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Registry: how to set up spontaneous reporting – practical challenges, information sharing, multi-source environment, limitation of registry data

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Registry: how to set up spontaneous reporting – practical challenges, information sharing, multi-source environment, limitation of registry data

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Consultant Gastroenterologist
Clinical Lead Adult IBD service
Clinical Lead UK IBD registry
What is the purpose of a registry?

“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 a predetermined scientific, clinical, or policy purpose(s)”

Gliklich et al 2010
Inputs: Obtaining data

- Identify and enroll representative patients
- Collect data from multiple sources and settings
- Use uniform data elements and definitions
- Link data from different sources
- Maintain security and access

Gliklich et al 2010
Outputs: Care delivery and coordination

• Provide real-time feedback (with decision support?)
• Generate patient level reports and reminders
• Send relevant notifications to providers and patients (supported self-management, monitoring etc)
• Share information with patients, other providers
• Link to relevant patient education  Gliklich et al. 2010
Outputs: population measurement and QI

- Provide population level reports
  - Standardised measures
  - Benchmarking
  - Different reports for different levels of user
- Enable ad-hoc reports
- Provide utilities to manage populations or subgroups
- Generate dashboards
- Facilitate 3rd party quality reporting

Gliklich et al 2010
IBD Registry

Making information work for patients, their clinical teams and the NHS
The IBD Registry will provide the first ever UK-wide repository of pseudonymised IBD adult and paediatric patient data for prospective quality assurance, audit and research purposes. Bringing this data together for the first time will:

• Drive continuous improvement in patient care and access to care across the UK
• Inform commissioning and service design
• Improve our understanding of long term outcomes
• Provide local, regional & national data in order to better define the pattern of ulcerative colitis and Crohn’s disease
• Support IBD research
Enter data once and use for multiple purposes
Data entry options

IBD Registry
UK IBD Registry
A Central Anonymised Dataset of IBD Patients

- Reports
- Outputs
- Analysis
- Feedback
- Data for Research
- Quality Measures
- Performance

e.g. Rotherham, EMIS etc
(discounted) costs payable to supplier
currently free of charge
Data Submission Framework

• Standardised data definitions
  – Demographics
  – Phenotype
  – Medications
  – Disease activity scores
  – PROM

• Data extract structure to facilitate upload to NHS Digital via secure portal
Data Collection tools

• Duplication of data entry
• Supplier engagement
• Technology?
• NHS IT
  – Resources
  – Engagement
Using the tools: behavior change?

• Cultural change
• Time
• Technology adoption
• IT system challenges
• Incentives?
• NHS support
IBD Registry Tools

- Patient Summary
- MDT
- Flare line
- Nursing support
- Drugs
  - Biologics
  - IMM monitoring
  - Steroids
  - 5-ASA
- Cancer Surveillance system
- Bones
- Letters
  - GP
  - Patient Summary, information etc.
- Virtual clinics
Overview of Registry data-flow & pseudonymisation in England

NHS Digital Data Safe Haven

- Receives and pseudonymises the data files from hospitals
- Allocates Registry identifier and maintains data file linking NHS number and Registry identifier
- Extracts and forwards data from HES and ONS datasets e.g. Death, cancer, hospital data etc.

IBD Registry web servers

The Registry Database for audit and research

- Separate database for each Trust/Board
- Patient identifiable data encrypted and accessed only by hospital users who then export their data to the Registry.

Web Tool databases

- N3

Local Trusts/Boards

- Legacy IBD database (on PC in hospital)
- Hospital or GI Dept IBD database e.g. Emis, Ferring, Hospital EPR
- IBD Registry PMS using InfoFlex software
- Data extract files from web tool returned to Trust server before upload to HSCIC.

Data files from hospitals

- All export through secure networks to NHS Digital

Web Tool access

- (Registry data set, national audit data and research data)
Data governance

NHS patient data to be made available for sale to drug and insurance firms

Privacy experts warn there will be no way for public to work out who has their medical records or how they are using it

Randeep Ramesh, social affairs editor
Sunday 19 January 2014 21.34 GMT

NHS data will not be sold to insurance companies, Jeremy Hunt says

Health secretary to provide assurance that confidential information will not be used for commercial insurance

Press Association
Friday 28 February 2014 23.31 GMT

Nearly 1 million patients could be having confidential data shared against their wishes

Calls for an official investigation as it is disclosed that at least 700,000 patients opted out to having their GP data shared with third parties only to have their demands ignored.

By Peter Dominiczak, Political Editor
6:34PM BST 05 Jun 2015
Why Pseudonymise? NHS Digital?

- Identification of patients for future research
- HES data linkage
- Linkage to other NHS England databases

BUT

Huge bureaucratic challenge
IBD Registry

Information for Patients

The IBD Registry is a national project to collect information about Inflammatory Bowel Disease (IBD) from across the UK for the first time.

Collecting this information will:
- Help hospitals to improve their care of people who have Crohn’s or Colitis disease
- Improve our understanding of how people’s lives are affected by IBD
- Help the NHS to design better services
- Support research into IBD

What does it mean for me as a patient?
Some information about you will be used by the IBD Registry. A system has been put in place to protect your confidentiality and you can read about this in the IBD Registry Information Leaflet.

The information collected will help to improve patient care. But if you do not want your information to be used then it is your right to opt out. Please speak to your IBD doctor or nurse if you have any questions or you want to opt out. Opting out will not affect your treatment in any way.

Please ask a member of staff for an information leaflet or you can obtain one from our website at www.ibdregistry.org.uk

IBD Registry
British Society of Gastroenterology
3 St Andrews Place, Regents Park, London W1H 4RB
Tel: 020 7935 1150
Email: info@ibdregistry.org.uk
Website: www.ibdregistry.org.uk


IBD Registry Consent Form

The purpose of the IBD Registry is to collect information about Inflammatory Bowel Disease (IBD) across the UK.

Collecting this information will:
- Help hospitals to improve their care of people who have Crohn’s or Colitis disease
- Improve our understanding of how people’s lives are affected by IBD
- Help the NHS to design better services
- Support research into IBD

Please read the IBD Registry Information Leaflet and then initial the boxes below to confirm how you wish your personal information to be managed:

1. I give permission for relevant information from my medical records to be submitted to the IBD Registry for analysis and audit.

2. I give permission for the information held and maintained by the Health and Social Care Information Centre and other central UK NHS bodies to be used to provide information to the IBD Registry about my health status.

3. I give permission for information from my health records to be submitted to the IBD Registry and used for studies run by approved researchers.

4. I give permission for the information held by the Health and Social Care Information Centre to be used to contact me in the event of a research project for which I might be suitable.

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Patient’s name: ____________________________ Date: ____________________________
Staff member’s name and role: ____________________________ Date: ____________________________
Staff member’s signature: ____________________________ Date: ____________________________

For further information about the IBD Registry, please look at the project website at www.ibdregistry.org.uk

The IBD Registry is managed by the British Society of Gastroenterology which is a charity registered in England and Wales. Charity number: 1110427.

www.consentform RAF adult ra in pregnant women January 2023
Consent

• Currently s251 exemption
• Linkage of registry data to NHS records
• Their information to be used for
  – non-commercial research projects
  – Commercial partners (report only)
    • Research
    • Pharmacovigilance
• Contacted for future research projects
Who should fund registries?

• NHS?
• Specialist Societies?
• Industry?
• Individual NHS trusts?
• Charities?
• Research funders?
Collaboration/opportunities

• UK IBD Biologics audit
• UK Quality Improvement Program
• Academic
  – Crohn’s and Colitis UK/Dr Keith Bodger
• Industry
  – Pharmacovigilance projects
  – Real world evidence
  – Specific projects
    • VEST
    • Anaemia service evaluation
The story so far....

- Infrastructure and governance
- 23,000 patients
- 40 sites actively uploading data
- 80 set up to upload data
- 150 expressions of interest to participate in audit
Aims for 2017

• Focus on biologics treated patients
• Funding model
  – Subscription model
  – Pharma projects/support
• Reporting
• Data visualisation
• Pharmacovigilance system
Conclusions

• Huge opportunity to change patient care
• Culture change
• Registry infrastructure
• IT platforms
• Funding
• Defined outputs