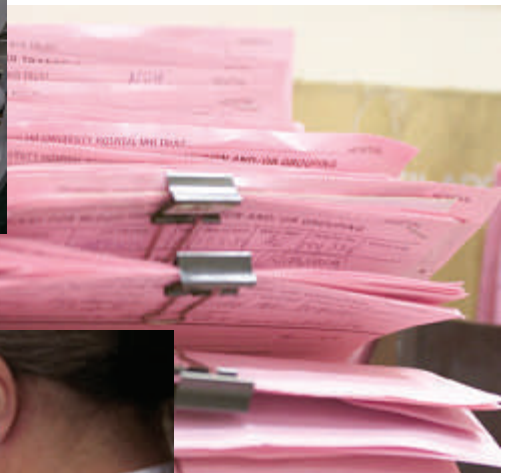


Access to Health Records by Diagnostic Staff

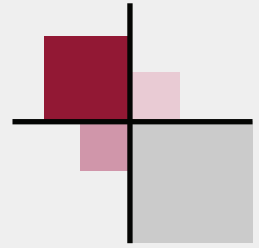


**Guidance for Patients and
Healthcare Professionals**

May 2011

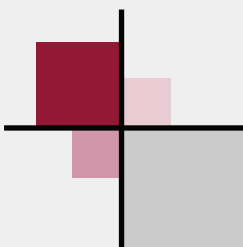
Acknowledgements

NIGB would like to thank Dr Nicola Strickland (Faculty of Clinical Radiology), Mr Geoff Lloyd (Institute of Biomedical Science), Ms Christina Freeman (Society of Radiographers) and Dr Peter Cowling and Professor David Marks (Royal College of Pathologists) for their help in preparing this guidance. Particular thanks to Professor Gifford Batstone (NHS Connecting for Health) for raising this matter with the Board and his support in this work.



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1. Introduction

1.1 The National Information Governance Board for Health and Social Care (NIGB) is a statutory body established by the Health and Social Care Act 2008. It provides guidance and promotes consistent and higher standards for information governance across health and social care. The Board reports annually to the Secretary of State for Health and is responsible for the NHS and Social Care Record Guarantees for England.

1.2 At the Board meeting of 17 June 2009, Board members considered the implications for diagnostic tests if NHS Connecting for Health were to implement a 'consent to view' model for Detailed Care Records.* This model would affect the work of Radiologists and Pathologists who do not have direct contact with patients and process patient's information, images and samples on the basis of implied consent. A Working Group was set up to consider the issues related to this and to produce guidance.

1.3 The purpose of this Guidance is to provide clarity for both patients and healthcare professionals about access to health records by Diagnostic Clinicians and their support staff when they do not have a direct relationship with the patient and therefore are not in a position to ask for consent to view the record themselves.

The NIGB's remit concerns the use of patient information but as the consent for the use of information is generally implied as part of consent for the test, the consent for both aspects need to be considered together.

Diagnostic Testing and investigations - defined as:

Taking samples, recording measurements and carrying out testing, supported by clinical opinion

Source: DH paper 'Liberating the NHS: Greater Choice and Control' p. 48, October 2010

* NHS Connecting for Health has not taken this proposal forward but given the local implementation of new health-care systems the NIGB agreed that issuing guidance would still be helpful.

2. Guidance for Patients

This guidance is provided for patients who undergo tests as part of a diagnostic procedure. It gives information on what you the patient, can expect regarding the access that healthcare professionals have to information about you when a sample is given for a laboratory test or you undergo a radiological examination. It is normal practice in these circumstances for your consent to be implied as part of your agreement to have the test or tests performed for access to your medical records.

Please note:

- Pathology and Radiology staff are both part of your wider clinical team and have an essential role to play in your care.
- If you have any concerns over the nature of the tests that are being undertaken your healthcare team can provide you with additional information.
- As pathology laboratories now work in networks, your sample may be analysed at a neighbouring hospital laboratory or an independent sector laboratory rather than the nearest.
- Not all pathology tests may be available in your local health service, therefore your sample may be sent to a specialist laboratory for analysis. This may involve sending samples to a NHS or independent sector laboratory in the UK or sometimes overseas.
- All independent sector and overseas laboratories will have to comply with the same information governance and clinical standards as any NHS laboratory as part of their contractual arrangements.
- Laboratory analytical systems often carry out tests in groups (often termed profiles) and many of the individual tests in the profile would not have been specifically requested by your healthcare professionals. Occasionally, this may give unexpected results. If anything unexpected is found this is reported to the doctor looking after you and the meaning of the results will be explained to you.
- Specialists in the pathology department may decide that additional tests to those already requested by your doctor will help in diagnosing your condition. If so they will undertake such tests only in order to help your doctor look after you appropriately. They would normally ask for your consent if they feel that such additional tests are necessary and are outside of the scope of the consent you have given.*
- The specialists in the pathology/radiology department will sometimes need to access results from previous laboratory tests/X-rays (scans, etc.) to look for changes which may be important to your healthcare.

* GMC Ethical Guidance “Consent: patients and doctors making decisions together” paragraph 37 http://www.gmc-uk.org/static/documents/content/Consent_0510.pdf

2. Guidance for Patients *continued...*

- On occasions, in order to help interpret the results of your laboratory tests, Pathology specialists may need to access your care record - for example to see if any medicines you are taking or if you have any pre-existing conditions which may be affecting the laboratory results. This is no different from any other Healthcare Professional involved in your direct care accessing your health records for the purpose of delivering your healthcare. By agreeing to the test(s) you are also agreeing to the pathology specialists accessing your medical record where they feel this is appropriate. If you are concerned about pathology staff accessing your medical records you should discuss this with the clinician taking the test. If you decide you do not want your records to be accessed then you should tell the clinician this so they can explain how this may affect the effectiveness of the test and consequently, the quality of your care. The clinician will then record what you decide.
- Also your radiology images may be reported on by radiologists outside of the hospital where your images were taken. This is to quality assure both the quality of the images and their meaning in relation to diagnosis. This helps to ensure you receive the best clinical attention available in a timely manner.

All of this is done routinely in order to gain the most accurate and useful result as soon as possible to enable your healthcare professionals to decide what is best for you and propose any treatment that may be required.



3. Guidance for Healthcare Professionals

3.1 The NHS Summary Care Record

The introduction of the NHS Summary Care Record brought with it the need to obtain 'consent to view' records. This has raised a number of concerns amongst health professionals with regard to routine access to patient records by Radiologists, Pathologists and other professional staff in the same position of direct support for the care of patients but not usually having contact with the patient. Routine access to health records is an important part of the assessment of the results of diagnostic procedures by examining their context, i.e. other clinical information which may be of relevance. Existing professional guidance is available elsewhere (see page 10). The purpose of this guidance on access to identifiable patient records and the consent requirements is provided to complement existing recommendations.

3.2 Why is access to the NHS Summary Care Record and Detailed Care Records important?

Both current and previous patient medications and conditions may have an impact on the interpretation of diagnostic test results. There is a risk to the patient if the appropriate healthcare professional is not aware of these and fails to take them into account when assessing test results or images.

3.3 What do patients need to know? What is the basis of consent?

It is a requirement of the Data Protection Act 1998 that patients are aware of how their personal and confidential information is used by the NHS. Additionally, the common law duty of confidentiality requires that information imparted in confidence is only used for stated purposes and only by those who the patient would expect to have access. Traditionally, consent for access to health records by Pathologists, Radiologists and other healthcare professionals is normally implied as part of consent to examination and treatment.

The tests for valid consent are that:

- the patient is provided with and understands relevant information;
- the person has the capacity to give consent;
- consent is freely given;
- the consent is specific to the circumstances;
- the person indicates their agreement.

Provision needs to be made therefore for meeting patient expectations in relation to the level of information to be given during the consent procedure. This should be negotiated with the patient as different patients will have different thresholds of information needs. Pathologists and Radiologists owe a duty of care if additional investigations are required for interpretation of a test, or to enable a diagnosis. In general, consent can reasonably be implied for this, as part of the consent for the original test unless a patient refuses or the test is outside of the scope of the original consent.*

Patients should be made aware that there is an obligation on the pathology or radiology specialists to inform their doctor if another diagnosis is detected in addition to that which was the original purpose of the test.

* GMC Ethical Guidance "Consent: patients and doctors making decisions together" paragraph 37 http://www.gmc-uk.org/static/documents/content/Consent_0510.pdf

3. Guidance for Healthcare Professionals *continued...*

3.4 To what extent are pathology and radiology service providers considered to be part of the clinical care team?

The boundaries of the clinical care team are defined by patient expectations. Information is imparted in confidence to an individual but patients realise that care is now delivered by teams of clinicians and also that they need administrative support staff to assist them in performing their roles most effectively. Being clear about the definition of the clinical care team is therefore an important part of the relationship of trust over who will treat the patient and who will have access to their confidential information. Patients are likely to expect Pathologists and Radiologists to have access to some of their confidential patient information but may not be aware of the full extent of what information they can access or of the tests they may perform in order to make a diagnosis. This does not mean that the vast majority of patients would in any way be dissatisfied with this. However, the basis of implied consent can be strengthened by improving the quality of information given to the patient about the nature of the tests being undertaken and of the role different members of the clinical care team have in their care.

It should be noted that Radiologists and occasionally Pathologists have direct conversations with patients about their diagnosis / treatment, which reinforces the opinion that they should be considered to be a key part of the care team by the patient.

3.5 How much information do patients need in order to give their valid consent both for the test itself and for the use of their information?

The majority of diagnostic tests are currently undertaken with implied consent. The issue is how much do patients actually realise what is involved in this so that there is a reasonable basis for implying consent to ensure the consent is valid. This needs to be balanced against how much people want or need to know. The challenge is communicating effectively with patients to achieve the right balance for them as individuals. Section 2 of this document 'Guidance for Patients' (page 6) could be used as a template when developing a patient information sheet for diagnostic tests.

Points to consider:

- Pathology is nowadays often delivered in regional networks and the patient is often not aware of this or how far the network may extend. Indeed both samples and information can sometimes be transferred overseas. Much diagnostic work is now carried out by multidisciplinary teams and as a consequence patients probably do not fully understand who may be authorised to access their information and under what circumstances.
- Whilst consent should not be an area for particular concern, there does need to be transparency of process from the patient's perspective. This will prevent unexpected consequences or queries.
- Provision has to be made for the unexpected when results have to be fed back to patients. Sometimes important incidental findings can be made and the validity of consent may be called into question if tests are seen as being out of scope. It is impossible to pre-empt what may be found, therefore it would be very difficult to provide explicit consent for every clinical eventuality. However, highlighting the possibility of unexpected results arising from investigations would help to mitigate this.

3. Guidance for Healthcare Professionals *continued...*

- This may vary depending on the sensitivity of the test being performed, for example, HIV tests would have an enormous impact on the individual. Professional guidance indicates that explicit consent should be sought (BSHG, RCP and RCPATH). Any test undertaken could constitute assault on the individual if performed without valid consent. It is vital therefore that adequate information is provided to patients about the nature and extent of the tests to ensure valid consent is obtained for the test itself. Providing details about how their information will be used should therefore be straightforward. The exception to this would be tests undertaken by clinicians in the best interest of a patient who lacked the capacity to give consent, for example, an unconscious patient. Genetic testing also will often require explicit consent.
- There are specific risks associated with radiological-based tests and there is particular need to avoid unnecessary and invasive testing, which makes access to previous tests all the more important.
- It is reasonable for healthcare professionals to assume that implied consent would cover the 'core' team for an episode of care and that staff carrying out diagnostic tests would fall within this core team. However, part of the consent process should be that patients are properly informed of possible consequences of the test itself and of what additional tests may be done in order to make a diagnosis. It is finding the appropriate level of detail which is key.
- Good practice would be to assess the needs of each patient in terms of the level of detail that *they would like to have* to ensure valid consent. Thus, information needs to be available at levels of increasing detail with ultimately a helpline telephone number in exceptionally complex circumstances.



4. Summary

If explicit consent was a requirement to perform all diagnostic tests, this could create a barrier to Pathologists/Radiologists or other key staff performing their job properly. There must be an element of trust so that the clinician can use their professional judgment to perform the necessary tests in order to make a diagnosis albeit with an opportunity for patients to express their desire not to have particular tests performed. It is for this reason that consent is normally implied for the use of medical records by diagnostic staff.

The basis of implied consent can be strengthened by improving the quality of information given to the patient about the nature of the tests being undertaken and of the role different members of the clinical care team have in their care. The NIGB has produced a guide to developing patient and service user information materials (available on the NIGB website, www.nigb.nhs.uk/advice) which may be helpful in relation to this.

5. Information and guidance already available

- Web site: lab tests online <http://www.labtestsonline.org.uk/>
- The Royal College of Radiologists: 'Consent to Imaging and Radiotherapy Treatment Examinations: An ethical perspective and good practice guide for the radiography workforce'. Society of Radiographers, 2007.
- 'Consent: patients and doctors making decisions together'. General Medical Council, 2008.
- British Medical Association: Consent Toolkit, 5th edition, December 2009, www.bma.org.uk/ethics/consent_and_capacity/consenttoolkit.jsp
- 'Consent and confidentiality in genetic practice' - British Society of Human Genetics, Royal College of Pathologists (RCPATH), Royal College of Physicians (RCP), April 2006.
- 'HIV testing – Guidelines for pre-test discussion on HIV testing' - Department of Health, March 1996, www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/DH_4005542
- 'Reference guide to consent for examination or treatment', 2nd ed., Department of Health, August 2009, http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_103653.pdf
- NIGB Guide to Producing Patient and Service User Information Materials www.nigb.nhs.uk/advice

6. NIGB Diagnostic Tests Working Group

6.1. Terms of Reference

The NIGB Diagnostic Tests Working Group was a time limited work group. The Group reported to the Chair of the NIGB and was set up to:

- Consider existing practices concerning implied consent for diagnostic testing services for specialist staff accessing patient records as part of normal clinical practice.
- Consider the implications of NHS Connecting for Health introducing 'Consent to view' for Detailed Care Records upon the ability of specialist staff to access the patient record if explicit consent has not been granted by the patient.
- Advise the NIGB on the provision of guidance to accompany the NHS Care Record Guarantee concerning consent for diagnostic testing (in particular for pathology and radiology) on the implementation of 'consent to view'. This may encompass advice concerning the mitigation of any risk to clinical care from any changes that may rise in normal clinical practice.
- Ensure that recommendations complement and support the existing guidance on ethical and regulatory governance frameworks.
- Consult and incorporate the views of relevant Stakeholders as appropriate.

6.2. Membership of the Working Group

NIGB Members

Gareth Beatty – Chair
Dr Michael Wilks
Dr Nadeem Khan
Rabbi Sylvia Rothschild
Sally Taber

Biographies can be found on the NIGB website:
www.nigb.nhs.uk/nigb/members

Representative Members

Royal College of Radiologists – Representative Member:

Dr Nicola Strickland - Registrar for the Faculty of Clinical Radiology

Institute of Biomedical Science – Representative Member:

Mr Geoff Lloyd - Institute of Biomedical Science Council Member

Society of Radiographers – Representative Member

Ms Christina Freeman

Royal College of Pathologists – Representative Members

Dr Peter Cowling and Professor David Marks



You can find out more about the NIGB on its website, www.nigb.nhs.uk or you can contact the Board:

- by email at nigb@nhs.net;
- by phone on 0207 633 7052;
- by writing to:

**National Information Governance Board for Health and Social Care
Skipton House, 5th floor
80 London Road
London
SE1 6LH**