The Royal College of Radiologists

Board of the Faculty of Clinical Radiology

Standards for patient consent particular to radiology

Second edition

RCR Standards

The Royal College of Radiologists (RCR), a registered charity, exists to advance the science and practice of radiology and oncology.

It undertakes to produce standards documents to provide guidance to radiologists and others involved in the delivery of radiological services with the aim of improving the service for the benefit of patients by defining best practice, and promoting advances in practice.

The standards documents cover a wide range of topics. All have undergone an extensive consultation process to ensure a broad consensus, underpinned by published evidence where applicable. Each is subject to review four years after publication or earlier if appropriate.

The standards are not regulations governing practice but attempt to define the aspects of radiological services and care which promote the provision of a high-quality service to patients.

Current standards documents

Standards and recommendations for the reporting and interpretation of imaging investigations by non-radiologist medically qualified practitioners and teleradiologists

Standards of practice and guidance for trauma radiology in severely injured patients

Standards and recommendations for the reporting and interpretation of imaging investigations by non-radiologist medically qualified practitioners and teleradiologists

Standards for the NPSA and RCR safety checklist for radiological interventions

Standards for the provision of teleradiology within the United Kingdom

Standards for the recording of second opinions or reviews in radiology departments

Standards for a results acknowledgement system

Standards for intravascular contrast agent administration to adult patients, Second edition

Standards for the introduction of new procedures and new devices - updated in January 2010 to reflect new guidance from the MHRA on 'off label' use

Standards for radiofrequency ablation (RFA)

Standards for providing a 24-hour diagnostic radiology service

Standards for patient confidentiality and PACS

Standards for providing a 24-hour interventional radiology service

Standards for the communication of critical, urgent and unexpected significant radiological findings

Standards for Self-assessment of Performance

Standards for Radiology Discrepancy Meetings

Standards for the Reporting and Interpretation of Imaging investigations

Cancer Multidisciplinary Team Meetings - Standards for Clinical Radiologists

Standards for Ultrasound Equipment

Contents

Foreword

Development of advice in respect of consent is an essential part of the recognition of patient autonomy and the right to choose. All radiologists and, indeed all doctors, recognise the need to involve patients fully in decisions about their care. Whenever possible, you must be satisfied before you provide treatment or investigate a patient's condition that the patient has understood what is proposed and why, is appropriately informed about the balance between risk and benefit, and has given consent.

The advice provided in this document is deliberately generic, rather than prescriptive. We have not provided lists of procedures which require written consent, nor those where implied consent would be appropriate and sufficient. In each case where you provide care, you will need to make a judgement on the basis of the nature of the procedure, level of risk versus the potential benefit, and your understanding of the needs of the patient. In making this judgement, you must ensure that:

1. The patient has the right information to make a decision
2. The information has been presented in a way that the patient can understand
3. The patient has shared in the process of decision-making and agrees with the outcome.

Above all, 'consent' is involving patients in decisions made about their care, and communicating information effectively, thus ensuring that decisions made about patient care are made with the patient, rather than for the patient.

The Royal College of Radiologists (RCR) is very grateful to members of the Faculty of Clinical Radiology's Standards Committee, in particular to Dr Rob Manns, who produced the original document during Dr Paul Dubbins' term of office as Dean and Vice President of the Faculty of Clinical Radiology in 2005 which has now been withdrawn. This document has been revised and updated by the Professional Support and Standards Board.

Dr P Cavanagh

Vice-President and Dean
Faculty of Clinical Radiology
The Royal College of Radiologists

1 Introduction

Successful relationships between patients and doctors depend on trust. Patients are becoming increasingly well informed and are rightly demanding more involvement in decisions relating to their medical care. Consent to treatment is an integral part of this involvement and underpins the trust that the patient places in their doctor and the confidence that the patient has in the process of care. The principle of patient consent requires the doctor to respect the patient's autonomy and right to decide whether to undergo any medical investigation or intervention.

2 Consent

Except in emergencies, in circumstances when consent cannot be obtained, patient consent to treatment is a legal requirement for medical care. It is good practice to ensure that consent is given in the appropriate environment, in the proper manner and in the presence of appropriate and relevant information.

For consent to be valid, the patient must be informed about the treatment concerned, competent to give consent and able to give it voluntarily. Effective communication is key to enabling patients to make informed decisions. Patients must be given information in a timely manner and in a way they can understand to enable them to exercise their right to make an informed decision about their investigations and treatment. The initial consent to a radiological examination or intervention should be obtained by the referring clinician in consultation with the patient through explanation of the reasons for the examination or intervention requested.

'Prudent doctor'/'prudent patient'

The courts used to apply the 'prudent doctor' principle – that is, where the doctor weighs the risk of a certain complication occurring against the risk resulting from putting a patient off necessary treatment. Complications with an extremely low incidence were generally considered not worth mentioning, unless the particular complication would have serious consequences for the patient. In recent years, however, there has seen a shift towards the 'prudent patient' model, prevalent in the USA. The emphasis of this model is on what the average 'prudent patient' would want to know about potential risks and treatment options.

Implied consent

Radiologists need to be able to explain to patients the potential risks and benefits of particular radiological examinations and procedures In the majority of examinations, the risk involved will be very low, and in these cases the implied consent of the patient will be obtained at the time of the examination by other members of the radiological team on behalf of the reporting or supervising radiologist. The patient's actions at the time of the examination will indicate whether the patient is content for the examination or other procedure to proceed.

Express consent

Judgement is required as to when express consent must be obtained and the degree of detail appropriate to a discussion with a patient about a particular radiological examination. Individual radiologists will, of course, vary the particulars presented in a discussion about, for example, a barium enema examination with different patients. This variation should not, however, detract from the consent required from the patient before the examination is initiated. Express consent can be given by the patient, either verbally or in writing.

Interventional/invasive procedures

Interventional or invasive radiological procedures require particular attention in obtaining the express consent of the patient. In a planned procedure, the patient should receive information, verbally or in writing, in sufficient time before the procedure to consider it and to consult others if they so wish. The patient should have their informed consent confirmed at a separate discussion with the radiologist performing the procedure. This discussion should occur close to when the procedure is to take place but still allow time for further open consultation, if it is needed. This further consultation should happen outside the immediate environment of the procedural room and, preferably, on a hospital ward, in an office or in an outpatient facility.

Emergency and planned procedures

Emergency, unplanned procedures require the judgement of the individual radiologist as to the time and opportunity available for obtaining informed consent.

With planned procedures, consideration should be given to asking the patient to sign a written consent form for those examinations and procedures which are recognised to be more complex to undertake or which potentially carry a more serious risk of complication. Sometimes, however, undue emphasis is placed upon the act of signing a consent form. Such forms are helpful and may be required by your employing trust, but they are not enough on their own. Most important in the process of informed consent are:

1. Having a detailed discussion with the patient
2. Clearly establishing that the patient has sufficient information to make an informed decision to proceed with the procedure concerned.

Written consent

The General Medical Council (GMC)[1] suggests that written consent should be taken in cases where:

- The treatment or procedure is complex and involves significant risk and/or side-effects
- Providing clinical care is not the primary purpose of the investigation or procedure (in particular, where the examination or procedure is for non-therapeutic purposes)
- There may be significant consequences for the patient's employment, social or personal life
- The treatment is part of a research programme. Written consent for some procedures is also required by the Mental Health Act[2] and the Human Fertilisation and Embryology Act.[3]

Consent must be freely given, without pressure from anyone. If consent is given under duress, that consent will be deemed invalid. If a patient asks for your opinion as a doctor involved in their care, this should be honestly, accurately and clearly given. This advice should be based on what is in the best interest of the patient, with due acknowledgement of the risk and benefit involved.

The Mental Capacity Act 2005[4] for England and Wales provides a framework to empower and protect people who may lack capacity to make some decisions for themselves. It makes it clear who can take decisions in which situations, and how they should go about this. It also allows people to plan ahead for a time when they may lack capacity. The Act's approach to capacity is to require you to consider it for the particular decision in question at any given time, when the patient may be unable to make a decision for themselves, and this may be permanent or temporary. You should consider whether it is likely that the patient will at some time have the capacity in relation to the particular decision, and when that is likely to be. Individuals may also lose their ability to give consent during treatment, regaining it later, and healthcare professionals must follow guidelines on mental capacity from their trusts.

Key principles of the Act

- Every adult has the right to make his or her own decisions and must be assumed to have capacity to make them unless it is proved otherwise.
- A person must be given all practicable help before anyone treats them as not being able to make their own decisions.
- Just because an individual makes what might be seen as an unwise decision, they should not be treated as lacking capacity to make that decision.

- Anything done or any decision made on behalf of a person who lacks capacity must be done in their best interests.
- Anything done for or on behalf of a person who lacks capacity should be the least restrictive of their basic rights and freedoms.

3 Documentation of consent

You should be prepared to explain and justify your involvement in the consent obtained. This may be required at a later date and should be supported by appropriate, contemporaneous documentation prepared at the time the consent was given.

Providing sufficient information

Patients have a right to information about their condition and the treatment options available to them. The amount of information you provide to each patient will vary, according to factors such as the nature of the condition, the complexity of the examination, the risks associated with the examination or procedure, the patient's own wishes, and the patient's age and mental state.

Key pieces of information

The GMC details 12 key pieces of information that patients should be given:

1. The diagnosis and prognosis
2. Any uncertainties about the diagnosis or prognosis, including options for further investigations
3. Options for treating or managing the condition, including the option not to treat
4. The purpose of any proposed investigation or treatment and what it will involve
5. The potential benefits, risks and burdens, and the likelihood of success, for each option; this should include information, if available, about whether the benefits or risks are affected by which organisation or doctor is chosen to provide care
6. Whether a proposed investigation or treatment is part of a research programme or is an innovative treatment designed specifically for their benefit. The patient should be told how the proposed treatment differs from the usual methods, why it is being offered, and if there are any additional risks or uncertainties. If you are considering prescribing unlicensed medicines or medicines for use off-label, you must follow the GMC's prescribing guidance
7. The people who will be mainly responsible for and involved in their care, what their roles are, and to what extent students may be involved
8. Their right to refuse to take part in teaching or research
9. Their right to seek a second opinion
10. Any bills they will have to pay
11. Any conflicts of interest that you, or your organisation, may have
12. Any treatments that you believe have greater potential benefit for the patient than those you or your organisation can offer.[1]

Information about risk and risk–benefit

Many radiological procedures carry a risk. These include radiation risks, as well as specific risks associated with more invasive interventional procedures. Patients should be informed of the details of the process of an examination, any expected discomfort and its likely duration, and also the risks of morbidity and of mortality. If several radiologists within a department undertake similar interventional procedures, it is useful and valuable to establish common views on the relative risks and benefits of these procedures to clarify matters for individual patients and referring clinicians. Leaflets in a clear and understandable form are valuable for communicating such factual detail.

The Royal College of Radiologists' website *(www.rcr.ac.uk)* has information templates on specific radiological examinations written and designed in collaboration with the RCR Clinical Radiology Patients' Liaison Group (CRPLG). These leaflets can be adapted for local departmental use.

Complex radiological procedures, for example some CT studies, may require a significant radiation dosage. Literature from the National Radiological Protection Board, now the Radiation Protection Division of the Health Protection Agency *(www.hpa.org.uk/radiation)* is available which explains the typical effective radiation doses from diagnostic medical exposure and their risks, and provides comparative information for exposure to natural background radiation encountered when, for example, flying in an plane.[5] The clinical radiologist will already have reviewed the clinical indication for the examination to ensure that risk–benefit has been properly evaluated. However, the patient may wish to discuss further the necessity for, or the desirability of, the radiation exposure involved. Additional information may be needed. The time and effort of the radiological team in discussing these aspects of radiological care require special workload and time tabling arrangements within the imaging department.

It is important to emphasise that patients cannot give valid consent unless they understand what they have been told. The presentation of information to patients must take account of the patient's values, culture, language, background, age and mental ability.

Patient literature should give clear information. Ideally, this resource should be available to the patient to take away to read and discuss with friends and family before discussion with the doctor or other medical professional obtaining consent.

Time for open discussion with patients about the balance of risk versus benefit, and alternative forms of investigation and treatment is essential to the process of obtaining informed consent.

Details about possible complications and their relative risk should be included in patient literature and, where possible, this literature should contain evidence of local audits and standards, as well as more generic information. This information will aid in the discussion of potentially distressing points.

Patient-initiated non-informed consent

If patients refuse to discuss potentially adverse events, gentle questioning, support and encouragement may be needed to make certain that no discussion is really what they want. It is appropriate to document this in the patient's record. If the patient is insistent and consistent in refusing to discuss potential adverse effects or complications from a proposed examination or intervention, this patient-initiated non-informed consent needs to be recorded at that time in the patient's case notes. It is advised that in such circumstances the patient's decision is witnessed by another team member who records their understanding of this discussion for the case notes. Involving other members of the healthcare team should always be considered in supporting the patient. The patient may also wish relatives to be present. The doctor obtaining consent must allow sufficient time for questions from the patient and must answer them fully and honestly. Patients must have adequate time to consider the information they are given before they have to make a decision as to their consent.

4 Patient autonomy

A doctor should find out what patients want to know and ought to know and respect the patient's decision. There should be dialogue resulting in clarity of objectives and understanding between patient and doctor.

5 Delegation

The delegation of responsibility for initial patient consent consultation to an appropriate member of the clinical radiological team may improve accessibility while maintaining a high standard of care. This should be in the best interest of the patient. The person to whom the role of obtaining initial consent is delegated must be suitably trained and qualified, have sufficient knowledge of the proposed investigation or treatment and understand the risks involved. They should adhere to GMC guidance on consent, as they are acting on the behalf of a doctor.[1] The final confirmation of informed consent at the time of the examination, however, remains the responsibility of the doctor involved in the radiological examination or intervention.

6 Intimate examinations

Intimate examinations require particular attention and understanding to establish trust and mutual confidence between patient and doctor. The appropriate setting, the need for privacy, preservation of the patient's dignity and respect for their personal beliefs will all influence this type of examination. Express consent, either verbally or in writing, should be obtained for intimate examinations and serious consideration should be given to the need to provide a chaperone.

7 Consent for the use of imaging in teaching and training

Imaging is now central to the practice of medicine, and training doctors to interpret medical images is, therefore, crucial to the provision of high-quality care. This is, of course, central to the training of clinical radiologists. In the development of training programmes, and the use of images to underpin that training, departments of clinical radiology must ensure that patient images are, wherever possible, anonymised to ensure patient confidentiality. This, of course, is not always possible and frequently not desirable, particularly when the process of anonymisation could compromise patient care and safety. This may occur in 'live case' situations where teaching is opportunistic, such as during reporting sessions, during the course of multidisciplinary team meetings (MDTMs), or during the review by colleagues and trainees of difficult cases.

The RCR supports the concept of 'anonymise or ask' proposed by the Patient Information Advisory Group (PIAG, now the National Information Governance Board for Health and Social Care [NIGB])[6] and recognises that both processes are intended to be thorough. However, processes for eliciting consent for the use of images in teaching radiologists, other professionals and medical students are not yet well established. Departments of clinical radiology and NHS trusts need to provide information about the nature of the training environment to patients in a number of ways. This will include posters within the hospital and the department, information contained within patient appointment letters, patient information sheets and general information provided by the trust. Every effort should be made:

1. To ensure that patients are aware of the information
2. To communicate the nature and importance of teaching in clinical practice in ways understandable by the patient.

Consultation with the trust's Caldicott Guardian will ensure that processes of anonymisation and consent are robust.

8 Establishing capacity to make decisions

An adult person is adjudged competent to give consent if they can comprehend information which has been presented in a clear way, believe it and retain it long enough to weigh it up and make a decision. A patient's decision may seem illogical, but this, in itself, is not evidence that the patient lacks competence. In such cases, you should review with the patient the reasons for their decision and establish that you have given to them all the relevant information. The patient with a fluctuating level of attention and concentration should be given any assistance that may help them to make an informed decision. *Particular care should be taken when sedative drugs have been administered to the patient.* It is necessary to record the patient's decision when they are competent and establish that their view is consistently held and can be relied upon. If in doubt, seek legal advice. For patients who are mentally incapacitated, provided they willingly comply with treatment you may carry out an investigation or intervention that you judge to be in their best interests. However, if they are unwilling to comply, you should seek legal advice before proceeding.

9 Children and consent

You must assess a child`s capacity to give consent before you attempt to obtain it. In general, a competent child will be able to understand the nature, purpose and possible consequences of the proposed procedure, as well as the consequences of non-treatment. Competent children under the age of 16 years may refuse treatment, but a person with parental responsibility (or the court) may authorise investigation or treatment which is in the child's best interest. This position is different in Scotland where those with parental responsibility cannot authorise procedures which a competent child has refused. If in doubt, you should seek legal advice.

10 Refusing consent

IIf a patient is competent to give consent, they are entitled to refuse consent, no matter how illogical their decision may seem. If the consequences of their refusal are potentially serious, you should discuss this decision with the patient to clarify the situation. In particular, you need to establish that they have understood the information they have been given, their condition, the proposed treatment and any possible side-effects. A patient's refusal to treatment may appear irrational but that is again, in itself, no reason to question their competence. However, a refusal might lead you to further investigate their mental capacity if, for example, it were at odds with previous decisions they had made. *When consent is refused, it should be recorded contemporaneously in the presence of a third party and placed in the patient's notes.*

11 Withdrawing consent

Patients can withdraw their consent at any time. They need to be competent to do so. If a patient asks you during a procedure to stop, you should temporarily do so, find out their concerns and explain the consequences of not proceeding. Establishing the competence of a patient during a procedure is difficult; pain, shock and medication they have received may have altered their capacity to make rational decisions. However, if the patient is competent and decides to withdraw their consent, you must respect their wishes and stop the treatment providing that, in so doing, they will not come to immediate harm.

12 Emergencies

In an emergency, when consent cannot be obtained, you may give medical treatment to anyone who needs it, provided the treatment is limited to what is immediately necessary to save life and avoid significant deterioration in the patient's health. You should tell the patient what has been done and why, as soon as the patient is sufficiently recovered to understand.

13 Consent to screening

Screening for disease can be an important tool in effective clinical care. The uncertainties involved in the screening process may, however, be significant, for example the risk of false-positive or false-negative results. The doctor involved must ensure that any patient considering screening can make a properly informed consent decision. The information outlined to the patient should include the purpose of the screening and the uncertainties and risks associated with it. Any significant medical, social or financial implications of screening for the particular condition or pre-disposition and any follow-up arrangements, including counselling and support services, should likewise be discussed with the patient.

14 Consent to research

The benefits of medical research may not apply to the individual research participant. Participants should understand this and that the results of research are not predictable. They should receive any information about possible benefits and risks that are known. A properly constituted research ethics committee approval should be made evident to the participants. It should be clearly stated that the participants can withdraw from the research programme at any time and that withdrawal will have no effect upon their subsequent medical care. Express consent in writing is required from the participants. No pressure must be put upon the potential participants to take part in the research activity from the individuals responsible for obtaining consent or from anyone involved in the research project.

An audit template is in preparation and will be available on AuditLive on *www.rcr.ac.uk*

Approved by the Board of the Faculty of Clinical Radiology: 21 October 2011

References

1. General Medical Council. Consent: patients and doctors making decisions together. http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance_index.asp (last accessed 12/7/12)

2. Mental Health Act 1983. http://www.cqc.org.uk/sites/default/files/media/documents/mental_health_act_1983_0.pdf (last accessed 12/7/12)

3. Human Fertilisation and Embryology Act 2008 http://www.legislation.gov.uk/ukpga/2008/22/contents (last accessed 12/7/12)

4. Mental Capacity Act 2005. http://www.legislation.gov.uk/ukpga/2005/9/contents (last accessed 12/7/12)

5. http://www.hpa.org.uk/Topics/Radiation/UnderstandingRadiation/UnderstandingRadiationTopics/DoseComparisonsForIonisingRadiation/ (last accessed 12/7/12)

6. Patient Information Advisory Group. Information about patients: An introduction to the Patient Information Advisory Group for health professionals and researchers. http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@ab/documents/digitalasset/dh_094619.pdf (last accessed 12/7/12)

Further reading

General Medical Council. Confidentiality. *http://www.gmc-uk.org/guidance/ethical_guidance/confidentiality.asp* (last accessed 12/7/12)

General Medical Council. Good Medical Practice. London: GMC, 2006.

Medical Protection Society. Consent – The basics. *http://www.medicalprotection.org/uk/wales-factsheets/consent-the-basics* (last accessed 12/7/12)

Medical Protection Society. General advice on assessing capacity. *http://www.medicalprotection.org/uk/guide-to-consent-in-the-uk/general-advice-on-assessing-capacity* (last accessed 12/7/12)

The Royal College of Radiologists. *Individual Responsibilities: A guide to good medical practice for radiologists.* London: The Royal College of Radiologists, 2004.

The Royal College of Radiologists 38 Portland Place London W1B 1JQ

Tel +44 (0)20 7636 4432 | Fax +44 (0)20 7323 3100 | Email enquiries@rcr.ac.uk | www.rcr.ac.uk |

A Charity registered with the Charity Commission No. 211540

The Royal College of Radiologists

Citation details:

The Royal College of Radiologists. *Standards for patient consent particular to radiology, Second edition.* London: The Royal College of Radiologists, 2012.

ISBN: 978-4-905034-57-4. Ref No. BFCR(12)8

Design by innov8 graphic design: www.innov8gd.com.