



Protecting patient confidentiality in research: the Scottish landscape

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Outline

- National data and SHIP
- Information governance
- The Scottish structures
 - Legal
 - NHS Scotland policy
 - Governing bodies
- Information governance in practice

‘Provisioning datasets for research’

(SHIP work stream 1)

- Access to data at individual patient level
- The data
 - Scottish Morbidity Records 1 and 6
 - Primary care prescribing records
 - General Register Office Death records
 - Some CHI fields
- Requirement for infrastructure meeting information governance and other constraints

Scottish morbidity records

- Individuals' personal and sensitive health information
- Collected alongside delivery of care
- Quality assured
- Held in ISD on behalf of NHS Scotland
- Secondary uses in the public interest
 - Management and planning
 - Audit
 - Epidemiological research
 - Clinical research

Information Services Division of National Services Scotland



- NSS is a special Health Board in NHS Scotland.
- National organisation for health information and statistics. (NHS (Scotland) order (2008))
- Required to operate to the highest information governance standards.
- Regulated by the UK Statistics Authority

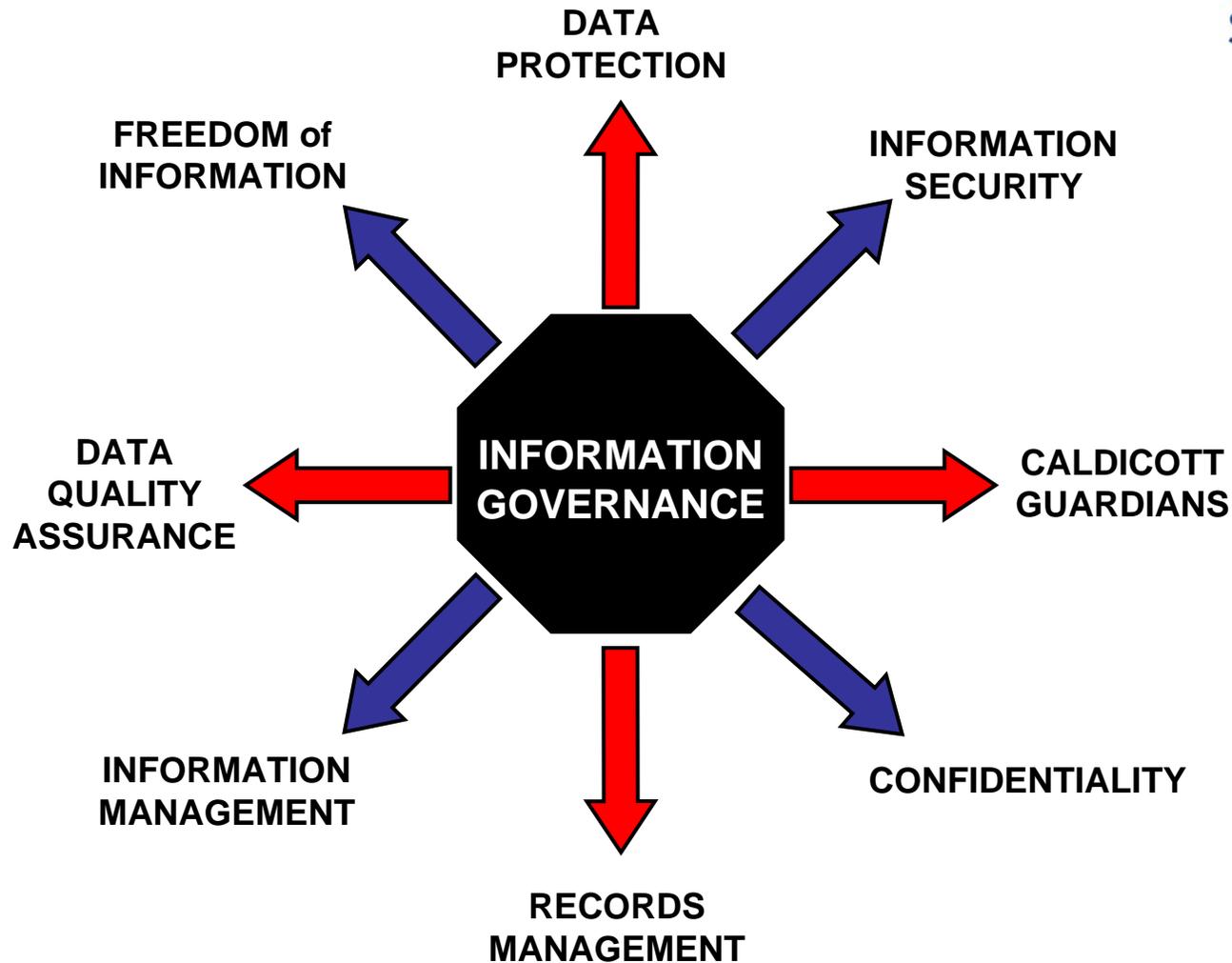
What is Information Governance?

“A framework enabling information to be handled in a confidential and secure manner to appropriate ethical, legal and quality standards”

Why does it matter

- Individuals' rights to confidential health care
- Confidential health service is a public good (GMC 2009)
- Secondary use of data relies on public confidence
- Withdrawal of consent threatens validity of datasets with detriment to
 - Health service management and planning
 - Research

Information Governance



Sources of Rights & Protections

- Common Law
- Data Protection Act 1998
- Human Rights Act 1998
- Freedom of Information Scotland Act 2002
- Professional Guidance e.g. GMC
- NHS Scotland guidance

Caldicott Principles

1. Justify the purpose
2. Don't use patient-identifiable information unless absolutely necessary
3. Use the minimum necessary patient-identifiable information
4. Access to patient-identifiable information should be on a strict need-to-know basis
5. Everyone with access should be aware of their responsibilities
6. Understand and comply with the law

Data protection principles

- 1. processed fairly and lawfully**
2. specified and lawful purposes
3. adequate, relevant and not excessive
4. accurate and up to date
5. not be kept for longer than is necessary
6. processed in accordance with the rights of the subject
- 7. safeguard the data**
8. not be transferred out with the EC unless.....equivalent standards of info management

Use and disclosure of health data: research

Processing in the substantial public interest
for the purpose of research
which is unlikely to cause substantial damage or
substantial distress to the data subject or any
other person.
(ICO 2002)

Confidentiality and research

“Confidentiality is central to trust between doctors and patients. Without assurances about confidentiality, patients may be reluctant to seek medical attention or to give doctors the information they need in order to provide good care.

But appropriate information sharing is essential to the efficient provision of safe, effective care, both for the individual patient and for the wider community of patients.”

(GMC 2009)

Information security

- Sensitive data requires commensurate level of security
- NHS Scotland Information Security Policy
- British Standard on Information management
- NHS compliant

Governing bodies

- Privacy Advisory Committee
- NHS Boards
- CHI Advisory Group
- Specific steering committees
 - Clinical datasets
 - Research datasets

Authority

Privacy Advisory Committee

- Advisory committee to NSS Board and Registrar General of Scotland
- Jurisdiction
 - datasets controlled by NSS and Registrar General
- Advice provided regarding
 - Disclosure of patient identifiable information
 - New linkage
 - Deaths, entry and exit to NHS, Health Board Area
- Criteria

Information Governance in practice

- Governing body
- Research and researcher approval and training
- Method of linkage
- Storage datasets: during analysis and while archived
- Access to dataset: safe haven, physical and virtual
- Rules of engagement
- Assessment of disclosure risk
- Audit and monitoring
- Capacity building