



Guidance on the use of patient images obtained as part of standard care for teaching, training and research

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Foreword

Millions of images are acquired daily. Primarily used for patient care, they are routinely used for teaching and research, and shared between healthcare providers to improve patient care in terms of diagnosis and follow-up. The RCR last issued guidance on consent for use of images in 2012.

The ability to readily share data, and the advent of computer assisted detection, machine learning and artificial intelligence, all of which rely on imaging data, makes this guidance document on consent acquired for the use of patient images as part of standard care, pertinent and timely.

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1. Background

Patient images are routinely used for teaching, training and clinical research. More recently it has been recognised that there is a major opportunity for data collection within the NHS through multicentre collaborations and data sharing with the ultimate aim of improving patient care and outcomes. Expected patient benefits include improved safety, integration of care and opportunities for innovative research such as imaging radiomics which is dependent on large datasets.

For radiology, an important justification for sharing patient images is the mandatory learning and discrepancy process.¹ Reviewing and learning from discrepancies and adverse events can contribute to evidence regarding safe practice and learning from events can mitigate against repeated adverse events and enhance patient safety. Indeed, radiologists have a duty of candour to engage with this process, but this is dependent on sharing of patient images.²

Images alone have limited value without accompanying clinical information. Large scale clinical data can also lead to innovative and rapid detection of previously unknown adverse drug-related events and similar approaches using patient images can be employed, for example, to identify patients at risk of developing malignancy or cardiovascular diseases. Patients are often aware of the wider benefits of data sharing and the The Royal Marsden Patient and Public Involvement panel offered this feedback 'What opportunities these images may "spark" for innovative research are not known but all cancer patients will wish future sufferers a good outcome and a new way of treating the disease.'

The potential advantages of sharing data are reflected in the policies of the UK's major research funding bodies. For example, Cancer Research UK are '... committed to ensuring that the data generated through its funding should be put to maximum use by the cancer research community and, whenever possible, is translated to deliver patient benefit. It is therefore our policy that all data generated as a result of our funding be considered for sharing and made as widely and freely accessible as possible ...'³ The Medical Research Council (MRC) '... expects valuable data arising from MRC-funded research to be made available to the scientific community with as few restrictions as possible so as to maximise the value of the data for research and for eventual patient and public benefit. Such data must be shared in a timely and responsible manner.'⁴ These statements apply to research data but have highlighted the need for a clear and safe pathway to facilitate imaging data collection and sharing within NHS and UK academic institutions. It is vital that this is done within an appropriate information governance framework, for the benefit of patients, while maintaining confidentiality.

The Information Commissioners Office (ICO) view is that 'provided there is no likelihood of anonymisation causing unwarranted damage or distress – as will be the case if it is done effectively – then there will be no need to obtain consent as a means of legitimising the processing.'⁵

The Review of Data Security, Consent and Opt-outs recognised the vital importance of data sharing for patient benefit but also outlined the importance of public trust and informed choice. Therefore an eight-point opt-out model was outlined.⁶ That review by the National Data Guardian has been welcomed by a recent Government response which outlines commitments to implement a national opt-out model and to ensure that NHS Digital implements a tool to enable patients to access and understand how their data has been safeguarded and used nationally to benefit others.⁷ However, the National Data Guardian and Department of Health agree that the opt-out should not apply to anonymised information in line with the ICO Code of Practice on Anonymisation.⁵⁻⁷ The Information Governance Alliance (IGA) is aiming to publish new anonymisation guidance in 2018.

2. What this guidance covers

This guidance refers to medical imaging that has been acquired as part of routine patient care and used for education, research and service delivery planning. The guidance also covers the use of relevant clinical data which may be needed for correlation, such as patient demographics, disease specifics and treatments.

Circumstances when consent from patients is not mandatory will be described, however, **this does not preclude the necessity for ethical approval for research.**

3. Confidentiality and consent

General Medical Council (GMC) guidance is clear that confidentiality is a central tenet in patient care, that appropriate information sharing is also important and that a means to share such information without consent is through anonymisation.⁸ To maintain public trust, the Government has pledged to put stronger sanctions in place by May 2018 through UK data protection legislation to protect against anonymised information being re-identified through recklessness or deliberate intent. It is also likely that data security will now form part of the Care Quality Commission's (CQC) inspection framework.⁷

General Medical Council guidance⁸



Confidentiality is central to trust between doctors and patients. Without assurances about confidentiality, patients may be reluctant to seek medical attention or to give doctors the information they need in order to provide good care. But appropriate information sharing is essential to the efficient provision of safe, effective care, both for the individual patient and for the wider community of patients.⁹

You may disclose anonymised or coded recordings for use in research, teaching or training, or other healthcare-related purposes without consent. In deciding whether a recording is anonymised, you should bear in mind that apparently insignificant details may still be capable of identifying the patient. You should be particularly careful about the anonymity of such recordings before using or publishing them without consent in journals and other learning materials, whether they are printed or in an electronic format.⁸

Explicit consent is only required if the patient is, or may be, identifiable.

4. What is anonymised data?

To ensure confidentiality, it is important to understand that there are several potential patient identifiers and the presence or absence of these will impact on the level of data sharing that is permitted. The *Information Governance Review* published useful guidance on the conditions under which data can be processed and disclosed.¹⁰ It is worthwhile to consider which category data falls in to, in order to understand the level of data sharing that can be undertaken (Figure 1).

Figure 1. Examples of patient identifiers on magnetic resonance imaging (MRI) images

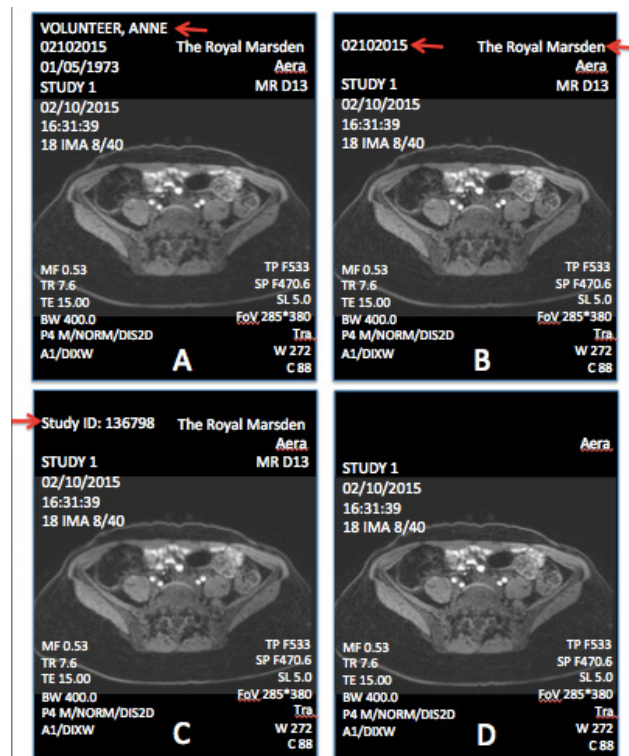


Figure 1A includes a direct identifier, the patient name.

Figure 1B includes indirect identifiers, hospital number and hospital name.

Figures 1A and B cannot be shared without the consent of the patient outside circumstances necessary for direct patient care

Figure 1C has been de-identified for limited access with a study ID and hospital name. This image can be only be shared with another institution if they are under the same contractual arrangements as the disclosing party with data stewardship arrangements.

Figure 1D has been de-identified to the point of publication. There are no means by which this patient can be identified. Direct consent is not required.

1. **Identifiable data (also known as personal confidential data).** Patient data may be directly or indirectly identifiable. An example of directly identifiable data is a patient name. Indirectly identifiable data may include information which could lead to an individual being reasonably able to use that information to find out the identity of a patient. An example of this would be hospital name and patient number on patient images.

The ICO introduced the concept of the 'motivated intruder'; it is useful to ask if a motivated individual could use the pieces of information to identify an individual, for example using internet searches or council records.⁵ Re-identification risk may change over time as the public availability of data changes.

What are the conditions for disclosure? Data that falls within this category cannot be shared without the consent of the patient outside circumstances necessary for direct patient care. Even if consent is obtained it is preferable to anonymise data as much as possible. If a person can give consent, they are also able to withdraw consent at a later date perhaps due to a change in personal circumstances.

Anonymised data can either be de-identified for limited access or de-identified to the point of publication

2. **De-identified data for limited access (also known as pseudoanonymised or key-coded).** This is data that does not include direct identifiers but may contain indirect identifiers that could be linked with other data that would lead to identification of the patient. However, the means to identify the patient should be reasonably unlikely to be accessible. This data can only be shared under strict technical and organisational controls, with named individuals, within contracted arrangements and with evidence that the risks of patient identification have been sufficiently mitigated. An example of this is where NHS radiologists share patient images with an academic partner who retains a hospital number or code number. The academic partner will not have access to NHS systems or the key code to identify the patient. It is important, however, to ensure that the patient's number is not composed of any patient-specific information such as date of birth.

What are the conditions for disclosure? This data can be shared with another institution if they are under the same contractual arrangements as the disclosing party with data stewardship arrangements.

3. **De-identified to the point of publication.** This is patient data that does not contain direct or indirect identifiers and there is no reasonable prospect of the patient being identifiable.

What are the conditions for disclosure? There are no conditions for disclosure.

5. What can go wrong?

De-identified patient data is health information from a medical record that has been stripped of all direct identifiers. It is important to be aware which information is removed from patient imaging datasets using local software anonymisation. For example, the 'anonymise' function from some picture archiving and communication systems (PACS) will remove patient names but leave behind date of birth and the named consultant.

Careful attention must be given to data which is burnt onto the images at source before sending to PACS. For example, patient data is often an integral part of ultrasound or nuclear medicine images sent to PACS and these can only be de-identified at source before archiving. Similarly, computed tomography (CT) images can have protocol sheets and dose cards embedded within the imaging which may contain identifiers. The potential for use of surface rendering techniques to reveal facial features using digital imaging and communications in medicine (DICOM) CT data should also be recognised.

PowerPoint presentations used for teaching are a potential source of error. If direct identifiers are removed from images using the cropping tool, the potential for another user to 'uncrop' images and reveal personal information persists.

6. Who is responsible for ensuring de-identification of patient images?

Each NHS hospital trust has a Caldicott Guardian responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information sharing. However, it is the personal responsibility of any radiologist using images for teaching, service evaluation or research to ensure that appropriate levels of de-identification/anonymisation have taken place with appropriate institutional review board approval.

The Information Governance Review Panel recommends that data containing personal confidential data, or data that can potentially identify individuals (de-identified data for limited disclosure or limited access), are only disclosed for linkage in secure environments.

These secure environments should be specialist, well governed and independently audited. The Information Governance Review Panel has outlined requirements which include robust governance arrangements for data flow, anonymisation processes, archiving, named responsible professionals (such as senior information risk officers), explicit standard timescales for keeping data and conditions of data use.⁸ There must also be clear processes for reporting breaches to senior management.

7. Aspects of data use: guidance under development

The *Review of Data Security, Consent and Opt-outs* reported concerns from the general public that information might be used by commercial companies for marketing or insurance. Therefore at present we would recommend consent for use of patient data which may be shared with commercial companies. Clarification of how data can be used with commercial partners will be essential. Academic–industry collaborations have been incredibly important for improving patient outcomes, for example in drug development, and it is likely that such collaborations will be necessary for implementation of innovative imaging into clinical practice.

8. Working with patients

The Information Governance Review in 2013 reported that 'the Review Panel has heard that more could be done to increase awareness of the benefits of research, what it entails, and how health and social care information may be used to support it. It is therefore vital that in order to improve and maintain public trust, researchers and the health and social care system more generally, must inform patients and the public of the benefits that the use of their information can bring to them, their families and the nation's health.'

Therefore, it is recommended that all departments which expect to use patient images for teaching, training and/or research should make reasonable efforts to inform patients. This could include posters in the imaging department or similar notifications to accompany patient appointment letters (Appendix A).

9. Scenarios

The following scenarios have been created to facilitate interpretation of the guidance:

Scenario 1

You hypothesise that the diagnosis of disease X would be improved by introducing MRI scans in patients with symptom Y. Is patient consent required?

Answer: Yes. Use of imaging outside of normal clinical practice is research and should be conducted within the research governance framework and direct consent from patients is required. As this imaging would not be performed as part of routine clinical practice, this does not fall within the remit of this guidance.

However, if patients with a particular symptom already had an MRI examination of the relevant area then the images could be used without direct consent (provided ethical approval for this new research question had been granted or formally waived).

Scenario 2

You are asked by a pharmacology company to provide patient CT images to enable a retrospective study of their drug on body fat composition. Is patient consent required?

Answer: This is a research question. This should go to an ethics committee first and they can decide whether or not patient consent is required. The recent *Review of Data Security, Consent and Opt-outs* has suggested that patients may feel uncomfortable about data sharing which is not for the clear benefit of patients and the NHS. This is an area under review and we suggest that where data might be shared with a commercial, profit-making organisation, direct patient consent should be obtained with explicit information given on the exact nature of the data which will be shared and the data confidentiality arrangements which would be put in place.

Scenario 3

You have been asked to give a lecture at a national conference and plan to show radiological images of patients. You are also providing case examples for a hands-on workshop. Do you need to obtain patient consent?

Answer: The answer in most cases is no so long as the images have been de-identified for publication (that is, no direct identifiers such as the name, or indirect identifiers such as hospital numbers, date of birth or other identifiers, are present on the image; in the hands-on workshop it is important that seemingly 'hidden' information embedded within the

imaging is removed if these are being used by others. See 'what can go wrong' section). In rare circumstances, patients with particularly unusual findings may be recognisable from radiological images and in these situations patient consent should be sought.

Scenario 4

You are planning to create a radiomics database of patient images, including corresponding cytogenetic data. This data will be collated with another four NHS organisations to allow a large and meaningful dataset to be acquired. Is direct patient consent required?

Answer: This database is being created to answer research questions and therefore ethical approval is required. It is likely that the ethics committee will agree that as long as the images and data have all been de-identified for publication, no consent is required. However ethical approval is required. Transfer of coded data must only be undertaken in a secure environment.⁷

10. Summary

Key point

Patient images that do not contain any patient identifiers can be used for teaching, training or research without direct consent.

- Improved patient safety, treatment, service development and research are dependent on data sharing.
- Patient trust and confidentiality are paramount and must be safeguarded.
- Patient images can be used for teaching, service development and research without consent if images are de-identified for publication.
- The National Data Guardian and Department of Health agree that the proposed national opt-out should not apply to anonymised information.
- Sharing of personal confidential de-identified data for limited access or identifiable data from more than one organisation for any purpose other than direct care between organisations must occur within secure environments which meet requirements set out by the Information Governance Review Panel.
- Imaging departments must make efforts to inform patients how their data is being used outside their direct care.
- Personal identifiable data currently must not be used for teaching, training or research without express consent from patients.

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Appendix A. Example of a privacy notice

This imaging department records information about you, your health and your treatment so that you receive the right care. The imaging department stores your images. We record this information so that it is available each time we see you and it is available to the clinicians responsible for your care. We have a legal duty to keep the information we record about you confidential.

The information recorded about you may also be used for reasons other than your direct personal care. Use of patient information is crucial for maintaining records on patient safety, for planning future services and teaching. This information can also lead to exciting research discoveries that may benefit future generations.

We are involved in research that requires access to patients' images and computerised notes. You cannot be identified from these images and notes by non-departmental staff as all personal details (name, address, postcode and date of birth) are anonymised.

If anything to do with the research would require that you provide additional information about yourself, you will be contacted by a member of our staff to see if you are willing to take part; you will not be identified in any published results.

You have a right of access to your health records. If at any time you would like to know more, or have any concerns about how we use your information, please ask at reception for more details.

Everyone working for the NHS has a legal duty to keep information about you
CONFIDENTIAL.

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