

PIAG

Patient Information Advisory Group

INFORMATION ABOUT PATIENTS:

An introduction to the Patient Information Advisory Group
for health professionals and researchers



OVERVIEW

The confidentiality of information about patients is protected by law and by professional values and practice. In a patient-centred health service, patients must be confident that their personal information is handled with appropriate care and respect.

In general, if information about patients is to be used for purposes beyond the delivery of personal treatment and care, the consent of patients should be sought or the information should be anonymised. There are, however, exceptional circumstances where a strong public interest exists to justify access to identifiable patient information where consent and anonymisation are impossible or inappropriate. Section 60 of the Health and Social Care Act 2001 permits such access with conditions.

Permission to use information about patients using the flexibilities of Section 60 is granted by the Patient Information Advisory Group (PIAG) on behalf of the Secretary of State. PIAG is an independent body established to advise the Government about the use of information about patients and to implement Section 60.

This leaflet describes the different ways in which information about patients is used in the NHS, including the specific circumstances in which an application to PIAG for Section 60 support may be appropriate.

THE LAW

Information about patients is subject to common law, the Data Protection Act 1998, and the Human Rights Act 1998:

- **in common law, information provided by patients in confidence must generally be handled in confidence; other uses are only possible if patients give their informed consent; or if there is another lawful basis for disclosure**
- **the Data Protection Act requires that patients are normally informed about how information about them is used**
- **the Human Rights Act requires that any invasion of an individual's private life is first subject to a test of necessity and proportionality.**

The law and related professional guidelines make clear that informed consent is of paramount importance. However, the implementation of the law has to take account of the complexities of modern health care and research and the conflicts that arise over access to information about patients.

Section 60 of the Health and Social Care Act 2001 allows non-anonymised information about patients to be used without their consent to support essential NHS activity. It is expected to be a transitional measure as better procedures for anonymisation are being developed. Its implementation is overseen by PIAG.

THE USE OF INFORMATION ABOUT PATIENTS IN ROUTINE TREATMENT AND CARE

Health professionals routinely obtain information from patients during clinical consultations. Patients provide this information in good faith, in the expectation that it will be kept confidential. Health professionals do not ask patients for their consent to keep information about them; they reasonably assume that this is implied in patients' consent to treatment.

When patients consent to treatment and care they understand that more than one health professional may be involved in the delivery of this care. Health professionals, therefore, reasonably imply that information can be shared with other professionals where this has a direct bearing on an individual's treatment and care.

ROUTINE USES OF INFORMATION THAT PATIENTS MAY NOT BE AWARE OF

When patients give personal information to health professionals they assume that this information will be used for their own personal treatment and care. They are, however, unlikely to be aware of the range of clinical and administrative activities that enable the delivery of this care. These include care pathway clinical audit, service planning, treatment payments and screening programmes.

It is reasonable for health professionals and managers to have access to information about patients if this is integral to the quality improvement or efficient management of the service. But because such uses of patient information may not be anticipated by patients themselves, professionals should inform patients about these uses and offer them the choice of opting out, making it clear that their care and treatment will not be affected if they choose to opt out.

For example, local clinical audit following a care pathway is integral to quality assuring the delivery and development of care. Such audit requires patient-identifiable information but is not a use of information that people ordinarily think about. PIAG has agreed that consent for this type of audit can be implied as part of consent to treatment as long as there is appropriate information provision about the audit process and mechanisms in place to enable patients to opt out of the audit process where patients object to this use of their information.

You cannot assume that any activity that has a possible bearing on clinical care is justification for using patient-identifiable information. National audit, for example, is too distant from the delivery of individual care to justify using information without either patient consent or anonymisation.

ANONYMISATION

Patients only have an interest in how information about them is handled if they can be personally identified by the information. When information is anonymised, this interest ceases. Fully anonymised information can be used by health professionals and researchers without regard to the rights of the originating patients.

Information that cannot be linked to patients by their name or address may, nonetheless, contain certain identifiers such as NHS number, hospital ID number, full or partial postcode, date of birth, ethnicity, gender and occupation which, either singly or in combination, could make the information identifiable. Care should be taken when disclosing information to researchers to ensure that identifiers are kept to a minimum and that the information is effectively anonymised. If there is any doubt, advice should be sought from the PIAG secretariat.

WIDER USES OF INFORMATION ABOUT PATIENTS

Patients who participate in research studies expect to be fully informed about the possible implications of their involvement. The use of personal information about them within the study should form part of their consent to participate. In certain circumstances, such as historical studies, consent may be difficult to obtain. In such cases, patient information should be anonymised prior to the study beginning.

There are occasionally circumstances when the use of patient-identifiable information is in the public interest but it is not possible or appropriate to gain consent from the patients involved. For example:

- in a historical study involving large numbers of patient records, it may be impossible to track down all the patients to ask for their consent or it would require disproportionate effort to do so. It may also be impossible to anonymise the data, especially if different records have to be linked
- it may be inappropriate to ask for parental consent in a study of child abuse where the parent may be responsible for, or complicit in, the abuse.

Where there is a genuine conflict between individual patient confidentiality and a wider public and patient interest, the case for an exceptional use of patient-identifiable information without patient consent must be made to PIAG. The principal role of PIAG is, therefore, to support the clinical and research communities by enabling research and other activities that would otherwise be outside the law.

PIAG is an independent public body with a multi-disciplinary membership including patient representatives, health professionals and researchers.

PIAG is committed to the priority of informed consent and to patient empowerment. Any organisation that is granted permission to access patient-identifiable information must show that it is developing mechanisms for gaining informed consent or for data anonymisation.

DO YOU REQUIRE SECTION 60 SUPPORT?

An application to PIAG for Section 60 support is only required in special circumstances. You do not need Section 60 support if any of the following conditions are met:

- **you are pursuing direct clinical care**
- **you need the information for local care pathway audit that will impact directly on the quality of care given**
- **you can fully anonymise the data**
- **you can obtain the informed consent of the patients involved.**

If none of these conditions are met, you must get advice about the legality of your use of information about patients. PIAG is only concerned with the use of this information for medical purposes, so if any or all of your aims are non-medical you must ensure that you have an alternative lawful basis for the use of the information e.g. social research into criminality.

You should seek advice from PIAG if you want to use information about patients for medical purposes (including medical research) where consent cannot be implied or gained and the data cannot be anonymised.

Patient information is sometimes 'pseudonymised' by stripping out some but not all personal identifiers. In such circumstances it may still be possible to identify individuals, so you should seek the advice of PIAG before assuming that your use of partly-anonymised information has a lawful basis.

SECTION 60 APPLICATIONS

Before applying for Section 60 support, please consult the guidance published on the PIAG website www.advisorybodies.doh.gov.uk/piag also available from the PIAG secretariat. The PIAG secretariat aims to reduce the burden of the application process as much as possible and will comment on draft applications to enable you to clarify aspects or provide supplementary information, thus facilitating passage through the approvals process.

For some, the PIAG application process may feel like one more administrative hoop to jump through in the pursuit of valuable research. PIAG is, however, critical to information governance within the NHS. PIAG's existence reflects renewed government commitment to promoting the rights of patients in health care following deep public concern about historical breaches of patient confidentiality.

Further information about ethical approval for research in the NHS can be found on the Central Office for Research Ethics Committees website www.corec.org.uk.

Given the rigour of the Section 60 application process, any project which gains PIAG approval should then gain the full support of the health service professionals who control access to the relevant patient information. When such professionals are aware of specific individuals who might object to the proposed use of their information, individual patient consent should be sought or the information should be fully anonymised for these cases.

KEY POINTS

- Information is provided by patients in the expectation that it will be kept confidential. Non-routine use of this information requires either the informed consent of patients or anonymisation.
- Health professionals must inform their patients about all routine uses of information that patients may not be aware of. This can be done with leaflets and posters as well as in direct discussions with patients. The Office of the Information Commissioner advises that putting posters up is not sufficient to meeting the fair processing requirements of the Data Protection Act to inform people about how their information is used and that more should be done to try to inform individual patients.
- Health professionals and managers should review their structures and procedures of information governance to prevent inadvertent disclosure of information and to ensure compliance with the law. Historical arrangements with external institutions, such as universities and the use of internal databases and should all be rigorously audited.
- Applications to PIAG to use the flexibilities in Section 60 of the Health and Social Care Act 2001 should only be made when informed consent and anonymisation are either impossible or inappropriate and when there is a clear public interest case for the proposed breach of patient confidentiality.
- PIAG is a temporary solution to the challenges of access to information about patients. In time, the NHS *Connecting for Health* programme will deliver more effective and efficient means of anonymisation.

- PIAG offers advice and guidance about all aspects of information governance within the NHS. Please contact the PIAG secretariat for more information or visit the PIAG website.
- PIAG's focus is on the use of patient information both for essential NHS activities and medical research. Research applicants will still need to obtain ethical approval to satisfy the broader ethical requirements.

Where to get more information

More information about PIAG's work and the Section 60 application process is available online at www.advisorybodies.doh.gov.uk/piag

The PIAG secretariat is based at:

2nd Floor
Princes Exchange
Princes Square
Leeds LS1 4HY

and can be contacted on 0113 397 3095/3378

Central Office for Research Ethics Committees: www.corec.org.uk

Office of the Information Commissioner: www.ico.org.uk

To obtain further copies of this leaflet please visit www.connectingforhealth.nhs.uk/publications or call 08453 700760 quoting reference number 2237