Research and Information Governance

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Legal and Ethical Framework:

• Data Protection Act 1998
• Human Rights Act 1998
• Breach of Confidence - Common law
• Ethical and Professional Standards
• Freedom of Information (Scotland) Act 2002
• Caldicott Guardian/Principles
Data Protection
DATA PROTECTION ACT 1998

- It applies to “personal data” that is information about a living individual
- However, if using such information intruded on the privacy of the relatives, then likely action under Human Rights legislation
- There are more stringent rules for some types of data known as ‘sensitive data’
- Those who process personal data are called ‘data controllers’
Data Protection Act 1998

- The Act grants individuals rights in relation to the processing by others of their personal data
- Ensures that Data Controllers do not process personal data without complying with the 8 data protection principles
The Data Protection Principles

1. processed fairly and lawfully
2. obtained and processed for specified purposes
3. adequate, relevant and not excessive
4. accurate and up to date
5. held for no longer than necessary
6. processed in accordance with the data subject’s rights
7. held securely
8. not transferred to countries which do not have adequate data protection laws
What is Personal Data?

Personal data is any data which relates to a living individual, e.g.:

- name
- address/full post code
- date of birth/age
- gender
- CHI number/NI number/unique identifier
- marital status
- photographs/digital images/x-rays etc
Any item or combination of items that allows you to identify, or probably identify an individual
What is Sensitive Personal Data?

- Race/ethnic origin
- Political opinions
- Religious beliefs
- Trade union membership
- Physical or mental health or condition
- Sexual life
- Criminal record
Data Protection Act 1998, Sched. 3

- Contains limited provision for sensitive personal data to be processed for medical research purposes
- (1) The processing is necessary for medical purposes and is undertaken by: (a) a health professional (b) a person who owes a duty of confidentiality equivalent if they were a health professional
Data Protection Act 1998, s33 Exemption

• Applies to personal data used for “research purposes”

Two Safeguard Conditions – Apply only to Research

• Research not used to make decisions about the individuals to whom they relate
• Processing must not cause substantial damage or substantial distress, or is likely to be caused, to any data subject
If conditions are met:

• Personal data may be used for research even if not collected for research purposes
• Personal data may be retained indefinitely for the purposes of research
• If the results of the research are anonymised AND the safeguard conditions met the individual data subject may be refused access to the data
However:

• No exemptions from requirement that Data Controllers have legitimate basis for processing personal data OR

• From the fair obtaining (p1) and processing (p2) codes
Permitted Disclosures

• Disclosure to any other person for research purposes only
• Disclosure to data subject of person acting on behalf
• Disclosure at request of DS or with their consent or person acting on behalf
• Where person disclosing has reasonable grounds for believing it falls within grounds above
In General -

• Records made for one purpose should not usually be disclosed for another purpose without the patient’s consent
• Where not practical, patients should be notified and given opportunity to object to use for research and their objections respected
Medical Research - ICO

• Information Commissioner has been critical of approach taken to use of patient information in research and for other non-treatment purposes

• E.g. Alder Hey Enquiry
Caldicott Guardian

NHS Board Medical Director

• To oversee how staff use personal health information and ensure that patients' rights to confidentiality are respected.
What is Caldicott?

• Caldicott is a set of Principles and processes which provide a framework of quality standards for the management of confidentiality and access to patient information under the leadership of the Caldicott Guardian

• NHSG CG is Medical Director - Dr Roelf Dijkhuizen
Caldicott Principles for Patient Information

1. Justify the purpose for use
2. Use it when absolutely necessary
3. Use the minimum that is required
4. Access on a strict need to know basis
5. Everyone must understand his/her responsibilities
6. Understand and comply with the law
CONFIDENTIALITY
Breach of Confidence – Common Law

• Divulging information where there is an obligation that it should not be disclosed

• Recognised relationship involving confidentiality preceding the obtaining of the information, e.g. doctor and patient

   (Delict, Wm Stewart)
Consent

- Consent alone not always enough
- Has to be a legal basis
- ‘If a public body does not have the vires to collect, use or share data it will be acting unlawfully and the fact that an individual may have consented would not make the activity legal’ Dept. Constitutional Affairs Guidance 2003
Consent and Capacity – Informed Consent

- Information
- Freedom of choice
- Comprehending and retaining treatment information
- Believing such information
- Weighing such information in the balance and arriving at a choice
Vulnerable Groups

- Children <16
- Adults with Incapacity
- Unconscious persons
- Ethnic minorities
- Mental Health patients
Human Rights Act 1998

- Collection, storage, use and disclosure of medical information by NHS and private health sector providers all relevant to Article 8 – right to respect for private and family life, home and correspondence
Additional:

• Use in connection with provision of care justified in consent given for treatment

• BUT for all other uses and disclosures of information NHS should follow full and informed consent by patient OR justification which fulfills 3 requirements of Art. 8(2)

• They are the legal basis
“Informed consent is crucial to the Government’s view of how a modern NHS should work. We simply cannot move to a patient centred service if patients are not informed and consenting participants in the services they receive.”

Minister for Health 2001
i.e.

• Where patient data is processed, the body responsible must comply with DP Act, HR Act and respect the obligation of confidence
Health and Social Care Act 2001, s60

- Provision of Sec. of State to make regulation for processing of patient information for medical purposes \textit{w/o patient consent}
- \textbf{NOT} applicable to Scotland
Data Controller and Research

- Important to ascertain the identity of the DC
- With NHS main DC is the Board but where research the DC is also the person in charge of the data
- i.e. Shared responsibility
Research NHS Grampian

- Identify Data Controller
- Register Database
- Inform
- Consent / Caldicott approval
- Staff Confidentiality/Honorary Contracts
Safeguarding Confidentiality

- Anonymisation
- Coded information
- Linked anonymised data
- Unlinked anonymised data
- Research team under duty of confidentiality
- Access to personal data restricted to few
- Security of data
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