

SECTION 60 OF THE HEALTH & SOCIAL CARE ACT 2001

USE OF PATIENT INFORMATION - LIFE BEFORE SECTION 60

- £500 Million annual R&D budget - dependent upon use of patient information.
- Widespread use of identifiable, confidential patient information.
- Advances in IT made it easier to access patient information
- Culture of professional staff and researchers:
 - professional, respecting confidentiality, but....
 - paternalistic
 - for the good of the patient
 - information - ‘a free good’.

THE LEGAL FRAMEWORK

- Common Law
 - processing requires consent or must be required by the Law.
- Data Protection Act 1998
 - processing must be for a medical purpose
 - processing must be transparent and meet ‘fair processing requirements’.
- Article 8, Human Rights Act 1998
 - a right ‘to respect for private and family life’.

CALDICOTT GUARDIANS

- Compliance with confidentiality requirements found to be patchy by the ‘Caldicott Committee’ (Dec 1997).
- Recommendation to establish a network of ‘Caldicott Guardians’ - senior staff responsible for advising their organisations on confidentiality issues.
- Guidance issued in March 1999:
 - legal and ethical requirements
 - 18 Audit areas of the Caldicott audit
- Caldicott did not focus on consent.

‘EVENTS, DEAR BOY, EVENTS.’

- Bristol Royal Infirmary Inquiry.
- Royal Liverpool Children’s Inquiry.
- GMC guidance.
- The Information Commissioner.

THE GOVERNMENT'S RESPONSE

'The traditional, paternalistic attitude of the NHS that the benefits of science, medicine or research are somehow self - evident regardless of the wishes of patients or their families is no longer acceptable.'

'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.'

'We are determined to address this. It is no small task, and the culture of the NHS will have to change radically as we move away from our comfortable habits and into practice based on real consent.'

CONSENT - POLICY DEVELOPMENT

- Consent:
 - traditional reliance on implied consent
 - express consent
 - informed consent
 - adequacy of consent
 - fully informed?
 - the right to opt out?
- Informing the public
- Changing the culture of professional staff

ELECTRONIC SOLUTION

- Alternatives to consent:
 - anonymisation
 - pseudonymisation.

SECTION 60 OF THE HEALTH AND SOCIAL CARE ACT 2001

- NHS - a long way from achieving the Government's objective on consent.
- Essential public health surveillance, research & development and trials of new drugs must continue.
- Much of this work reliant on identifiable data obtained without consent.
- Technical alternatives of anonymisation and pseudonymisation still being developed.
- Need to legitimise use of identifiable data for essential medical purposes.

SECTION 60 - THE LEGACY

- Section 60 - difficult passage through Parliament.
- Strong lobbies from groups with different perspectives and objectives ;
 - research & professional staff vs patient & civil rights groups.
- Extensive consultation on Section 60.
- The Patient Information Advisory Group established to assist the consultation process and develop Section 60.

ESTABLISHMENT OF THE PATIENT INFORMATION ADVISORY GROUP

Safeguards are built into the new arrangements

- PIAG to be appointed as a non-departmental public body, with members drawn from a wide range of interest groups.
- PIAG appointed to ensure safeguards are met and with a remit to:
 - advise Secretary of State about Section 60,
 - consider applications for use of powers under Section 60
 - review regulations annually and
 - give advice on any other information issues as required by Secretary of State.

REGULATIONS MADE UNDER SECTION 60

Regulations support 7 medical purposes:

“Specific Support” - approved by Parliament

- Communicable disease surveillance and “other public health uses”
- Activities carried out by cancer registries

“Class Support” - approved by Secretary of State

- Work to anonymise records
- Work to identify and contact people to gain their consent
- Analysis of geographical data e.g. postcode
- Record linkage and validation
- Clinical audit and monitoring of healthcare provision

PIAG - Key Principles

- That where an organisation has a direct relationship with a patient then it should be aiming to obtain consent
- “Third Party” organisations should be seeking anonymised/pseudonymised data
- All organisations using Section 60 should make information materials available to patients describing the information they use and why they need it

PIAG - Key Principles (cont)

- Organisations that have regular contact with patients should be able to quickly implement procedures for obtaining consent
- It is never necessary to have 100% coverage
- Organisations should not hold data on patients who specifically refuse consent

PIAG - Key Principles (cont)

- Organisations need to recognise that Section 60 is an interim measure
- Those who obtain Section 60 support must map out an exit strategy - with end dates - for obtaining consent or working with de-identified data