Department of Health

The Health and Social Care Act 2001: Section 60 and 61 Background Information

Background

The Government has made it clear that informed consent is the fundamental principle governing the use of patient identifiable information by any part of the NHS or research community. The NHS Plan proposed to develop a patient centred service where information is shared between all those involved in delivering or developing care presents an opportunity to make the best possible use of patient information. But the informed consent of patients must underwrite that objective. Alternatively, and this may be a better solution in many cases, information which no longer identifies individual patients must be used.

Ministers have taken a very public stand on the issue. In response to the Royal Liverpool Children's Inquiry they said that,

> "*The traditional paternalistic attitude of the NHS, that the benefits of science and research are somehow self-evident, was no longer acceptable.*"

The challenge to the NHS was twofold: to change the culture and to move to systems of using patient identifiable information based upon the informed consent of patients.

The Law

Although this policy direction has an ethical basis, there are important legal considerations. Patients provide information about themselves in confidence and where information is held in confidence, common law provides no other reliable justification other than informed consent for use of the information in a patient identifiable form. Further, the NHS must comply with the Data Protection Act 1998 which requires certain information to be provided to patients and the Human Rights Act 1998 which subjects any invasion of the private life of an individual to a test of necessity. Guidance from the General Medical Council, the Medical Research Council, the British Medical Association and draft guidance from the office of the Information Commissioner reflect the evolving legal position and reinforce the requirement for consent.

The Problem

There are also situations where informed consent cannot be obtained. For example, important research projects may involve tens of thousands of patients where contact would be impracticable. The essential nature of some of this research means that the public good outweighs issues of privacy. Some patients are not capable of giving consent, but the health service still needs to know about them and their conditions. Sometimes excluding those who refuse consent might bias data collection to the extent that it loses all value.

The Solution

Section 60 of the Health and Social Care Act 2001 provides a power to ensure that patient identifiable information needed to support essential NHS activity can be used without the consent of patients. The power can only be used to support medical purposes that are in the interests of patients or the wider public, where consent is not a practicable alternative and where anonymised information will not suffice. It is intended largely as a transitional measure whilst consent or anonymisation procedures are developed, and this is reinforced by the need to review

each use of the power annually.

How It Will Work.

Proposals will be developed by the Department of Health or by those wishing support in law for the processing of information. A standard approach to presenting proposals is being developed and will be communicated to interested parties over the summer. The Act requires proposals to be considered by the Advisory Group termed the Patient Information Advisory Group and for many proposals will also require wider consultation.

The Patient Information Advisory Group's (PIAG) key responsibilities will be:

- To advise the Secretary of State on regulations which should be made under Section 60 of the Health & Social Care Act

- To advise the Secretary of State as required on the use of patient information and other NHS information

The advice of the PIAG must be published. Resulting regulations must be laid under affirmative process (debated in Parliament by each House).

It is worth noting that the passage of the Health and Social Care Bill provided clear evidence of the strength of feeling, particularly within the House of Lords, about the perceived erosion of patient rights. PIAG's role, therefore, will be to scrutinise carefully applications to use patient identifiable information made under section 60 to ensure the criteria are met.

Issues

It is estimated that there are over 250 disease registers, probably more than 50 public health related initiatives, and possibly several thousand research projects that potentially require some degree of support. Clearly the PIAG would not be able to consider a volume of individual applications numbering in the thousands. Ministers therefore propose to establish class regulations that will provide support for broad classes of activity, reducing the number of individual projects that require consideration to the minimum. There is a balance to be struck between the pragmatic need to support activity and the need to sustain pressure for change. Further, whilst key activity must be supported, overuse or misuse of the power is likely to draw considerable criticism, media attention and opposition in parliament.

Proposals for broad class support are being developed with the aim of providing a limited measure of support in law for a large number of activities. Initial proposals for class regulations are as follows:

- To support activities within a single care organisation where patient information is shared outside the normal care team to assist research and audit activities;
- To support disclosure of information outside the normal care team and care organisation to enable suitable patients to be approached for consent for participation in clinical trials or research and epidemiological studies;
- To permit an approach to patients for consent to re-use stored identifiable data or human tissue, organs or samples.

Initial soundings from the GMC, BMA, MRC and patient organisations suggest general acceptance of the need for class actions. Additional class actions are likely to be developed to cover other types of activity. For example, a fourth class is proposed to permit disclosure of identifiable information to maintain disease registers, their analysis and research uses.

The PIAG will therefore deal with individual proposals that are not covered by the class regulations.

Published by The Department of Health

Last updated 22 August 2001