health outcomes, patient safety and quality of life

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What is the Health Research Support Service (HRSS)?

- Technology (hardware, software and development)

- Services (helpdesk, users guidance, analytical, research informatics expertise)

- Information Governance services (assistance, guidance and audit)

- Data sources (ONS, IC, Cancer, Heart disease etc)

- Data processing (meta-data, linkage etc)

- Secure tools and environment for researchers to access data and work

The HRSS Pilot Programme

- The HRSS Pilot Programme has been developed to implement the *initial* Health Research Support Service capability

- The objectives of the Pilot HRSS are to:
  – Prove the functionality and feasibility of the Pilot HRSS
  – Demonstrate some initial benefits of the service
  – Create useful lessons learned and provide feedback for the development of the main service

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What is the Pilot HRSS? (i)

- Will link to a number of (initial) data sources through a single point of access

- Link datasets and analyse data and linkage quality

- Anonymise / pseudonymise / de-pseudonymise data

- Provide data to Health Researchers (within the agreed regulatory framework) to support observational studies and clinical trials

Planned Pilot HRSS Studies

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Organisation	Area of study
Kings College, London	Mental disorder and cancer
National Cancer Intelligence Network	Post colonoscopy complications
Imperial College, London	Migratory movements amongst births in England
Health Protection Agency	Monitoring Hepatitis C related care
	Gynaecological complications following Chlamydia diagnoses
GlaxoSmithKline	Paediatric Pilot Study: The Utility of Linking Additional Patient-Level Data Sources in England for Epidemiological Studies
UK Renal Registry	Measuring quality and driving change in renal services using routinely collected data
MEMO/Hypertension Research, University of Dundee	The Standard care versus Celecoxib Outcome Trial (SCOT): A Large Streamlined Safety Study
University of Oxford Clinical Trial Service Unit & Epidemiological Studies Unit	ASCEND (A Study of Cardiovascular Events in Diabetes)
	Study of Heart and Renal Protection (SHARP)
General Practice Researcher Database	Evaluating the comparative effects of Statins
	Evaluating antibiotics to treat chronic lung disease (COPD)

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Planned Pilot HRSS Data Sources

IMS Hospital Prescribing (NHS IC)	UK Renal Registry
Hospital Episode Statistics (NHS IC)	Socio-economic reference data
Death Registrations (ONS)	Medical Research Information Service (NHS IC)
Primary Care (Multiple physical source acquisition strategy)	Birth Registrations (ONS)
National Cancer Register (ONS)	Address point (via Imperial)
Coronary Care Audit Database (CCAD): British Cardiovascular Intervention Society (BCIS)	Thames Cancer Registry
Coronary Care Audit Database (CCAD): Myocardial Infarction Audit Project (MINAP)	Demographics (NSTS)
Local CTSU Recruited Cohort: ASCEND	NHS Cancer Screening Programme: Bowel
Local CTSU Recruited Cohort: SHARP	SLAM BRC Case Register
Master Patient Index Local Dundee Recruited Cohorts	British Isles Network of Congenital Abnormalities Register (BINOCAR)

The challenges for now and future

- Information Governance
  - Rights to access information (DPA)
  - Processing of data in a secure and safe way
  - Continued trust in the way data is used by the public
- The Professions
  - Consistent education programmes to ensure clinical professionals know why it is important to use linked data in ethical way to support research
- Future data types
  - The development of genomic data-set mean data becomes highly personalised and thus its use pre-consent is an ethical challenge!

Questions