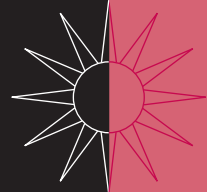


THE COLLEGE OF
RADIOGRAPHERS



CLINICAL IMAGING
RADIOTHERAPY AND
ONCOLOGY

**Consent to Imaging
and Radiotherapy
Treatment
Examinations:
An ethical perspective
and good practice
guide for the
radiography workforce**

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Examinations:
An ethical perspective and good practice guide for
the radiography workforce**

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Foreword

This Society and College of Radiographers' (SCoR) document contains information, advice and guidance on the general principles of good practice in seeking consent from patients prior to examinations and treatment undertaken by the radiography workforce in clinical imaging and radiotherapy departments. It has been informed by current available evidence.

The information in this document has used published evidence and other professional sources. The purpose of this document is to provide guidance to those working in the United Kingdom. However, readers are advised that the law and practices may vary in each country of the UK and outside the UK.

The radiography workforce in any doubt about an issue relating to consent are advised to seek further information from the Society of Radiographers and/or independent legal advice.

The guidance principles outlined here should be read in conjunction with the Department of Health recommendations and implementation guides, particularly the *Good practice in consent implementation guide: consent for examination and treatment*¹, together with any appropriate employer policies on obtaining consent for both examination and treatment.

In addition, those working in Scotland should familiarise themselves with the Scottish Executive document *A good practice guide on consent for health professionals in NHS Scotland*².

Those working in Northern Ireland should familiarise themselves with the Department of Health, Social Services and Public Safety (DHSSPS) document *Good practice in consent: implementation guide for health professionals*³.

Those working in Wales should familiarise themselves with the Welsh Assembly Government document *Reference guide for consent to examination or treatment*⁴. NB: This guide is under revision.

This guidance replaces Appendix B in the Society and College of Radiographers document *Statements for Professional Conduct*⁵.

The Society and College of Radiographers is grateful to Val Challen, Radiographer and formerly Director of the Centre for the Development of Learning and Teaching (CDLT), St Martin's College, Lancaster for all her hard work in producing this advice and guidance document for the profession and to Kathlyn Slack, Health Protection Agency (HPA) Radiation Division for her helpful comments.

Executive summary of guidance

Radiographers who are delivering radiotherapy treatment or undertaking a clinical imaging examination have a duty of care to ensure that patients are fully aware of the procedure and have consented. *'The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later'*¹.

Assistant practitioners in clinical imaging are not registered health professionals but, in the limited contexts in which they practice, they may obtain patient consent for some procedures. Assistant practitioners in radiotherapy are not registered health professionals and may not obtain patient consent for treatment procedures.

Why consent is important (Section 4)

- Seeking patient consent prior to undertaking an examination or treatment regime is a fundamental ethical and legal requirement of a health professional.
- Touching a patient prior to obtaining valid consent may constitute battery under civil or criminal law or, in some circumstances, sexual assault, hence the need for the patient to be aware of the requirements surrounding patient positioning.
- It is an ethical requirement, a common courtesy and establishes a convincing and appropriate trust relationship between radiographer and patient.

Valid and Legal consent (Sections 5 & 6)

- Consent is ensuring the patient is aware of the purpose and nature of any procedure to be carried out. The radiographer must ensure that the patient is fully aware of his/her options, including alternatives, the right to refuse and the consequences of refusal. The radiographer is advised to always seek the patient's explicit verbal affirmation to proceed.
- Radiographers must distinguish between patient compliance and implied consent, both signalled through behaviour, as implied consent requires that the patient is provided with sufficient information on which to proceed with the examination or treatment.
- The radiographer should provide the patient with a limited amount of relevant and accurate information in a form that the individual radiographer deems the particular patient is able to grasp and thus understand. The amount will depend on the nature of the examination and whether there are any **significant** risks attached to the procedure.
- The radiographer should ask the patient to confirm in his or her own words their understanding of the procedure and whether they agree to continue.
- Radiographers should be aware of the circumstances and procedures requiring written consent and liaise with the appropriate medical or dental practitioner if delegated the task of obtaining consent in these instances.

Information giving (Sections 7 & 8)

- Patients are entitled to know that they will receive a dose of radiation and should be informed of the benefits of the procedure.
- Some patients, on being made aware that radiation is involved in their examination, may ask pertinent questions about potential risks to themselves or future offspring. Radiographers should respond in an appropriate way using their own judgement to decide on the ability of the patient to understand a risk:benefit approach.
- Radiographers should respond to queries by avoiding the use of the term 'safe' in favour of terms that describe a radiation risk as being very low or acceptable compared with other risks in society. (Refer to broad levels of risk for common x-ray examinations and isotope scans, Appendix 4).
- In the case of procedures such as some CT examinations, certain nuclear medicine examinations, interventional procedures, or radiotherapy treatment, patients should be informed of any significant radiation dosage and the inherent risks of radiation.
- Information about other possible non-radiation linked side effects arising from any diagnostic or therapeutic procedure, should be part of an agreed departmental policy and made known to all radiographers working in the field
- Radiographers should be cogniscent of the potential harm that information on risk could cause.

Consent and children (Section 9)

- If a child is not capable of understanding the nature of the procedure to be undertaken, the child's parent or guardian should be asked for their consent to proceed.
- Radiographers should be aware of the issues surrounding consent for procedures and consent to disclosure where children are involved. (Refer also to *The child and the law: roles and responsibilities of the radiographer, SCoR*⁶.)

Adults and capacity (Section 10)

- Adults are presumed to be competent unless proven otherwise. The legal definition of an adult in England, Wales and Northern Ireland is anyone who is 18 years or over; in Scotland it is 16 years or over. In most clinical situations, the issue of patient competency will not arise because usually the radiographer is not the first point of contact for the patient.
- The key factor for radiographers is the requirement of the *Mental Capacity Act 2005*⁷ which establishes that primacy is given to the “best interests of the person lacking capacity” and this forms the basis for any treatment decision. Section 64(1) of this Act makes it clear that treatment includes diagnostic or other procedures.
- For radiographers in Scotland, the appropriate legislation is the *Adults with Incapacity (Scotland) Act*⁸.

Students (Section 11)

- It is not necessary in law to gain consent to treatment which will be undertaken by a student as the nature and purpose of the procedure remains the same whoever undertakes the task. However, the SCoR takes the view that from an ethical perspective, patients do have a general right to refuse treatment by persons other than a qualified member of staff. Patients must be made aware that a student radiographer is not a qualified member of staff. Prior to a student undertaking any examination, permission should be asked of the patient, preferably by the supervising radiographer.
- Where a student may be present during an intimate procedure (eg, transrectal/transvaginal ultrasound, mammography, prostate brachytherapy, etc), maintaining the balance between the educational needs of the student and the ethical requirement of respect for the individual person is crucial. Clinical teachers/supervisors should obtain patients’ explicit verbal consent for a student(s) to be present. Patients must be made aware which students and how many students will be present prior to being asked to give explicit verbal consent.
- Radiographers should not put the patient into a position where refusing an examination by a student would make it difficult for them without causing possible offence to the student.

Documentation (Section 12)

- Should a patient refuse an examination, the radiographer must discuss with the patient the implications of their decision and record the details of the incident on the request card. Date, timings and witnesses should be recorded.

Screening (Section 13)

- Radiographers/sonographers must gain explicit verbal consent after assessing the individual’s understanding of the procedure and be prepared to provide further information, as well as answering questions.
- The radiographer/sonographer must use his/her professional judgement to note the physical and/or psychological behaviour of the attendee, which may indicate unwillingness to continue with the procedure and should respect the right of the attendee to withdraw consent at any time.

Research (Section 14)

- Similar legal principles are applicable regarding the seeking of consent for research purposes as when seeking consent for diagnostic or treatment purposes.
- The Information Commissioner has decided that whilst obtaining consent for medical research involving **identifiable** personal health data is the default position, there are circumstances where consent to process data may not be required. Radiographers should be aware of their “duty of confidence” in relation to the processing of personal health data and always seek advice from the relevant Regional Ethics Committee (REC) and from Patient Information Advisory Group (PIAG) if deemed appropriate.
- For medical or biomedical research involving the application of radiation, radiographers should be aware of IR[ME]R⁹ in this respect and the necessity for the appropriate regulations to be reflected in their employer’s written policies on informing patients, in advance, of the risks of exposure.

Use of chaperones (Section 16)

- Radiographers are expected to use their professional judgement on whether a chaperone is necessary for a particular examination/treatment. A chaperone must be present during transrectal and transvaginal procedures.
- Practitioners might usefully consider the issue of chaperoning together with consent, and it is advisable to ensure that the patient agrees with and understands the role of staff that might be present during intimate examinations.
- Recent changes in the law with regard to sexual offences may have a significant impact on the circumstances in which chaperoning is advisable. The notion that chaperoning is only appropriate when a male practitioner carries out an intimate examination on a female patient is outdated and does not reflect the implications of the law as it now stands.

1. Introduction

- 1.1 It is imperative that all radiographers are aware of the issues surrounding the gaining of consent from patients and others attending a clinical imaging or radiotherapy department.
- 1.2 Radiographers have professional duties and responsibilities in terms of conduct, performance and ethics including a requirement to undertake only those tasks in which they are competent and for which appropriate patient consent has been obtained^{5,10}.
- 1.3 The principle of consent to an examination carried out by a registered health professional is the right of patients to determine what happens to their bodies and the radiographer who does not respect this principle is potentially liable to both legal action by the patient and action by the Health Professions Council (HPC).
- 1.4 Radiographers who are delivering radiotherapy treatment, or undertaking a clinical imaging diagnostic examination, have a duty of care to ensure that patients are fully aware of the procedure and have consented. "The health professional carrying out the procedure is ultimately responsible for ensuring that the patient is genuinely consenting to what is being done: it is they who will be held responsible in law if this is challenged later"¹.
- 1.5 The Health Professions Order 2001 (Statutory Instrument 2002 No 254)¹¹ legally recognises radiographers as registered health professionals but, at the time of writing, assistant practitioners are not recognised as being regulated professionals.
- 1.6 Assistant practitioners in clinical imaging, work under the direction of a registered health professional¹² and undertake predominantly plain film examinations on the cooperative, communicative and conscious adult patient. In these limited contexts, the assistant practitioner may take responsibility for obtaining patient consent as long as s/he is proved competent to do so following education and training. For other examinations (investigations involving CT, MRI or fluoroscopy) in which assistant practitioners may be involved, including radiotherapy treatment procedures, patient consent may only be obtained by a registered health professional.

2. Background to principles of consent to examination or treatment

- 2.1 Worthington¹³ is clear about the ethical necessity of the health professional in seeking consent from a patient and that awareness of the following aspects is crucial:
- Failure to follow recommended protocols for obtaining meaningful, lawful consent is unethical and can harm patients both physically and psychologically;
 - Failure to obtain consent can end in civil litigation (or in rare cases criminal prosecution)
 - Quality of health care demands more than mere technical proficiency
- 2.2 In the UK, the process of information disclosure is underpinned by case law: Bolam and Bolitho rulings, further endorsed by the Sidaway case. The duty of care of a health professional in relation to any aspect of their practice, including information disclosure, will be measured against a required standard for that profession. To bring a claim of negligence against a health professional a claimant must show that, on balance, the standard of care fell below what could reasonably have been expected from that health professional.
- “A doctor was not negligent, if he has acted in accordance with the practice accepted at the time as proper by a responsible body of medical opinion”¹⁴.*
- The judgement given by the House of Lords in relation to the Bolitho case imposes a requirement that the standard of care must be based on logic, which may be interpreted as based on evidence, as well as being accepted by a body of opinion¹⁵.
- The Sidaway case applied the principles to the ‘doctor’s duty to inform his patient’¹⁶. These principles can now be generally applied to all registered health professionals not just to the medical and dental professions. The Bolam test can be regarded as the principle to be followed to determine the required standard of care:
- “... the test is the standard of the ordinary skilled person exercising and professing to have that special skill”.*
- 2.3 Negligence in the case of information disclosure about a procedure is in the failure to make a patient aware of certain features and risks of the procedure with the result that the patient suffers damage.
- 2.4 The Bolam principle established that, in the communication of risks, a health professional must communicate such information and risks in accordance with contemporary practice accepted by a responsible body of professional opinion¹⁷.
- 2.5 The 2004 House of Lords ruling in the case of Chester v Afshar¹⁸ resulted in the NHS Litigation Authority (NHSLA) issuing a risk alert for clinicians with a series of recommendations¹⁹. When obtaining consent, careful and comprehensive warnings of adverse outcomes must be given, they must be properly recorded in the notes, with the patient being asked to sign the relevant entry to confirm that he/she has been given the warning, has understood it and accepts the risk.
- 2.6 The Department of Health’s Good Practice in consent implementation guide¹ has provided a blueprint for a model consent process and four consent forms to assist NHS organisations to promote good practice in the obtaining of consent to care, treatment or research. Radiographers should ensure they are conversant with their employing authority’s policies in this regard. These policies may not, however, provide guidance on the level of information disclosure to be provided for patients. (See section 7 of this document relevant to this aspect).

3. Background to consent relevant to radiography

- 3.1 The initial consent to a radiographic examination or intervention should be sought by the referrer in consultation with the patient and should comprise reasons for the procedure and information about the procedure, in order that the patient can exercise his/her self determination.
- 3.2 In cases where an ionising radiation examination (between the diaphragm and upper femur) will be undertaken on a patient of child-bearing age and pregnancy cannot be ruled out and alternative imaging modalities deemed inappropriate, the radiographer will need to consult with the referring clinician to ascertain the risk to the mother of postponing until after delivery. In the event of the examination proceeding, the risk to the foetus (dependent on the stage of pregnancy) must be explained to the patient and written informed consent obtained. Prior to consent being obtained, patients must also be advised of any risks of not having the examination. In addition to this, radiographers should not confuse the completion of any LMP declaration form with completion of an informed consent form as they are not the same.
- 3.3 Further information about a procedure or treatment regime is often provided through written information leaflets, often produced by the clinical imaging or radiotherapy and oncology team, with leaflets being the most widely used information medium in the NHS²⁰. However, the Audit Commission has noted that the quality and distribution of such is often patchy²¹ and may not always be suitable given that the average reading age is nine years²². In addition, written leaflets may not always be accessible to people with reading difficulties, or where English is not their first language. Translation in a variety of languages may overcome some of the latter concerns.
- 3.4 Radiographers should consider undertaking an audit(s) to identify patient understanding, or lack of understanding of the leaflets used in their department and are strongly advised to involve patients in producing patient-centred information that addresses any issues identified through the audit process.
- 3.5 Research undertaken by radiographers in Scotland indicated that there is considerable diversity in hospital practices regarding informed consent for imaging procedures²³. There appears not to be any similar research undertaken in the other countries making up the UK. A pan UK research survey undertaken in relation to informed consent for radiotherapy examinations, found that the Department of Health model consent process was in operation in the majority of cancer centres, but that radiographer involvement in the process of obtaining informed consent was limited²⁴.
- 3.6 An Australian survey concerning the use of written consent forms in radiotherapy concluded that a reduction in patient dissatisfaction was more likely to be achieved if resources were invested in better communication between patients and staff, less time spent waiting for treatment, and the use of a multidisciplinary approach, than the use of written consent forms²⁵.

4. Why the seeking of consent by the radiographer is important

- 4.1 Seeking patient consent prior to undertaking an examination or treatment regime is a fundamental ethical and legal requirement of a health professional. It is also a common courtesy and establishes a convincing and appropriate trust relationship between radiographer and patient. The principle of gaining consent demonstrates the practitioner's respect for the patient's autonomy and decision making process.
- 4.2 The gaining of consent prior to any procedure should not be viewed as a burden or a bureaucratic process but as a "standard of communicatory excellence" required of all health care professionals²⁶.
- 4.3 Touching a patient (or as might be surmised, delivering a dose of radiation to a patient) without their consent, could be construed under English law, at least, as battery under the tort of trespass to the person. Traditionally, the importance of gaining consent was to protect a doctor against an allegation of battery. Battery being defined as "...intentionally bringing about a harmful or offensive contact with the person"²⁷. Legal actions for battery against health professionals are relatively rare in the UK and unlikely to succeed^{28,29}. To avoid misunderstandings surrounding the necessary touching of patients, please read Section 16 'Avoiding misunderstandings and use of chaperones'.
- 4.4 It has been established that the focus of legal actions against any health professional is more likely to be on the nature of the information given to or withheld from a patient on which s/he decides to proceed with an examination or treatment and comes under the tort of negligence. However to succeed through a case of negligence, a plaintiff has to prove duty of care, standard of care, causation, and that damage has occurred²⁸. Damage, in such cases, might be physical or psychological. It would appear from some sources that the health professional is in a stronger position than the plaintiff to defend such an action²⁴. However, this does not absolve the radiographer from informing the patient, or seeking his/her consent to carry out a procedure.
- 4.5 Radiographers should not assume that patients attending a department for a diagnostic or treatment examination have already given informed consent because often patients are unaware of the exact nature of the procedure which they will undergo³⁰.
- 4.6 Radiographers have a legal requirement and an ethical duty to seek consent prior to undertaking any examination on a patient.
- 4.7 In emergency situations where patients are unable to make any decisions and it will not be possible to gain consent, the radiographer may provide imaging services provided it is immediately necessary to either prevent deterioration of a condition or to save a life.

5. Types of consent

- 5.1 Valid legal consent to treatment or examination can be implied consent or express consent (oral or written). A radiographer should not undertake any procedure unless s/he is satisfied that the patient has given consent and understands the nature of the procedure.
- 5.2 Implied consent is an agreement signalled by the behaviour of an informed patient who may not express him/herself verbally but does as requested by the radiographer. The giving of information to the patient distinguishes implied consent from compliance with a request (eg, lying on an x-ray couch, or presenting an arm for an injection). The radiographer is advised to always seek the explicit verbal affirmation of a patient prior to undertaking any procedure and not rely on patient compliance³¹.
- 5.3 Express consent is needed for treatments and investigative procedures which carry any significant risks. This must by definition include a number of diagnostic and radiotherapy procedures. The law, however, does not require consent to be in written form; verbal consent is acceptable as long as the patient is legally competent, the consent was voluntary and the patient was provided with sufficient information on which to base their consent.
- 5.4 Written consent may be required for certain cases dependent on the employing authority's policies and/or as advised by the General Medical Council (GMC) and may include:
- Invasive/interventional procedures;
 - Treatments/procedures involving a significant risk and/or side effects.

6. Consent requirements

6.1 For consent to be both valid and legal, three elements must be satisfied:

- i) the patient has the capacity to consent, ie must be legally competent;
- ii) the consent must be voluntary, ie patient not acting under duress;
- iii) the patient must have received sufficient information³².

If any one of these three elements is not met, then the consent is negated and any procedure will be illegal.

6.2 Valid legal consent to treatment or examination can be implied consent, or express consent (oral or written). A radiographer should not undertake any procedure unless s/he is satisfied that the patient has given consent and that the three elements have been satisfied. Each element will now be considered in turn.

6.3 Element 1. Legal Capacity – The patient has the capacity to consent

6.3.1 Adults are presumed to be competent unless proven otherwise. The legal definition of an adult in England, Wales and Northern Ireland is anyone who is 18 years or over; in Scotland this is 16 years or over. In most clinical situations, the issue of patient competency will not arise because usually the radiographer is not the first point of contact for the patient.

6.3.2 The radiographer, as part of his/her professional education and practice, must be able to assess the level of a patient's understanding. This should be done by asking the patient to confirm in his/her own words their understanding of what the procedure involves and whether they agree to continue.

6.3.3 Should a patient's decisional response appear to be irrational or unexpected, this may not be a sign of incapacity, merely that more information or a clearer explanation should be provided by the health professional².

6.3.4 With regard to in-patients, the radiographer undertaking a procedure on the ward or unit must satisfy him/herself that the procedure is justified and it is being undertaken in the best interests of the patient. Consent should ideally be sought from the patient to carry out the procedure but may not always be possible should the patient lack capacity.

6.4 Element 2. Voluntary agreement by the patient

6.4.1 Patient autonomy requires that any decisions made must not be as a result of coercion or duress. Radiographers, in line with all other health care professionals, need to recognise that they have influence and should refrain from consciously or subconsciously manipulating the decision making process of the patient³³.

6.4.2 It is not appropriate to wait until the patient is in a vulnerable state, eg, undressed, or lying on a couch before seeking or confirming consent. The differential power relationship between professional and patient may make it difficult for a patient to make a rational, considered decision and might be construed as duress.

6.4.3 The radiographer should inform the patient of the benefits of the procedure but ensure that patients understand they may change their minds at any time if they do not wish to continue.

6.4.4 Radiographers need to acknowledge that consent is not a 'once only' decision but a 'process over time' and that, at any time during a procedure, the patient may withdraw their consent. Information describing procedures, especially interventional procedures, should be given to the patient at a time before the procedure. This allows the patient to take time to read the information and then be given the opportunity to ask questions. This enables consent to be informed. It is not good practice for elective examinations for the procedure to be described verbally immediately before the examination and the patient then asked to sign the consent form.

6.4.5 Radiographers should not be judgemental about a competent patients' decision to refuse an examination at any stage even if it is thought to be irrational.

6.5 Element 3. Sufficient Information

- 6.5.1 The provision of information is central to the process of consent. What information, how much information, who should provide it and in what format, are all crucial issues surrounding patient autonomy and patient satisfaction and have important implications for the radiographer and for patient consent.
- 6.5.2 The giving of information prior to gaining consent to proceed should not be regarded as a rigid process but as a flexible process to facilitate meaningful decision making by the patient³¹.
- 6.5.3 The referrer may have initially gained the consent of the patient and may have provided some information to the patient but it is self evident that:
 - a. there might be a lengthy period between this and the procedure being undertaken and;
 - b. the referrer may not be aware of the full details of the procedure themselves.
- 6.5.4 Patients are entitled to have information provided prior to any procedure. The radiographer should give a limited amount of accurate and relevant information in a form that the patient is able to grasp and thus understand. This amount and form will vary from patient to patient and the radiographer must tailor these to the individual using his/her professional judgement³⁴.
- 6.5.5 The radiographer should be aware that the presentation of an overwhelming amount of information may hinder the patient's decision making ability. Radiographers need to ensure they have developed competencies in information giving as well as understanding and assessing patients' characteristics and values in relation to decision making in healthcare.
- 6.5.6 The whole process should be patient led and not practitioner led, as patients' beliefs, culture and social background may have a bearing on the type and nature of the information required³⁵. The use of a tick box approach to information-giving is neither appropriate in a professional context nor helpful for the individual patient.
- 6.5.7 The radiographer has a duty of care, not just to inform the patient of the nature and purpose of the procedure, but to inform the patient about the benefits of the procedure and any material or significant risks involved. The patient must also be informed of any alternatives to the procedure and the risks to them of doing nothing³⁶.

7. Information about risk:benefit and significant risks

- 7.1 Many procedures undertaken in imaging and radiotherapy departments carry a risk, including a radiation risk³⁷. The referrer for a clinical imaging procedure involving ionising radiation is often unaware of the radiation dose associated with that procedure and therefore any related potential radiation risk³⁸. The practitioner under the Ionising Radiation (Medical Exposure) Regulations (IR[ME]R) 2000 and IR[ME]R amendments 2006⁹ is responsible for considering the clinical indications and expected benefit to society, as well as the individual, against any potential detriment associated with the radiation dose and therefore justifying the procedure where appropriate. The practitioner is often, but not always, a radiologist or radiographer and must be aware of the radiation dose and associated risks for that procedure.
- 7.2 Many patients may not be aware that the use of ionising radiation is involved in their examination and will not ask questions about risks from radiation. Such patients are entitled to know that they will receive a dose of radiation and should be informed of the benefits of the procedure.
- 7.3 Some patients on being made aware that radiation is involved in their examination may ask pertinent questions about potential risks to themselves or future offspring. Radiographers should respond in an appropriate way using their own judgement to decide on the ability of the patient to understand a risk:benefit approach. Radiographers should be cognisant of the potential harm that information on risk could cause³⁹.
- 7.4 Radiographers should respond to queries by taking the advice of the Health Protection Agency (HPA) avoiding the use of the term 'safe' in favour of terms that describe a radiation risk as being very low or acceptable compared with other risks in society⁴⁰.
- 7.5 It is only in the case of more complex procedures, such as some CT examinations or certain nuclear medicine examinations, interventional procedures, or radiotherapy treatment regimes, that patients should be informed of any significant radiation dosage and the inherent risks of radiation and other possible side effects⁴¹. It is necessary in these cases, however, that a balance is struck between providing appropriate information to enable informed consent and causing considerable, and possibly unnecessary, concern.
- 7.6 The RCR Clinical Radiology Patients' Liaison Group has suggested that examinations or procedures with a known potential risk of complications greater than 1 in 2000 should be mentioned to patients when seeking consent³⁷. A study undertaken by Mayberry and Mayberry⁴² found that 83 per cent of their patient sample only wanted to be told of any procedural risks greater than 1 in 1000.
- 7.7 A patient information leaflet published by the National Radiological Protection Board (NRPB), now the Radiation Protection Division of the HPA, describes broad levels of risk for common x-ray examinations and isotope scans in terms of equivalent period of natural background radiation and the lifetime additional risk of cancer per examination. Radiographers are advised to ensure that they are familiar with these figures and can provide patients with the appropriate risk factor and equivalent period of natural background radiation if asked about radiation risks. (See Appendix 4 for NRPB broad levels of risk.)

8. Issues around consent for the administration of a contrast agent, radiopharmaceutical or other medicines

- 8.1 Radiographers who have undergone education and training in the administration of contrast agents, smooth muscle relaxants and radiopharmaceuticals will be accredited to be clinically competent on receipt of the SCoR certificate of competence in administering intravenous injections, or have met requirements of the employing authority by successfully completing training provided by the employing authority.
- 8.2 As with any procedure, consent must be sought prior to an injection being carried out with the patient having been provided with information related to the procedure including any significant risks.
- 8.3 The almost exclusive use of non-ionic agents in the UK has now made adverse reactions to contrast agents considerably less common⁴³. Acute life threatening reactions to intravascular contrast agents often referred to as anaphylactoid are not true allergies, are rare, but can occur unpredictably⁴⁴. They may show some of the features of anaphylaxis such as bronchospasm, angio-oedema, airway obstruction, or cardiovascular collapse⁴⁵, hence the reference.
- 8.4 Where the use of an iodinated contrast agent, or a radiopharmaceutical, or other drugs used in diagnostics and radiotherapy is concerned, the issue of conveying risk information to the patient is contentious. Some Trusts and other employers require written informed consent from the patient and any risks associated with the contrast agent are disseminated via prior circulated written patient information leaflets.
- 8.5 Bettmann⁴⁴ indicates that the major questions associated with contrast agent usage include the most appropriate way to inform patients of the risks and benefits associated with contrast agent use, how to deal practically with patients who may have risk factors for an adverse event (eg prior reaction, strong history of allergies, compromised renal function, diabetes mellitus, etc) and how to deal with concerns of nephrotoxicity. Delegated radiographers who inject contrast agents need to gain information from patients before the injection and supply information to patients regarding the nature of the contrast media. If in doubt, they should liaise with the delegating radiologist prior to continuing.
- 8.6 Further reading on task delegation in the performance of intravenous injections is recommended. (See Keenan, Muir and Cuthbertson⁴⁶.)

9. Consent and children

(Several parts of this section are taken from the SCoR's 'The Child and the Law: roles and responsibilities of the radiographer'⁴⁷.)

- 9.1 If a child is competent to give consent for him/herself for either an examination or treatment, the radiographer should seek consent directly from them. The legal position on competence is different for children under 16 years of age and for those over 16.
- 9.2 Legally, a child is a person who has not yet attained the age of 18 years but by virtue of Section 8 of the *Family Law Reform Act 1969* children aged 16-17 years are deemed capable and therefore competent to give consent in the same way as an adult. It is, however, prudent for the radiographer to encourage children of this age to involve their families in the decision making process unless the radiographer believes that it is not in the best interests of the child to do so.
- 9.3 For children under the age of 16 years, competence to consent may not be presumed. A child under 16 will be competent to give valid consent if they have "*sufficient understanding and intelligence to enable him/her to understand fully what is proposed*" (known as either Gillick competence or Fraser ruling competence)⁴⁸.
- 9.4 Criteria for judging Gillick competence and the lower age range are not clear and radiographers are advised that "*legal capacity by a child varies according to the particular matter and maturity and understanding of the particular young person*"⁴⁹. Although there is no clear legal guidance, it would appear to be unlikely that the courts would consider children of 13 years and under to be Gillick competent⁵⁰. This, however, may well depend on the nature of the procedure to be undertaken. It is important, therefore, for radiographers to recognise that they must exercise professional judgement in this regard each time they carry out a diagnostic examination or treatment procedure.
- 9.5 Gillick ruling does not apply in Scotland. Young people in Scotland have a statutory right to give their own consent to treatment. Section 2 (4) of the *Age of Legal Capacity (Scotland) Act 1991* allows a young person with no specified age range to consent on his or her own behalf to a medical procedure provided that, in the opinion of a qualified medical practitioner, s/he is capable of understanding the nature and possible consequences of the treatment⁵¹.
- 9.6 Should a Gillick (Fraser) competent child consent to a procedure, a parent cannot override that consent. However, a parent can consent to a procedure should a Gillick (Fraser) competent child refuse.
- 9.7 In the event of a parent/carer or competent child subsequently refusing consent to the examination once in the clinical department, the radiographer will need to liaise with the requesting physician. If further discussion with the persons holding parental responsibility does not lead to consent then it is likely that the local authority would ultimately make an application for a court order under the *Children Act 1989* for the procedure to be carried out in the best interests of the child.

10. Adults with impaired capacity

- 10.1 Consent principles must apply to all patients and where a patient has a diagnosis of a mental disorder or a learning disability, it must not be automatically assumed that the patient is unable to make any decision for their self.
- 10.2 A person may be considered to lack capacity if, at any time, he is unable to make a decision for himself because of an impairment of, or a disturbance in the functioning of the mind or brain (*Mental Capacity Act 2005* section 2[1]⁵²).
- 10.3 An incompetent adult is not able to give valid consent to any healthcare activity and in common law practice, no person may give valid consent on behalf of an adult lacking capacity. (See section 6(3) of this document on the importance of seeking consent.)
- 10.4 The *Mental Capacity Act 2005* is applicable to people 16 years and over who are resident or present in England or Wales who lack mental capacity. It is underpinned by a set of five key principles designed to empower and protect vulnerable people who cannot make their own decisions. Two principles of the Act include a presumption of capacity (unless proven otherwise) and a requirement that all practicable steps should be taken to support a person to make a decision.
- 10.5 The Act sets out that a person who lacks capacity is someone who is unable to make a decision for him/herself as s/he is unable to:
- understand relevant information
 - retain that information
 - use or weigh up the information as part of the process of decision making
 - communicate the decision.
- 10.6 Radiographers should be aware that the doctrine of necessity provides justification for healthcare treatment and Section 5 of the *Mental Capacity Act 2005*, based on this doctrine, provides statutory protection for healthcare professionals to perform procedures for/on people who lack capacity and are thus unable to give valid consent⁵³.
- 10.7 Radiographers should also be aware that Section 5 of the Act protects against liability in battery but does not offer protection if the action is carried out negligently.
- 10.8 The key factor for radiographers is that the requirement of the Act establishes that primacy is given to the “best interests of the person lacking capacity” and this forms the basis for any treatment decision. Section 64(1) of the Act makes it clear that treatment includes diagnostic or other procedures.
- 10.9 The appropriate legislation for Scotland is the *Adults with Incapacity (Scotland) Act 2000*⁸ which is applicable to people 16 years and over who are resident or present in Scotland who lack mental capacity. Radiographers working in Scotland must familiarise themselves with the requirements of this Act. (See also the Scottish Executive Good Practice Guide on consent for Health professionals in NHS Scotland [2006])⁵⁴.

11. Student involvement in procedures

- 11.1 It is not necessary in law to gain consent to treatment which will be undertaken by a student as the nature and purpose of the procedure remains the same whoever undertakes the task so long as consent to the treatment or procedure has been initially sought from the patient by the radiographer or registered health professional.
- 11.2 The Department of Health's guidance also states that the patients' specific consent is not required for procedures undertaken by students if such procedures are part of the patients' normal care.
- 11.2 However, the Society and College of Radiographers (SCoR) take the view that from an ethical perspective, patients do have a general right to refuse treatment by persons other than a qualified member of staff. Patients must be made aware that a student radiographer is not a qualified member of staff. Prior to a student undertaking any examination, the patient should be asked for permission to proceed on this basis and give explicit verbal consent.
- 11.3 Where a student may be present during an intimate procedure (eg, transrectal/transvaginal ultrasound, mammography, prostate brachytherapy, etc), maintaining the balance between the educational needs of the student and the ethical requirement of respect for the individual person, is crucial. Clinical teachers/supervisors should obtain patients' explicit verbal consent for a student(s) to be present. Patients must be made aware of which students and how many students will be present prior to being asked to give explicit verbal consent.
- 11.4 In all situations where consent is sought from a patient for a student to perform a procedure or to be present during a potentially embarrassing examination, the radiographer must ensure that a patient can decline without fear of offence⁵⁵.
- 11.5 Radiographers through adherence to this practice act as appropriate role models to students for ethical practice.

12. Documentation

- 12.1 Consent forms in the format recommended by the Department of Health³⁷ may be used for certain examinations with individual Trusts and other organisations stipulating requirements.
- 12.2 If not part of the employing authority's policy, the SCoR recommends that written consent should be obtained for those intimate examinations, eg, vaginal, rectal, etc if there is any possibility that consent for the process may be disputed at any time in the future.
- 12.3 Radiographers may be delegated by radiologists or other medically qualified clinicians to obtain written informed consent for radiotherapy or oncology treatments and for certain imaging examinations. The SCoR policy is to recommend this extension in the scope of radiographic practice, if appropriate education and training at postgraduate level in specific skill development is carried out and that training records identify professionals who are competent in obtaining consent for specific procedures.
- 12.4 Radiographers should be aware that the Royal College of Radiologists (RCR) has provided examples on their websites of consent forms and information sheets for oncology treatments taken from a number of different departments in the UK⁵⁶.
- 12.5 In the case of written or verbal consent having been obtained, radiographers must record, preferably on the request card or within an electronic record, any refusal or withdrawal of consent by a patient. The radiographer must discuss with the patient the implications of refusal or withdrawal and record the details of the incident including the fact that discussions on implications were carried out with the patient. The date and timings must also be included.
- 12.6 By 2010, all patient records will be electronic, as part of the national drive to make the NHS more patient focused and improve patient choice. Radiographers should be familiar with ways of recording patient data and ensure adherence to the principles of the Data Protection Act 1998⁵⁷.

13. Consent for screening

- 13.1 Asymptomatic screening for disease is seen as an important public health measure in effective clinical care³⁷ on the basis of the assumption that the benefits outweigh any harm. There are, however, uncertainties associated with any screening procedure including false positive and false negative results, as well as possible physical and psychological detrimental effects including anxiety, over treatment and over diagnosis⁵⁸.
- 13.2 Individuals must be provided with full accurate information on which to make an informed choice of whether to participate or not. This information should be based on the best available current evidence and include what they want to know as well as what they need to know. Information should include the purpose of screening, the uncertainties and any associated risks. The health care team involved in any screening programme must regularly audit the information being sent out in advance of any procedure to ensure currency.
- 13.3 Edwards et al⁵⁹ recommend the use of numerical information in a form that is readily understandable with data presented as integers (eg three in 10 people) rather than as probabilities (eg 30% people) as it has been shown that relative risks increase the tendency of lay people to accept screening⁶⁰. Barratt et al⁶¹ have published data in easy to use, age specific estimates of benefits and harms of biennial mammography screening that could help support individual women's informed choices.
- 13.4 By attending a screening session, it might be assumed that the individual has made an informed choice rather than merely complying with an invitation to participate. Radiographers/sonographers must gain explicit verbal consent after assessing the individual's understanding of the procedure and be prepared to provide further information as well as answering questions. If the individual requires detailed information then it might be prudent to consider re-booking the appointment to allow time to consider the new information before consenting.
- 13.5 In addition, the radiographer/sonographer must use his/her professional judgement to note the physical and/or psychological behaviour of the attendee, which may indicate unwillingness to continue with the procedure and should respect the right of the attendee to withdraw consent at any time⁶².
- 13.6 In 2006, the Department of Health asked the Committee on Medical Aspects of Radiation in the Environment (COMARE) to address issues of radiation doses arising from new medical procedures starting with unregulated screening. The COMARE secretariat established a Medical Practices Subcommittee (MPS) to address these issues. Radiographers may wish to access the COMARE website to view any current reports⁶³.
- 13.7 Foetal anomaly screening has been described as an option rather than an inevitable aspect of routine antenatal care⁶⁴. Sonographers and referrers seeking and/or confirming consent should make it clear that refusal is an option. Prior to consent being given, sonographers should discuss with the woman the merits/demerits of foetal anomaly ultrasound including current values of sensitivity and specificity. Patients should also be made aware that there is potential to receive bad news both during and/or after the scan. Details of the nature of the discussions undertaken plus a record of the woman's verbal consent should be documented in the form of an entry in her healthcare record⁶⁵.

14. Consent and research

- 14.1 The Society and College of Radiographers is clear that radiographers have a professional and ethical responsibility to actively engage in research in order to develop the body of knowledge for the profession⁵.
- 14.2 The Central Office for Research Ethics Committees (COREC) provide advice and guidance, including consent issues, for researchers working in the NHS⁶⁶ and the Patient Information Advisory Group (PIAG) has provided information for patients about safeguarding information held about them and information about patients for health professionals and researchers⁶⁷. Radiographers who are involved in research undertaken on human subjects are advised to keep abreast of the publications arising from these two offices.
- 14.3 Any research on humans that involves NHS patients and resources usually have to submit a written proposal detailing the research to the appropriate research ethics committee (REC) to ensure that it accords with the accepted principles of ethical practice⁶⁸. COREC published a common application form for all applications to NHS RECs in 2004; since then the form has been further developed and COREC will continue to revise and improve the form in response to user feedback⁶⁹. COREC has also developed guidance for researchers to support them in terms of what research proposals require ethical review as part of the remit of an NHS REC⁷⁰.
- 14.4 Radiographers must be aware that the tenets of obtaining consent to participate in a research programme are exactly the same as for a diagnostic, treatment or care procedure (see Section 6 of this document).
- 14.5 Potential participants in a research project need information on which to base their decisions. Researchers should therefore seek consent following the provision of appropriate information (National Research Ethics Service, part of the National Patient Safety Agency that superseded COREC on 1 April 2007⁷¹).
- 14.6 For the purposes of research, explicit consent is usually required. However, implicit consent may be forthcoming, eg if an individual receives, completes and returns a questionnaire. The act of completion implies they have consented to participate. Radiographers should be aware though that the person completing the questionnaire must have received sufficient adequate information, have understood that information and was not coerced into completing the questionnaire.
- 14.7 For research involving the processing of personal health data, there is no absolute legal requirement under the *Data Protection Act (1998)* to obtain explicit consent as confirmed by the Information Commissioner (IC) – an independent official appointed by the Crown to oversee the Act. Data processing includes collection, use and disclosure of personal health records.
- 14.8 Of the eight principles of the Data Protection Act (1998), the First Principle “...personal data shall be processed fairly and lawfully..” and the Second Principle “personal data shall be obtained only for one or more specified and lawful purposes...” are applicable to research activities using personal data. The Act does, however, envisage some exceptions to the Second Principle, where personal data are processed for the purposes of research; these exceptions are set out in Section 33 of the Act commonly known as the ‘research exemption’. These exceptions can be applied where the processing (or further processing) is only for research purposes, and where the following conditions are met:
1. The data are not processed to support measures or decisions relating to particular individuals, and
 2. The data are not processed in such a way that substantial damage or substantial distress is, or is likely to be, caused to any data subject⁷².

- 14.9 The IC has clarified this further⁷² in relation to records-based research through clarification of two cases:
1. Where it is proposed to conduct research on current records or ones yet to be created the patient should be informed as part of the standard for processing information that their data may be used for research purposes and have the right to opt out.
 2. Where it is proposed to conduct research using existing records of patients who are no longer being treated for their condition such patients who may be contacted (without involving disproportionate effort) should be given fair processing information those patients who cannot be contacted (without disproportionate effort) need not be given the fair processing information but the researcher should record this fact.
- 14.10 However, the IC's general assumption is that the processing of health data by a health professional is subject to a "*duty of confidence*" even though explicit consent for processing is not a requirement of Schedule 3 of the *Data Protection Act 1998*. The Act does, however, require that personal data be processed lawfully in order to adhere to Principle One.
- 14.11 A distinction needs to be made in the processing of information between essential uses and disclosures of data (ie that data without which treatment could not be given) and non-essential uses and disclosures of data (ie that data used for secondary purpose including research or teaching, the former being implicit in the acceptance of treatment and thus not requiring consent for essential use. If standard fair processing information has been provided, and patients are advised that their records may be made available to researchers, they should be given the opportunity to opt out of this non-essential use.
- 14.12 The Information Commissioner has decided that whilst obtaining consent for medical research involving identifiable personal health data is the default position, there are circumstances where consent to process data may not be required. Radiographers should be aware of their "duty of confidence" and always seek advice from the relevant REC and from PIAG if deemed appropriate.
- 14.13 Radiographers undertaking medical or biomedical research which involves the application of radiation must be aware of IR(ME)R⁹ in this respect and the necessity for the appropriate regulations to be reflected in their employer's written policies and procedures. IR(ME)R 3(d) applies to the "exposure of patients or other persons voluntarily participating in medical or biomedical diagnostic or therapeutic research programmes." IR(ME)R 7(4) requires that for each medical or biomedical research programme falling into Reg 3(d), that "employer's written procedures should provide that (a) the individuals concerned participate voluntarily in the research programme and (b) the individuals concerned are informed in advance about the risks of the exposure".

15. Education and training

- 15.1 Radiography undergraduate programmes must include various aspects of consent issues from both legal and ethical perspectives. In addition, radiographers should be educated and trained in how to provide accurate, appropriate and timely patient information relative to diagnostic procedures and treatment regimes.
- 15.2 Education and training in the writing of notes related to a patient/client should ideally be part of any undergraduate course and a mandatory part of any postgraduate course because patient notes are legal documents. If formulated accurately and legibly, they will provide continuity of care for a patient and, in extreme cases, may provide a measure of protection for radiographers in litigious cases.
- 15.3 Competency in information giving and gaining consent must be maintained through individual continuing professional education ensuring that current evidence based practice in this field is adhered to.

16. Avoiding misunderstandings and use of chaperones

- 16.1 For all procedures which involve touching the patient in a place that they may deem to be sensitive, or where such areas might be exposed, it is essential that an explanation be given to the patient before the procedure commences. The explanation must include what part of the body will be touched and why it is necessary. For example, for an imaging examination of the hip, the radiographer might say "I will need to feel your hip bones so that I can position you correctly and get a good picture of your hip..." this needs to be done before the patient is asked to lie on the couch so there can be no possibility of coercion. In this way, it is hoped that the likelihood of any misunderstandings is avoided.
- 16.2 Radiographers are expected to use their professional judgement on whether a chaperone is necessary for a particular examination/treatment. A chaperone must be present during transrectal and transvaginal procedures. It may be prudent to involve a chaperone for other situations as judged by the radiographer.
- 16.3 Practitioners might usefully consider the issue of chaperoning together with consent and it is advisable to ensure that the patient agrees with and understands the role of staff that might be present during intimate examinations. Staffing levels may not permit the presence of a dedicated chaperone, but it is essential that support or other staff present accept this dimension to their role in such circumstances.
- 16.4 Individual departments may wish to develop protocols on when to employ chaperones in line with the guidelines of the employing authority and advice from the relevant Department of Health. Individual queries should be directed to the Society and College's Professional and Education team.
- 16.5 Recent changes in the law with regard to sexual offences may have a significant impact on the circumstances in which chaperoning is advisable. The notion that chaperoning is only appropriate when a male practitioner carries out an intimate examination on a female patient is outdated and does not reflect the implications of the law as it now stands. The law no longer defines the sex of alleged perpetrator or victim in the case of a sexual offence. The definition of rape includes penetration by an object and this can have serious implications for transvaginal and transrectal procedures. It is therefore advisable to have a chaperone present during all such examinations, irrespective of the sex of practitioner(s) and patient.

17. Forensic imaging

- 17.1 Forensic medicine refers to the application of medical knowledge in the collection of evidence to be used in a court of law. Individuals therefore may be imaged for legal and not for clinical purposes. In these cases, the procedure for obtaining consent from subjects and/or from relatives should be detailed within local written protocols and written informed consent must be obtained prior to the commencement of any examination⁷³.
- 17.2 Further information may be obtained from the new edition of the SCoR Forensic Imaging Guidance to be published in late 2007 or early 2008.

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Appendices

1. Twelve key points on consent: the law in England March 2001
2. Quick reference to key points. A good practice guide on consent for health professionals in NHSScotland
3. 12 key points on consent: the law in Northern Ireland

Appendix 1. Twelve key points on consent: the law in England & Wales

When do health professionals need consent from patients?

1. Before you examine, treat or care for competent adults you must obtain their consent.
2. Adults are always assumed to be competent unless demonstrated otherwise. If you have doubts about their competence, the question to ask is: "can this patient understand and weigh up the information needed to make this decision?" Unexpected decisions do not prove the patient is incompetent, but may indicate a need for further information or explanation.
3. Patients may be competent to make some health care decisions, even if they are not competent to make others.
4. Giving and obtaining consent is usually a process, not a one off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them.

Can children consent for themselves?

5. Before examining, treating or caring for a child, you must also seek consent. Young people aged 16 and 17 are presumed to have the competence to give consent for themselves. Younger children who understand fully what is involved in the proposed procedure can also give consent (although their parents will ideally be involved). In other cases, some one with parental responsibility must give consent on the child's behalf, unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent cannot override that consent. Legally, a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare.

Who is the right person to seek consent?

6. It is always best for the person actually treating the patient to seek the patient's consent. However, you may seek consent on behalf of colleagues if you are capable of performing the procedure in question, or if you have been specially trained to seek consent for that procedure.

What information should be provided?

7. Patients need sufficient information before they can decide whether to give their consent: for example information about the benefits and risks of the proposed treatment, and alternative treatments. If the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.

Is the patient's consent voluntary?

8. Consent must be given voluntarily: not under any form of duress or undue influence from health professionals, family or friends.

Does it matter how the patient gives consent?

9. No: consent can be written, oral or non-verbal. A signature on a consent form does not itself prove the consent is valid – the point of the form is to record the patient's decision, and also increasingly the discussions that have taken place. Your Trust or organisation may have a policy setting out when you need to obtain written consent.

Refusals of treatment

10. Competent adult patients are entitled to refuse treatment, even where it would clearly benefit their health. The only exception to this rule is where the treatment is for a mental disorder and the patient detained under the Mental Health Act 1983. A competent pregnant woman may refuse any treatment, even if this would be detrimental to the foetus.

Adults who are not competent to give consent

11. No one can give consent on behalf of an incompetent adult. However, you may still treat such a patient if the treatment would be in their best interests. 'Best interests' go wider than best medical interests, to include such factors as the wishes and beliefs of the patient when competent, their current wishes, their general well being and their spiritual and religious welfare. People close to the patient may be able to give you information on some of these factors. Where the patient has never been competent, relatives, carers and friends may be best placed to advise on the patient's needs and preferences.
12. If an incompetent patient has clearly indicated in the past, while competent, that they would refuse treatment in certain circumstance (an 'advanced refusal'), and those circumstances arise, you must abide by that refusal.

This summary cannot cover all situations. For more detail, consult the *Reference guide to consent for examination or treatment*, available from either England www.doh.gov.uk/consent

Wales www.wales.gov.uk/subihealth/toc-e.htm

Department of Health & Welsh Assembly

Appendix 2. A good practice guide on consent for health professionals in NHSScotland (Key Points) 16/7/06

When is it necessary for health professionals to obtain consent from patients?

1. Before you examine, investigate or treat patients you must have authorisation to proceed. This is often called 'getting consent'.
2. People aged 16 and over are presumed to have the capacity to make their own decisions. If you have doubts about someone's capacity, you may find it helpful to ask yourself "Can this person understand, retain and use the information they need to make this decision?" Decisions which are unusual or unexpected do not necessarily mean that the patient lacks capacity: it may indicate a need for further information or a clearer explanation.
3. People may have the capacity to take some healthcare decisions for themselves but may lack the capacity to decide about other, more complex matters.
4. Consent is usually a process, not an event. People can change their minds and withdraw their consent at any time. If in doubt, check with your patient to ensure that they still wish to continue with the healthcare being offered.
5. In an emergency, it is acceptable for you to save life or prevent serious deterioration in someone's medical condition without obtaining consent.

Can children consent to treatment themselves?

6. Once a person reaches the age of 16, Scots law gives them the legal capacity to make decisions for themselves. However, persons under the age of 16 have the legal capacity to authorize medical or dental care where, in the opinion of the practitioner looking after him or her, he or she is capable of understanding its nature and possible consequences. If the child has capacity, the child's decision must be respected. When a child cannot understand, then a parent or an adult with parental responsibility can make the decision on their behalf.

Who is the right person to ask for consent?

7. It is usually preferable for the health professional who will be carrying out the examination, investigation or treatment to obtain consent. However, you can ask on behalf of colleagues, if you are capable of performing the procedure in question or if you have been trained to seek consent for it.

What information should be provided?

8. People need sufficient information expressed in a way that they can understand before they can reach a decision. This should include the benefits and significant risks of the proposed intervention and any relevant options, including not having the intervention. The patient's questions must be answered truthfully. If you do not know the answers, you should identify a colleague who does know and listen when they discuss the issues with the patient.

Has consent been given voluntarily?

9. Consent to proceed must be given voluntarily, without pressure, deceit or undue influence from family, health professionals or others.

Does consent have to be in writing?

10. Some statutes require written consent to be obtained before a procedure can be carried out. Where there is no statutory requirement to obtain written consent, consent can be oral or non-verbal depending on the circumstances. A signature on a form is not in itself proof of valid authorisation. Its purpose is to record the decision and the discussions which have taken place beforehand. Your Board may have a policy setting out the circumstances in which you need to obtain the patient's consent in writing.

Refusing healthcare

11. People with capacity are entitled to refuse healthcare, even though you believe that it would be beneficial to them. However, an exception to this occurs where the treatment is for mental disorder and the patient detained under the Mental Health Care and Treatment (Scotland) Act 2003. The 2003 Act sets out the provisions for detention and treatment under the Act and the circumstances in which a patient's consent is not required.

Adults with Incapacity

12. The Adults with Incapacity (Scotland) Act 2000 sets out a framework for regulating interventions into the property, financial affairs and personal welfare of adults impaired capacity. It protects the interests of adults who are incapable of taking a decision because of mental disorder or because of physical disability which makes them unable to communicate. (Scottish Executive guidance is available on this Act and how it affects health professionals) The adult may be able to reach a healthcare decision where a relatively simple and low risk procedure is being proposed. If the adult is incapable in relation to a decision about the medical treatment in question and is not excepted treatment under the AWI Act), the AWI Act sets out a process to proceed with that medical treatment. (See further Chapter 3 of the full guidance document)

What about consent to disclose healthcare information?

13. Usually, you need the patient's permission before identifiable information about them is shared with other people. However, there are some exceptions to this rule. Examples include the statutory requirement to report particular events and where a court requires disclosure. There are other clinical situations where disclosure of healthcare information may be required as a matter of public safety. Non-identifiable information can be used for audit and planning healthcare services without the consent of the patient. See the Scottish Executive's guidance NHS Code of Practice on Protecting Patient Confidentiality for more information. Speak to your Caldicott Guardian or Data Protection Officer for advice.

The guidance will be reviewed and updated annually and is available at: www.show.scot.nhs.uk/publicationsindex.htm

Appendix 3. Good Practice in consent: Implementation guide for health care professionals 12 key points on consent: The Law in Northern Ireland (Department of Health, Social Services and Public Safety, 2003)

When do health professionals need consent from patients?

1. Before you examine, treat or care for competent adult patients, you must obtain their consent.
2. Adults are always assumed to be competent unless demonstrated otherwise. If you have doubts about their competence, the question to ask is: "Can this patient understand and weigh up the information needed to make this decision?" Unexpected decisions do not prove the person incompetent, but may indicate a need for further information or explanation.
3. Patients may be competent to make some health care decisions, even if they are not competent to make others.
4. Giving and obtaining consent is usually a process, not a one-off event. Patients can change their minds and withdraw consent at any time. If there is any doubt, you should always check that the patient still consents to your caring for or treating them.

Can children give consent for themselves?

5. Before examining, treating or caring for a child, you must also seek consent. Young people aged 16 and 17 are presumed to have the competence to give consent for themselves. Younger children who understand fully what is involved in the proposed procedure can also give consent (although their parents should ideally be involved). In other cases, someone with parental responsibility must give consent on the child's behalf, unless they cannot be reached in an emergency. If a competent child consents to treatment, a parent cannot override that consent. Legally a parent can consent if a competent child refuses, but it is likely that taking such a serious step will be rare.

Who is the right person to seek consent from a patient?

6. It is always best for the person actually treating the patient to seek consent. However, you may seek consent on behalf of colleagues if you are capable of performing the procedure in question, or if you have been specially trained to seek consent for that procedure.

What information should be provided when seeking consent?

7. Patients need sufficient information before they can decide whether to give their consent: for example information about the benefits and risks of the proposed treatment or course of action, and appropriate alternatives. If a patient is not offered as much information as they reasonably need to reach an informed decision, and in a form they can understand, their consent may not be valid.

Is the patient's consent voluntary?

8. Consent must be given voluntarily: not under any form of duress or undue influence from health professionals, family or friends.

Does it matter how the patient gives consent?

9. No: consent can be written, oral or non-verbal. A signature on a consent form does not itself prove the consent is valid – the point of the form is to record the patient's decision, and also increasingly the discussions that have taken place. Your Trust or organisation may have a policy setting out when you need to obtain written consent.

Refusals of treatment

10. Competent adults have the right to refuse treatment, even where it would clearly benefit them. A competent pregnant woman may refuse any treatment, even if this would be detrimental to the fetus.

Mental Health Legislation

11. Mental health legislation provides the possibility of treatment for a person's mental disorder or its complications without their consent. This legislation does not give power to treat unrelated physical illness without consent.

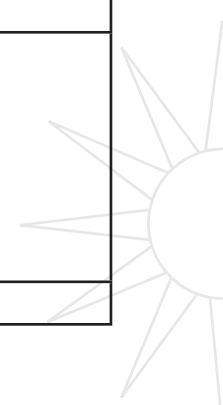
Adults who are not competent to give consent

12. No-one can give consent on behalf of an adult who is not deemed competent. However, you may still treat such a patient if the treatment would be in their best interests. 'Best interests' go wider than best medical interests, to include factors such as the wishes and beliefs of the patient when competent, their current wishes, their general well-being and their spiritual and religious welfare. People close to the patient may be able to give you information on some of these matters. Where the patient has never been competent, relatives, carers and friends may be best placed to advise on the patient's needs and preferences. If people no longer have capacity but have clearly indicated in the past that they would wish to refuse such treatment in the circumstance in which they now find themselves (an 'advance refusal'), the refusal must be accepted.

This summary cannot cover all situations. For more detail, consult the Reference Guide to Consent for Examination, Treatment or Care, available from your HPSS Trust and at www.dhsspsni.gov.uk

Appendix 4. Broad levels of risk for common x-ray examinations and isotope scans (X-rays how safe are they? NRPB May 2001, reproduced here by kind permission of the Health Protection Agency)

X-Ray examination (<i>nuclear medicine or isotope scan</i>)	Equivalent period of natural background radiation	Lifetime additional risk of cancer per examination *
Chest Teeth Arms & legs Hands & Feet	A few days	NEGLIGIBLE RISK Less than 1 in 1,000,000
Skull Head Neck	A few weeks	MINIMAL RISK 1 in 1,000,000 to 1 in 100,000
Breast (mammography) Hip Spine Abdomen Pelvis CT scan of head (<i>Lung isotope scan</i>) (<i>Kidney isotope scan</i>)	A few months to a year	VERY LOW RISK 1 in 100,000 to 1 in 10,000
Kidneys and bladder (IVU) Stomach- barium meal Colon- barium enema CT scan of chest CT scan of abdomen (Bone isotope scan)	A few years	LOW RISK 1 in 10,000 to 1 in 1,000
* These risk levels represent very small additions to the 1 in 3 chance we all have of getting cancer		







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