

Obtaining consent: a clinical guideline for the diagnostic imaging and radiotherapy workforce

Executive Summary

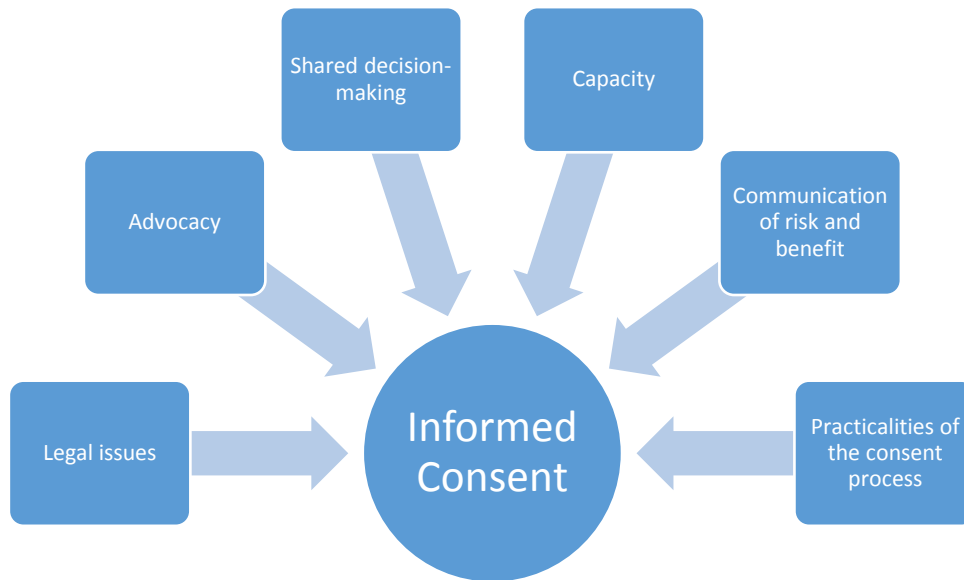
Seeking patient consent prior to undertaking an examination or treatment procedure is not only a fundamental, ethical and legal requirement of all healthcare practitioners, it is also a common courtesy as part of the process of creating a relationship of trust between healthcare practitioners and the patient or service user. When carrying out any procedure, the healthcare practitioner is ultimately responsible for ensuring that the patient or service user is genuinely consenting to the procedure being undertaken; it is they who will be held responsible in law if this is later challenged.

*The Final Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*¹ recommendations included the principle that the NHS and its staff must prioritise patients' needs at all times, be honest, transparent, and candid. Healthcare practitioners must adhere to this by placing the needs and values of patients, carers, and service users at the forefront of service delivery. This includes the requirement to seek and utilise service user feedback to drive future service improvements, so recognising patient and service users' needs at all levels of care and decision making.

It is recognised that all members of the diagnostic imaging and radiotherapy workforce are under a great deal of time pressure but it is imperative that they are aware of the issues surrounding the process of gaining consent from patients, service users, and others attending a clinical imaging or radiotherapy department. Healthcare practitioners should not assume that patients and service users attending a department for a diagnostic procedure or radiotherapy treatment have fully understood the information given to them and have thereby given true informed consent, because they are often unaware of the exact nature of the procedure which they will undergo.

This practice guideline provides a set of 10 evidence-based recommendations for the whole diagnostic imaging and radiotherapy workforce, including students and learners. It has been developed systematically using the best available evidence from research and expert opinion, including service users, and subjected to peer professional assessment. The aim is to encompass guidance relevant for use by clinical and non-clinical, registered and other practitioners, service managers, educationists and researchers. The guideline population covers people who attend diagnostic imaging and radiotherapy departments in all health and care sectors in the United Kingdom.

The ten recommendations are divided into specific sections reflecting six key themes identified from a literature search and review and also includes sections relating to: consent and children; student radiographers and trainee assistant practitioners' involvement in consent procedures; consent for screening; use of chaperones and consent.



Themes identified from the literature review

SCoR recommendation 1 - Legal issues:

In order for a patient or service user to give valid informed consent they should be in possession of all the information they require to make a decision, and should be able to do so voluntarily, without pressure from external influences. They will need to be made aware of the nature and purpose of any treatment/examinations and all relevant benefits and risks that may be important to them.

Patients are usually referred to diagnostic imaging or radiotherapy departments for diagnostic procedures or treatment. The referring clinician may have given some explanation of procedures and/or treatment, but it is essential for the healthcare practitioners obtaining or confirming consent to ensure that sufficient information has been given and that the opportunity to ask questions is allowed.

The SCoR recognises the time pressures radiographic practitioners are operating under and thereby recommends all departments adopt a consent process to ensure a valid informed consent has been achieved.

SCoR recommendation 2 - Advocacy:

There is a need to ensure that healthcare practitioners support and encourage their patients’ autonomy and patients’ rights. In some scenarios, patients and service users lack the ability or desire to be assertive at a time when they are potentially vulnerable. In these situations they may need a person to ‘speak on their behalf’, thereby acting as an advocate with regard to their care choices or concerns about the service they find themselves accessing.

The SCoR expects all practitioners to recognise their responsibilities with regard to patient advocacy and to equip themselves with the knowledge and skills to be able to perform this function.

SCoR recommendation 3 - Shared decision-making:

Consent is not a once-only decision but a process or a journey that happens gradually over time. Nor is it a rigid process; it must be personalised to suit the individual concerned, as all individuals vary in the rate at which they can assimilate the given information and make decisions. It is not good practice for a procedure to be described verbally immediately before it is undertaken.

The giving of information prior to gaining consent should not be regarded as a rigid process but as a flexible process to facilitate meaningful decision-making by the individual concerned.

The use of a tick box approach to information-giving is neither appropriate in a professional context nor helpful for the individual. Where centres produce information such as a list of tick boxes to facilitate the consent process, they should ensure that the process has been personalised to meet the individuals' needs.

SCoR recommendation 4 - Capacity:

Every adult has the right to make their own decisions and must be assumed to have capacity to do so, unless it is proven otherwise. Individuals have the right to be supported in making their own decisions and must be aided to do so. They retain the right to make what may seem as eccentric or unwise decisions.

Consent principles must apply to all patients and service users and where a patient or service user has a diagnosis that may affect their capacity to consent, it must not be automatically assumed that they are then unable to make any decision for themselves. Any decisions made on behalf of people without capacity must be in their best interests and done in the least restrictive manner possible, to preserve their basic rights and freedoms.

It is important that practitioners keep up to date and comply with the laws and codes of practice that apply to their work place. If there is any uncertainty about how the law applies in a given situation, they should consult with their employer, the SCoR, or seek independent legal advice.

SCoR recommendation 5 - Communication of risk and benefit:

It is incumbent upon the practitioner to find out the individual patient's priorities and concerns in order to tailor the information for consent accordingly.

The healthcare practitioner should inform the individual of the benefits, side effects and possible risks of the procedure, and the risks that not having the procedure may bring, whilst ensuring that they understand they are able to change their minds at any time if they do not wish to continue.

Such communication acknowledges that consent is not a 'once only' decision but a 'process over time' and that at any time during the procedure consent may be withdrawn. Information describing procedures should be given at a reasonable time before the procedure. This allows the patient or service user time to read the information, and then be given the opportunity to ask questions, enabling consent to be informed. Health care practitioners are reminded it is not good practice for the procedure to be described verbally immediately before the examination (as stated in recommendation 3).

Healthcare practitioners should not pass judgement on a competent person's decision to refuse an examination at any stage, even if the decision could be regarded as irrational. Practitioners must respect the patient's own lifestyle priorities and choices.

Effective communication and discussion at a level appropriate to the individual concerned is essential. This must include the risks that may arise as well as the benefits of undergoing imaging and/or treatments when using ionising and non-ionising radiation. The 2013 BSS EU Directive² (to become UK law by Feb 2018) states that the information must also include radiation doses for each specific

examination. Therefore, from 2018, radiographers will also be required to give an explanation to their patients about the radiation dose they will receive.

SCoR recommendation 6 - Practicalities of the consent process:

Consent can take a variety of forms: verbal, implied and written. The processes and practicalities involved can vary, and consent can be withdrawn at any time during the procedure. Technological changes in clinical practice are influencing the practicalities, with a necessity that processes evolve to be fit for purpose in an increasingly paperless working environment.

In the case of written or verbal consent having been obtained, records must be kept, preferably on a request card or within an electronic record. Any refusal or withdrawal of consent by a patient or service user must be discussed in terms of the implications of this decision. Details of the consent process must be recorded, including discussions about any possible implications, stating dates and times.

Practitioners should check their employing authority's policy regarding the requirement to obtain written consent for intimate and invasive examinations and procedures. Members of the imaging and radiotherapy workforce may be responsible for obtaining written informed consent for specified imaging examinations, radiotherapy and/or oncology treatments. These responsibilities will be detailed in their individual scope of practice, as defined in their job description.

SCoR recommendation 7 - Consent and children:

If a child is competent to give consent themselves, for either an examination or treatment, the healthcare professional 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.

In the event of a parent /carer or competent child subsequently refusing consent to an examination once in the clinical department, the practitioner will need to liaise with the requesting physician.

SCoR recommendation 8 - Student radiographers and trainee assistant practitioners' involvement in consent procedures:

Where a student may be present during an intimate procedure (e.g transrectal/transvaginal ultrasound, mammography, prostate brachytherapy) 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 and the student should also obtain consent themselves.

Patients must be made aware of which students and how many will be present prior to the request for explicit verbal consent. In all situations where consent is sought from a patient for a student to perform a procedure or to be present during an examination or procedure that may be considered to be intimate, the healthcare practitioner must ensure that a patient can decline without fear of offence.

SCoR recommendation 9 - Consent for screening:

Individuals must be provided with full, accurate information on which to make an informed choice whether or not to participate in asymptomatic screening. This information should be based on the best current evidence available and include what they want to know as well as what they need to know. The purpose of screening, the uncertainties, and any associated risks should be included.

The healthcare team involved in any National Screening Programme must regularly audit the information being disseminated to ensure that it remains current.

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. The healthcare professional responsible for the examination must gain explicit verbal consent after assessing the individual's understanding of the procedure and be prepared to provide further information and answer any 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.

In addition, healthcare professionals must use their professional judgement to note the physical and/or psychological behaviour of the attendee which may indicate an unwillingness to continue with the procedure and should respect the right of the attendee to withdraw consent at any time.

SCoR recommendation 10 - Use of chaperones and consent:

Practitioners might usefully consider the issue of chaperoning together with consent and it is advisable to ensure that the individual agrees with, and understands the role of, staff that might be present during intimate examinations or examinations deemed to be so by the patient.

Individual Trusts, Health Boards and other employers will also have their own intimate examination and chaperone policies to which healthcare practitioners should refer.

To assist practitioners a '*Remember ...*' information sheet is also available (see Appendix 4).

N.B since the development of this document the Health and Care Professions Council (HCPC) has produced '*Confidentiality – guidance for registrants*' which contains sections on consent. For further information please go to: <https://www.hcpc-uk.org/registration/meeting-our-standards/guidance-on-confidentiality/>

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Obtaining consent: a clinical guideline for the diagnostic imaging and radiotherapy workforce

1. Introduction

1.1 How was the topic identified?

The Society and College of Radiographers' (SCoR) pre-existing patient consent guidance consisted of several documents which had been published for some time. Changes in clinical practice arising from the emergence of increasing numbers of both consultant and advanced practice-level radiographers in all specialities within the radiography profession, the publication of Government reports such as *The Final Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*,¹ and the advent of new case law necessitated the review of this SCoR professional guidance. It was hoped that such a review would enable these to be amalgamated into one new, updated publication incorporating the latest evidence in relation to best practice.

For the purpose of clarity and consistency the following terms are used throughout this document. All other terminology is described in the *Glossary of Terms* at the end of the document.

Patient

A person who is under medical care or treatment. The patient is at the heart of all that SCoR members do and to whom a duty of care is owed.

Service user

Use of the term 'service user' is a broad phrase to refer to those who use or are affected by the range of services provided by SCoR members. There are occasions when the use of 'patient' may not be completely appropriate e.g in asymptomatic screening.

Diagnostic imaging and radiotherapy workforce

A broad term applying to SCoR members undertaking a wide scope of practice within diagnostic imaging, interventional and radiotherapy services.

Radiographer

The term 'radiographer' is used when it specifically applies to an individual who is registered with the Health and Care Professions Council (HCPC) with the protected title of radiographer, diagnostic radiographer or therapeutic radiographer.

Practitioner

A generic title used for a member of the SCoR to whom this consent guidance applies. As a practitioner they will work in varied diagnostic imaging and radiotherapy services and may be from varied backgrounds. The term can therefore apply to (for example) radiographers, sonographers, mammographers, nuclear medicine specialists and assistant practitioners. The use of this term does not imply *Agenda for Change*³ band or *Career Progression Framework*⁴ level or similar.

1.2 Why is consent important?

The legal context

Consent is defined as "*the principle that a person must give permission before they receive any type of medical treatment, test or examination*": such consent must be based on an explanation by the clinician.⁵

Seeking patient or service user consent prior to undertaking an examination or treatment regime is a fundamental ethical and legal requirement of a practitioner. It is also a common courtesy and establishes an appropriate relationship of trust between practitioner and patient. The principle of gaining consent demonstrates the practitioner's respect for the patient's autonomy and involvement in the decision making process.

"Touching a patient without their consent is, without lawful reason, capable of amounting to a charge of battery or trespass to the person": this is based upon the judgment of Lord Goff in *re F* [1990] 2 AC 1 (p 73).⁶ 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".⁷ Legal actions for battery against practitioners are relatively rare in the United Kingdom (UK) and unlikely to succeed. This guidance takes into consideration all four UK nations and differences have been identified where appropriate.

It has been established that the focus of legal action against any healthcare practitioner is more likely to be on the nature of the information given to, or withheld from, a patient on which they decide 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 a lack of duty of care, standard of care, causation, and that damage has occurred. Damage, in such cases, might be physical or psychological. It would appear from some sources that the healthcare practitioner is in a stronger position than the plaintiff to defend such an action. However, this does not absolve them from informing the patient, or seeking their consent to carry out a procedure.

1.3 How does this guidance fit with existing radiographic practice?

The SCoR gives professional leadership to the radiographic workforce and offers advice and guidance that promotes patient-centred care as part of high quality services. It provides a range of guidance including *The Code of Professional Conduct*⁸ which builds upon the *Health and Care Professions Council (HCPC) Standards of Conduct, Performance and Ethics*.⁹

This consent guidance publication supersedes previous publications¹⁰⁻¹⁴ by revising all previous guidance in the light of changes in professional practices, legal precedents and evolving technologies. As a consequence all previous consent publications are to be archived when this guidance is published.

All current SCoR policy, advice and guidance documents are available from the SCoR document library.

1.4 The policy context

Government policies over the years have been directed towards driving quality improvements to ensure equity of provision and consistency of high quality care while ensuring patient-centred care. There may be slight variations in Scottish Law. However the basic principles are the same.

Legislation in place includes:

- *The Human Rights Act*¹⁵ as the foundation for many of the issues raised in *The Final Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*¹
- *Mental Capacity Act*¹⁶ which states that the patient's best interest regarding treatment has to be at the centre of any decisions made
- *Equality Act*¹⁷ which states that reasonable adjustment has to be made for a disabled person
- *Mental Health Act (Scotland)*¹⁸
- *Patient Rights Act (Scotland)*¹⁹

*The Final Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*¹ recommended that NHS trusts must make it their first priority to deliver high class standards of care to all patients by putting their needs first. Person-centred care means putting patients and service users at the centre of all care and treatment, by empowering them through collaborative working and fostering the active participation of patients in decision-making at all levels.

1.5 Consent in the context of radiography

It is imperative that all members of the diagnostic imaging and radiotherapy workforce are aware of the issues surrounding the process of gaining consent from patients, service users and others attending a clinical imaging or radiotherapy department.

Radiographers, as one sector of the diagnostic imaging and radiotherapy workforce, 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 as outlined within *The Code of Professional Conduct*.⁸

The principle of consent to an examination carried out by a healthcare practitioner is the right of patients to determine what happens to their bodies.^{20, 21} The healthcare practitioner who does not respect this principle is potentially liable to both legal action by the patient and action from the relevant statutory regulatory body, such as the Health Care Professions Council (HCPC) or Nursing and Midwifery Council (NMC).

As professionals, radiographers 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 healthcare practitioner 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”*.²²

Healthcare practitioners should not assume that patients and service users attending a department for a diagnostic procedure or radiotherapy treatment have already given informed consent because often patients are unaware of the exact nature of the procedure which they will undergo.

In emergency situations where patients are unable to make any decisions and it may not always be possible to gain consent, the healthcare practitioners may provide imaging services and radiotherapy, provided it is immediately necessary to either prevent deterioration of a condition or to save a life.

2. Scope and purpose

The requirement to update the SCoR patient consent guidance was identified in the light of changes in legislation and professional practices with the need to incorporate updates to the original 2007¹⁰ guidance whilst amalgamating the subsequent related publications.¹¹⁻¹⁴ This task was prioritised by the SCoR Director of Professional Policy (DPP) in August 2016. It was deemed appropriate to develop a NICE accredited clinical practice guideline on obtaining consent for the entire diagnostic imaging and radiotherapy workforce. This practice guideline provides a set of evidence-based recommendations for the whole diagnostic imaging and radiotherapy workforce including students and learners. The aim is to encompass guidance relevant for clinical and non-clinical, registered and other practitioners, service managers, educationists and researchers. The guideline population covers people who attend diagnostic imaging and radiotherapy departments in all health and care sectors in the United Kingdom.

It has been developed systematically using the best available evidence from research and expert opinion including service users, and been subjected to peer professional assessment. The guideline has recommendations for all individuals working within the radiographic workforce, service managers, academic institutions and the Society and College of Radiographers.

3. Guideline question

The aim of this guidance is to answer the question: what evidence is there to assist radiographers and others to ensure informed consent is obtained from patients during their examination or treatment pathway in imaging and radiotherapy?

4. Guideline development process

4.1 Core group

The core group was brought together in October 2016 by a professional officer who was also the core group leader, under the direction of the DPP. The remaining five members were: an additional SCoR professional officer, an experienced academic therapeutic radiographer working as associate professor, an academic researcher with a diagnostic radiography background working as a senior lecturer in diagnostic imaging, and two members of the SCoR Public, Patient Liaison Group (PPLG). Details are listed in Appendix 1.

4.2 Stakeholder group

The 18 stakeholder group members providing responses to the first draft comprised 8 diagnostic radiographers and 10 therapeutic radiographers. They were drawn from both imaging and radiotherapy communities across the UK. They came forward as a result of an appeal in *Synergy News*, which is the SCoR monthly magazine, and the SCoR website. The names of stakeholder group members are listed in Appendix 1.

4.3 Peer review consultation process and outcomes

A first draft of the recommendations was circulated to an original stakeholder group of 51 members for comment on 19th May 2017, 18 of whom responded. There were approximately ninety comments made collectively which were duly considered by the core group members during May - June 2017 and a number of minor amendments and additions were made in response.

The revised draft guidance was sent to representatives from both NHS Improvement and NHS Screening Programmes for appraisal, scrutiny and comment in July 2017. All comments were conserved and amendments made in response. The finalised guidance document was sent to one external reviewer.

The responses received were considered by the core group and the final guidance document produced for UK Council approval.

4.4 Funding arrangements

One of the academic members of the core group was commissioned (with payment by honorarium of £500) to conduct and assimilate the literature review with her remaining time dedicated to core group activities given voluntarily. The professional officer members of the core group gave their time in their respective capacities as employees at the Society and College of Radiographers.

All other core and stakeholder group members and external reviewers gave their time and expertise voluntarily.

4.5 Conflict of interest

The SCoR policy and procedures for managing conflicts of interest was adhered to (Process Manual Appendix G.) All members of the core and stakeholder group have signed the Conflicts of Interest Declaration Form. No conflicts of interest were declared.

4.6 SCoR approval process

The practice guideline was submitted to the UK Council of the SCoR on the 5th July 2017. The document was approved with one amendment request.

Final document approval by the core group occurred in November 2017.

5. Guideline methodology

5.1 Literature search

The review was based on a systematic search of, Medline, Pub Med, Cinahl, EBSCO, Science Direct, Web of Science, NICE evidence, OVID, Index to Thesis and ZETOC databases and platforms.

5.2 Methodology

Previous literature searches that have informed SCoR publications, such as the *Guidance for skin care advice for patients undergoing radical external beam megavoltage radiotherapy*²³ have employed the PICO (patient/population, intervention, comparison, outcome) framework. The studies and publications that will inform this guidance did not include either a direct intervention or comparison approach so it was decided to adapt this framework in order to define the search parameters more accurately. The initial search strategy is outlined in Table 1.

Table 1: Adapted PICO method

Domain	Patient population	Outcome	Setting/ professional group
Keywords	Patients undergoing imaging and radiotherapy treatment and examinations	Consent to treatment	Radiography
		Informed consent	Radiotherapy
		Advocacy	Radiology

While the focus of this review was to inform radiography and radiotherapy practice, it is evident that this issue has been addressed by various other healthcare professional bodies and has also been the focus of extensive philosophical, ethical and legal debate. The core group were therefore mindful that this evidence be considered when attempting to answer the research question.

The scope of the review was further restricted since it only included sources published in the English language between the years 2007 and 2016. Informed consent within the research environment was also excluded.

An adult population (over 18 years of age) was the main focus, as separate guidance specifically for children and young adults was being developed in parallel with the proposed revised guidelines. Many of the key principles will, however, be applicable to all patient groups.

All appropriate full text articles and documentation underwent assessment for quality using the *Grading of Recommendation, Assessment, Development and Evaluation (GRADE) system*.²⁴

This approach did have to be adapted because none of the literature sources contained an intervention but it was still possible to assign a quality rating to each source of evidence.

5.3 Literature review

A flowchart indicating the number of sources identified and the final number of sources included is shown in Figure 1.

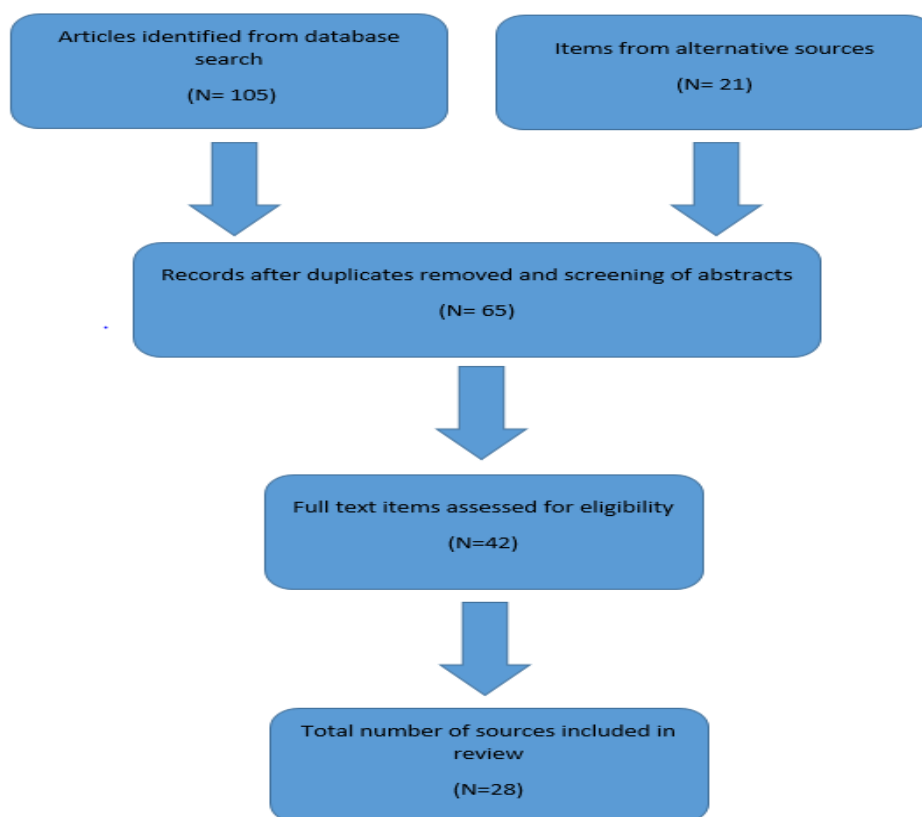


Figure 1: Flowchart of literature sources

The final number of sources selected for inclusion was 28. The constitution of their methodology/ approach is summarised in Table 2.

Table 2: Methodology of sources

Method	Number of Sources
Narrative analysis	7
Guidance from Professional bodies, Associations and networks	15
Empirical	5
Case Study	1
TOTAL	28

5.4 Description of how recommendations were developed

The evidence summarised below was considered by the core group and used as a foundation for the updated guidance, in keeping with development guidance issued by NICE.²⁵

5.5 Main review of evidence

This review was produced in order to provide information for updating the previously published guidance on *Consent to Imaging and Radiotherapy Treatment examinations*.¹⁰ Since the previous version there has been a slight change in the legal underpinning of the consent to treatment process and many professional bodies have issued comprehensive guidance in this area; notably the Department of Health,²⁰⁻²² the British Medical Association²⁶ and the General Medical Council.²⁷

The following review summarises the 28 sources of evidence that were identified by the systematic literature review and highlights key issues that will inform the core group in their updating process.

5.6 Summary and critique of articles.

A summary and critique of articles from the review can be found in Appendix 2 – with all articles in reference order as per main document and includes Table 3.

5.7 Summary of guidance from professional bodies, networks and associations

A summary of the guidance from professional bodies, networks and associations can be found in Appendix 3 – with all articles in reference order as per main document and includes Figure 2 and Table 4.

5.8 Themes identified

Figure 3 highlights the key themes identified from the review.

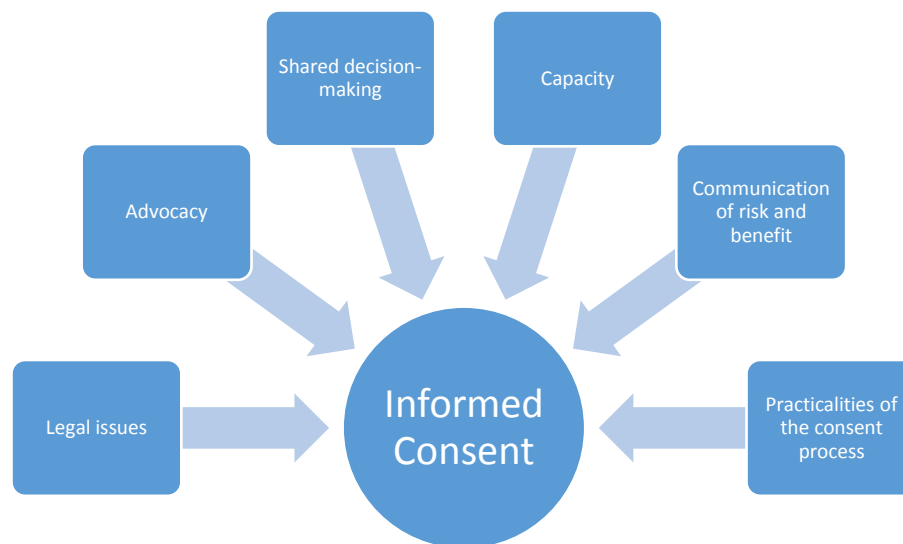


Figure 3: Themes identified from the literature review

5.9 Overview of evidence

The six main themes identified were:

1. Legal Issues: the main case being the *Montgomery v. Lanarkshire Health Board*.²⁹ The notion of consent for a specific patient will need to be included in any update.
2. Advocacy: practitioners should act as advocates so that patients are afforded sufficient information to be able to make an informed decision.
3. Shared decision making: consent to treatment should not be seen as an event but should be viewed as a process. Practitioners should support a patient's decision by responding to questions at any point before, during and after treatment.
4. Capacity: a patient should be assumed to have capacity to make a decision but some assessment of capacity may be necessary.
5. Communication of risk and benefit: this includes risks and benefits of the treatment or examination and the radiation risk (if appropriate).
6. Practicalities of the consent process: who should take the consent, what form it should take and sample documentation are important elements of the process.

These identified themes were considered by the core group members in order to update the existing guidance and to develop the recommendations for this guidance.

5.10 Limitations of the guideline including considerations of possible bias

The review focussed upon consent to treatment and excluded publications relating to research. This omission may have introduced some bias as consent in both areas is covered by the same general principles.

6. Background

Seeking patient consent prior to undertaking an examination or treatment procedure is not only a fundamental, ethical and legal requirement of all healthcare practitioners, it is also a common courtesy as part of the process of creating a relationship of trust between healthcare practitioners and the patient or service user. When carrying out any procedure the healthcare practitioner is ultimately responsible for ensuring that the patient or service user is genuinely consenting to the procedure being undertaken; it is they who will be held responsible in law if this is later challenged.

*The Final Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry*¹ recommendations included the principle that the NHS and its staff must prioritise patients' needs at all times, be honest, transparent, and candid. Healthcare practitioners must adhere to this by placing the needs and values of patients, carers, and service users at the forefront of service delivery. This includes the requirement to seek and utilise service user feedback to drive future service improvements, so recognising patient and service users' needs at all levels of care and decision making.

It is recognised that all members of the diagnostic imaging and radiotherapy workforce are under a great deal of time pressure but it is imperative that they are aware of the issues surrounding the process of gaining consent from patients, service users, and others attending a clinical imaging or radiotherapy department. Healthcare practitioners should not assume that patients and service users attending a department for a diagnostic procedure or radiotherapy treatment have fully understood the information given to them and have thereby given true informed consent, because they are often unaware of the exact nature of the procedure which they will undergo.

Increasing evidence that good patient experience is associated with safety reiterates the importance of patient involvement at all levels to help in the drive for safe, patient-centred service provision.⁴⁹

7. Guideline recommendations

The following recommendations are divided into specific sections to reflect the six key themes identified from the literature search and review, including sections relating to: consent and children; student radiographers and trainee assistant practitioners' involvement in consent procedures; consent for screening; use of chaperones and consent.

7.1 Legal issues

The Department of Health²⁰ stated that:

"It is a general legal and ethical principle that valid consent must be obtained before starting treatment or physical investigation, or providing personal care, for a person. This principle reflects the right of patients to determine what happens to their own bodies, and is a fundamental part of good practice."

In the UK, the process of information disclosure is underpinned by case law including the *Bolam Principle* - *Bolam v. Friern Hospital Management Committee Case*⁴¹- and *Bolitho Rulings* - *Bolitho v. City and Hackney HA Case*⁵⁰ - and was further endorsed by the *Sidaway v. Board of Governors of Bethlem Royal Hospital Case*.⁵¹ However, in 2015 the decision in the *Montgomery v. Lanarkshire Health Board Case*²⁹ moved legislation in this area towards a more patient-focussed approach to informed consent. The duty of care of healthcare practitioners 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 healthcare practitioner, a claimant must show that on balance the standard of care fell below what could reasonably have been expected from that healthcare practitioner: *"... 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."*⁴¹

The judgement given by the House of Lords in relation to the *Bolitho v. City and Hackney HA Case*⁵⁰ imposed 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 opinion.

The *Sidaway v. Board of Governors of Bethlem Royal Hospital Case*⁵¹ applied the principles to the "doctor's duty to inform his patient". These principles can now be generally related to all registered healthcare professionals and not just to the medical and dental professions.

The *Montgomery v. Lanarkshire Health Board Case*²⁹ however, signalled the need for consent that is tailored to "the specific patient" and the disclosure of risks that may be important to that patient. Analysis of this case by Sokol⁴⁰ suggested that practitioners should ask themselves the following questions when considering the legal aspects of the informed consent process:

Does the patient know about the material risks of the treatment I am proposing?

- *What sort of risks would a reasonable person in the patient's circumstances want to know?*
- *What sorts of risks would this particular patient want to know?*

Does the patient know about reasonable alternatives to this treatment?

Have I taken reasonable care to ensure that the patient actually knows all this?

Do any of the exceptions to my duty to disclose apply here?

Have I properly documented my consent process?

The General Medical Council²⁷ has always advocated that the consent process should be tailored to the individual patients according to:

- a. *their needs, wishes and priorities*
- b. *their level of knowledge about, and understanding of, their condition, prognosis and treatment options*
- c. *the nature of their condition*
- d. *the complexity of their treatment and*
- e. *the nature and level of risk associated with the investigation or treatment.*

GMC²⁷ p. 11

Negligence, in the case of information disclosure about a procedure, is the failure to make a patient aware of certain features and risks of a procedure resulting in the patient suffering damage.

The *Bolam Principle* - *Bolam v. Friern Hospital Management Committee Case*⁴¹ - established that, in the communication of risks, a health professional must communicate such information in accordance with contemporary practice accepted by a responsible body of professional opinion.

The House of Lords ruling in the case of *Chester v. Afshar*⁵² resulted in the NHS Litigation Authority (NHSLA) issuing a risk alert for clinicians with a series of recommendations.⁵³ When obtaining consent, careful and comprehensive warnings of adverse outcomes must be given. They must be properly recorded in writing, with the patient being asked to sign any relevant entry to confirm that they have been given the warning, have understood it and accept the risk.

The Department of Health's *Good Practice in Consent Implementation Guide*²² 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. Healthcare practitioners 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.

A recent publication by The Royal College of Surgeons - *Consent: Supported Decision-Making: A guide to good practice*⁴⁷ suggested a 10 step overview of the consent process to ensure that their members adhere to ethical and legal principles during the consent process. This advice has been adapted, as shown in Table 5, to suggest a step-by-step guide for healthcare practitioners involved in the consent process.

Table 5: Overview of consent process adapted from The Royal College of Surgeons⁴⁷

Step	Task	Comments
1	Explain the procedure or treatment to the patient.	Ensure that the information is given in a format that the patient can understand, appropriate to the patient's needs to ensure parity of care for all. This includes meeting the needs of individuals with physical difficulties and learning difficulties, and adequate provision of information in languages other than English.

2	Explain the risks/benefits for the procedure or treatment along with any alternative options (if applicable).	Explain the risks and benefits (including the radiation risk) of the various procedures or treatments.
3	Explain the consent and decision making process so the patient understands what is expected of them.	Ensure that the patient is supported during the decision making process. Make sure that they have access to an advocate if required.
4	Allow time for the patient to deliberate before being asked to consent to a procedure or treatment.	This can be difficult in a busy department but the patient should be afforded sufficient time for their deliberations.
5	Discuss the patient's wishes, needs, views and expectations regarding any procedure or treatment.	It is important not to make assumptions about what is "the best outcome" for a patient. They should be supported to come to the decision that is the best for them.
6	Provide any relevant information not already covered, or any emerging information.	This can help to clarify and again supports informed decision-making.
7	Has the patient understood?	The person taking the consent should be satisfied that the patient has understood the information provided.
8	Respect the patient's decision.	You must always respect the decision made by an adult patient with capacity.
9	Make sure the consent is documented. (The nature of the documentation may alter subject to the nature of the procedure /treatment).	In some instances a signed form should be retained in the patient's notes.

SCoR recommendation 1 - Legal issues:

In order for a patient to give valid informed consent, they should be in possession of all the information they require to make a decision and should be able to do so voluntarily, without pressure from external influences. They will need to be aware of the nature and purpose of any treatment/examinations and all relevant benefits and risks that may be important to them. Patients are often referred to diagnostic imaging or radiotherapy departments for diagnostic procedures or treatment. The referring clinician may have given some explanation of procedures and/or treatment, but it is essential for the healthcare practitioners obtaining or confirming consent to ensure that sufficient information has been given and that the opportunity to ask questions is allowed.

The SCoR recognises the time pressures radiographic practitioners are operating under and thereby recommends all departments adopt a consent process to ensure a valid informed consent has been achieved.

7.2 Advocacy

It is important for a patient to be supported during the informed consent process. The *SCoR Code of Conduct and Ethics*⁸ states that:

“1.3. You must listen to, and respect, the wishes of patients, seeking to empower them to make decisions about their care and treatment.

Working in partnership with patients is more than just giving appropriate information before undertaking examinations or treatment. It means transferring the decision-making to them, respecting their autonomy to make decisions about their own care or treatment and advocating with others on their behalf even if you do not agree with their decision. Full and truthful answers must be given to any question reasonably asked by the patient.”

For radiographers as Health Care Professions Council (HCPC) registered Allied Health Professionals, the advocacy role is also reflected in the *HCPC Code of Conduct, Performance and Ethics*.⁹

In some instances it may be appropriate for a radiographer to take on the role of patient advocate and this may necessitate the radiographer:

1. representing patients' values and rights to others
2. promoting patients' health through ensuring appropriateness of examination or treatment
3. ensuring that any radiation dose is appropriate and as low as reasonably achievable
4. recognising when patients are too shy to ask questions and who may be feeling powerless or intimidated by professionals or their environment
5. helping patients to communicate with doctors
6. recognising in patients the possibility of illiteracy or poor command of the English language and ensuring their needs and wants are clearly communicated
7. recognising those patients who may be unaware of their right to refuse an examination/treatment and supporting them after this refusal

SCoR recommendation 2 - Advocacy:

There is a need to ensure that healthcare practitioners support and encourage their patients' autonomy and patients' rights. In some scenarios, patients and service users lack the ability or desire to be assertive at a time when they are potentially vulnerable. In these situations they may need a person to 'speak on their behalf', thereby acting as an advocate with regard to their care choices or concerns about the service they find themselves accessing.

The SCoR expects all practitioners to recognise their responsibilities with regard to patient advocacy and to equip themselves with the knowledge and skills to be able to perform this function.

7.3 Shared decision making

Boyd³¹ highlighted that consent is not a 'once only' decision but it should be regarded as a process. He concluded that the partnership model for gaining consent is likely to be most useful and that it should also be remembered that at any time during a procedure the patient or service user may withdraw their consent.

Both Caulfield³³ and Colyer³⁴ recognised that radiographers should have greater awareness of the consent process and provide more input since they are capable of leading on patient consent in their areas of practice, i.e. that a medical practitioner is not necessarily needed to lead on consent for

treatment. They concluded that greater involvement of radiographers is likely to lead to benefits for the patients concerned, helping to ensure the delivery of patient-centred services.

Information describing procedures, especially interventional practice, should be given to the patient at a time before the procedure.^{54, 55} This information should include typical radiation doses for the procedure so the patient knows the risks and benefits.² This allows the patient time to read the information, and the opportunity to ask questions. This enables consent to be informed.

Farrell³⁵ discussed the consequences of the *Montgomery v. Lanarkshire Health Board Case*²⁹ as signalling that a more patient-focused approach to consent is required and that it should be patient-led and not practitioner-led. It is also important to remember that individuals' beliefs, culture, and social background may have a bearing on the type and nature of information required.

SCoR recommendation 3 - Shared decision-making:

Consent is not a once-only decision but a process or a journey that happens gradually over time. Nor is it a rigid process; it must be personalised to suit the individual concerned, as all individuals vary in the rate at which they can assimilate the given information and make decisions. It is not good practice for a procedure to be described verbally immediately before it is undertaken.

The giving of information prior to gaining consent should not be regarded as a rigid process but as a flexible process to facilitate meaningful decision making by the individual concerned.

The use of a tick box approach to information-giving is neither appropriate in a professional context nor helpful for the individual. When centres produce information, such as a list of tick boxes to facilitate the consent process, they should ensure that the process has been personalised to meet the individuals' needs.

7.4 Adults with impaired capacity

Many of the issues in the *Mental Capacity Act*¹⁶ are covered in sections 62 and 63 of the GMC²⁷ consent guidance which states:

'Making decisions about treatment and care for patients who lack capacity is governed in England and Wales by the Mental Capacity Act 2005, and in Scotland by the Adults with Incapacity (Scotland) Act 2000. The legislation sets out the criteria and procedures to be followed in making decisions when patients lack capacity to make these decisions for themselves. It also grants legal authority to certain people to make decisions on behalf of patients who lack capacity.¹³ In Northern Ireland, there is currently no relevant primary legislation; and decision-making for patients without capacity is governed by the common law, which requires that decisions must be made in a patient's best interests.'

The guidance that follows is consistent with the law across the UK and is based on the GMC²⁷ guidance and previous SCoR advice.

A person may be considered to lack capacity if, at any time, they are unable to make a decision for themselves because of an impairment of, or a disturbance in, the functioning of the mind or brain.¹⁶

A person who lacks capacity 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. There are however circumstances where the health care practitioner may 'act in the best interest' of the patient.

*The Mental Capacity Act*¹⁶ 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.

*The Mental Capacity Act*¹⁶ sets out that a person who lacks capacity is someone who is unable to make a decision for themselves as they are 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.

Practitioners should be aware that the doctrine of necessity provides justification for healthcare treatment and Section 5 of *The Mental Capacity Act*,¹⁶ based on this doctrine, provides statutory protection for healthcare practitioners to perform procedures for, or on, people who lack capacity and are thus unable to give valid consent.⁵⁶

Practitioners should also be aware that Section 5 of *The Mental Capacity Act*¹⁶ protects against liability in battery, but does not offer protection if the action is carried out negligently.

A key factor and 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. In England and Wales, it is required that an independent mental capacity advocate (IMCA) be consulted to represent and support persons under section 37 (1) of *The Mental Capacity Act*¹⁶; this is not required in Scotland or Northern Ireland.

The appropriate legislation for Scotland is the *Adults with Incapacity (Scotland) Act*⁵⁷ which is applicable to people 16 years and over who are resident or present in Scotland who lack mental capacity. Practitioners working in Scotland must familiarise themselves with the requirements of this Act and the *Scottish Executive Good Practice Guide on Consent for Health Professionals in NHS Scotland*.⁵⁸

The GMC have an interactive tool to help with decisions about consent when there are capacity issues⁵⁹ and Public Health England (PHE) screening has a useful blog on the issue of consent and mental capacity.⁶⁰

Lasting power of attorney

A lasting power of attorney (LPA) is a legal document that lets the patient appoint one or more people (known as ‘attorneys’) to help them make decisions or to make decisions on their behalf. There are two types of LPA:

- health and welfare (healthcare);
- property and financial affairs

The health care power of attorney is a document in which a person may designate one or more people to be their representative, or agent, in the event that they are unable to make or communicate decisions about all aspects of their health care. This is especially important in the area of consent to

examination or treatment. The attorney can then act as an advocate to make decisions that are in the patient's best interest.

SCoR recommendation 4 - Capacity:

Every adult has the right to make their own decisions and must be assumed to have capacity to do so, unless it is proven otherwise. Individuals have the right to be supported in making their own decisions and must be aided to do so. They retain the right to make what may seem as eccentric or unwise decisions.

Consent principles must apply to all patients and service users and where a patient or service user has a diagnosis that may affect their capacity to consent, it must not be automatically assumed that they are then unable to make any decision for themselves. Any decisions made on behalf of people without capacity must be in their best interests and done in the least restrictive manner possible, to preserve their basic rights and freedoms.

It is important that practitioners keep up to date and comply with the laws and codes of practice that apply to their work place. If there is any uncertainty about how the law applies in a given situation, they should consult with their employer, the SCoR or seek independent legal advice.

7.5 Communication

The Clinical Human Factors Group (CHFG), a coalition group of healthcare professionals, managers, service users and experts in human factors, define communication as a “*process of passing information or instructions between people so that it is received and understood as intended*” to enhance and support patient safety.⁴⁹ This intention has to be balanced with the ruling from *Montgomery v. Lanarkshire Health Board Case*²⁹ which introduced the concept of ‘*material risk or significant risk*’. These terms imply that doctors need to inform the patient of the risks inherent in the proposed treatment and make a judgement on whether a reasonable person would attach significance to the risk and/or all possible options.⁶¹

As a result, the healthcare practitioner is expected to approach any clinical communication from a patient-centred perspective, that is, ‘*what a reasonable person would want to know to make informed choice*’.⁶²

Other notable considerations include the *Bolam Principle - Bolam v. Friern Hospital Management Committee Case*⁴¹ - which established that, in the communication of risks, a healthcare practitioner must communicate such information and risks in accordance with contemporary practice accepted by a responsible body of professional opinion.

The House of Lords’ ruling in the case of *Chester v. Afshar*⁵² resulted in the NHS Litigation Authority (NHSLA) issuing a risk alert for clinicians with a series of recommendations.⁵³

Guidance on communication

Voluntary agreement by the patient

It is not appropriate to wait until the patient is in a vulnerable state, e.g. 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.⁶³

When obtaining consent, careful and comprehensive warnings of adverse outcomes must be given; they must be properly recorded in writing with the patient being asked to sign any relevant entry to confirm that they have been given the warning, have understood it, and accept the risk.

Sufficient information

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 practitioner and for patient consent.

To facilitate meaningful decision making by the patient, flexibility should be adopted in the information giving process prior to gaining consent for the procedure.

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 able to carry out the procedure or be aware of the full details of the procedure themselves, but have sufficient knowledge to fully inform the patient of the benefits, side effects and risks of the said procedure.

Patients and service users are entitled to have information provided prior to any procedure. The 2013 BSS EU Directive² (to become UK law by Feb 2018) states that the information must include radiation doses for each specific examination. Therefore, from 2018, radiographers will be required to give an explanation to their patients about the radiation dose they will receive.

The healthcare practitioner should give accurate and relevant information in a form that the patient is able to grasp and thus understand. The amount and form of information will vary from patient to patient and the practitioner must tailor these to the individual using their professional judgement.

The healthcare practitioner should be aware that presenting an overwhelming amount of information may hinder the patient's decision-making ability. They must ensure that they have developed competencies in information-giving and in understanding and assessing patients' needs and values in relation to decision making in healthcare.⁵⁴

The whole process of gaining informed consent 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 required. The use of a tick box approach to information-giving is neither appropriate in a professional context nor helpful for the individual patient.²⁷

The practitioner 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 or unavoidable risks, even if small; and the risk of doing nothing. The patient must also be informed of any alternatives to the procedure.²⁰

In providing written information to assist understanding, healthcare practitioners should take note of the readability level of the content. Readability involves matching the *'reading level of the written material to the reader's ability to read and understand the content'*.⁶⁴ Most people are considered to have a readability of 10. Around 5.1 million people have literacy levels below that of an 11 year old

meaning that they would have difficulty in reading information from unfamiliar sources.⁶⁴ Written content in information leaflets may be checked by using the *SMOG* (simplified measure of gobbledygook) test to calculate a score.

There may be a need to provide information in languages other than English. NHS England has produced guidance on providing high quality interpretation services. It states that “Information relating to health and primary care services should be available in languages appropriate to local communities and using appropriate communication formats (such as written, audio and sign language video)”.⁶⁵

Information requirements may also need to be adjusted to suit the needs of patients, carers and service users with learning difficulties. One to two percent of the general population have learning difficulties.⁶⁶ ⁶⁷ Such patients have high levels of unmet needs, with service users experiencing “*feelings of unfairness and inequality*”.⁶⁸ In communication for consent, practitioners are advised to establish the type of learning difficulty unless this is already known, and assess the patient’s requirements.

Communication should be appropriate to support a patient’s understanding and the use of different formats, e.g. audio, easy-reading information leaflets and video should be considered to support information giving and discussion.⁶⁹

For healthcare practitioners involved in triaging patients in minor trauma units, communication is important in ascertaining the patient’s concerns and providing information effectively to support the patient’s decision-making.

Information about risk: benefit and significant risks

Many procedures undertaken in imaging and radiotherapy departments carry a risk, including a radiation risk.⁴⁶ 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 risk. The practitioner, under the *Ionising Radiation (Medical Exposure) Regulations (IR[ME]R)*⁷⁰ and *IR[ME]R amendments*⁷¹, 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. Although “consent” is not specifically mentioned in the *Ionising Radiation (Medical Exposure) Regulations (IR[ME]R)*,⁷⁰ it is good practice that information about the risks and benefits should still be given to the patient.

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 proposed benefits and risks of the procedure. At the time of writing it is not a legal requirement to know the dose of radiation given, but disclosure of a radiation risk could be mandatory in the future when the new legislation is published.

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. Practitioners should respond in an appropriate way using their own judgement to decide on the ability of the patient to understand a risk: benefit approach.^{72, 73} Radiographers should be cognisant of the potential harm that information on risk could cause.⁷⁴

Practitioners should respond to queries by taking the advice of Public Health England's *Patient dose information: guidance*⁷⁵ avoiding the use of the term "safe" in favour of terms that describe a radiation risk as being low or very low⁷⁶ compared with other risks in society.⁷⁵

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 regimens that patients should be informed of any significant radiation dosage and the inherent risks of radiation and other possible side effects.⁷⁷ 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.

SCoR recommendation 5 - Communication of risk and benefit:

It is incumbent upon the practitioner to find out the individual patient's priorities and concerns in order to tailor the information for consent accordingly.

The healthcare practitioner should inform the patient of the benefits, side effects and possible risks of the procedure, and the risks that not having the procedure may bring, whilst ensuring that they understand they are able to change their minds at any time if they do not wish to continue.

Such communication acknowledges that consent is not a 'once only' decision but a 'process over time' and that at any time during the procedure consent may be withdrawn. Information describing procedures should be given at a reasonable time before the procedure. This allows the patient or service user time to read the information, and then be given the opportunity to ask questions, enabling consent to be informed. Health care practitioners are reminded it is not good practice for the procedure to be described verbally immediately before the examination (as stated in recommendation 3).

Healthcare practitioners should not pass judgement on a competent person's decision to refuse an examination at any stage, even if the decision could be regarded as irrational. Practitioners must respect the patient's own lifestyle priorities and choices.

Effective communication and discussion at a level appropriate to the patient concerned is essential. This must include the risks that may arise as well as the benefits of undergoing imaging and/or treatments when using ionising and non-ionising radiation. The 2013 BSS EU Directive² (to become UK law by Feb 2018) states that the information must also include radiation doses for each specific examination. Therefore, from 2018, radiographers will also be required to give an explanation to their patients about the radiation dose they will receive.

7. 6 Practicalities of the consent process

Valid legal consent to treatment or examination can be implied consent or express consent (oral or written). Procedures should not be undertaken unless the practitioner is satisfied that the patient has given consent and understands the nature of the procedure.

Implied consent is an agreement signalled by the behaviour of an informed patient or service user who may not express themselves verbally but does as requested by the healthcare practitioner. The giving of information to the patient distinguishes **implied** consent from **compliance with** a request (e.g. lying on an X-ray couch or presenting an arm for an injection). It is advisable to always seek the explicit verbal affirmation of a patient or service user prior to undertaking any procedure and not rely on their compliance.⁷⁸

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. Express consent may be:

- a) Verbal consent. This is acceptable as long as the patient or service user is legally competent, the consent was voluntary and they were provided with sufficient information on which to base their consent;
- b) Written consent. This 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.

According to the Health and Safety Executive, significant risks are '*capable of creating a real risk to health and safety which any reasonable person would appreciate and take steps to guard against*'.⁷⁹

The adaptation of the Royal College of Surgeons 10 step guide⁴⁷ (Table 5, p. 22) of the consent process assists with ensuring healthcare practitioners adhere to the necessary ethical and legal principles.

The Department of Health²⁰ highlights the requirement for consent forms and includes suggested phrases to be included in written consent forms which may be used for certain examinations with individual Trusts and other organisations stipulating requirements.

The SCoR policy⁸⁰ is that any extension in an individual's scope of radiographic practice is allowable, provided 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. Individual extensions to scope of practice must comply with their employer's local governance requirements and be approved at board level.

Radiographers should be aware that the Royal College of Radiologists (RCR) has provided examples of consent forms and information sheets for oncology treatments⁸¹ on their website from a number of different departments in the UK.

Electronic patient record keeping is commonly in use. The SCoR expects that all members of the radiographic workforce should be familiar with ways of recording patient data and ensure adherence to the principles of the *Data Protection Act*.⁸²

SCoR recommendation 6 - Practicalities of the consent process:

Consent can take a variety of forms: verbal, implied and written. The processes and practicalities involved can vary and consent can be withdrawn at any time during the procedure. Technological changes in clinical practice are influencing the practicalities, with a necessity that processes evolve to be fit for purpose in an increasingly paperless working environment.

Practitioners should check their employing authority's policy with regard to the requirement to obtaining written consent for intimate and invasive examinations and procedures. Members of the imaging and radiotherapy workforce may be responsible for obtaining written informed consent for specified imaging examinations, radiotherapy and/or oncology treatments. These responsibilities will be detailed in their individual scope of practice, as defined in their job description.

In the case of written or verbal consent having been obtained, records must be kept, preferably on a request card or within an electronic record. Any refusal or withdrawal of consent by a patient or

service user must be discussed in terms of the implications of this decision. Details of the consent process must be recorded, including discussions about any possible implications, stating dates and times.

7.7 Consent and children

Legally a child is a person who has not yet attained the age of 18 years. However, Section 8 of the *Family Law Reform Act*⁸³ states 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 practitioner to encourage children of this age to involve their families in the decision making process unless the practitioner believes that it is not in the best interests of the child to do so.

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 them to understand fully what is proposed*”, known as either ‘Gillick competence’ or ‘Fraser ruling competence’.⁸⁴

Fraser competence

The Fraser guidelines were set out by Lord Fraser in his judgment of the *Gillick v. West Norfolk and Wisbech AHA Case*⁸⁵ which apply specifically to contraceptive advice. Lord Fraser stated that a doctor could proceed to give advice and treatment “provided he is satisfied in the following criteria:

1. that the girl (although under the age of 16 years of age) will understand his advice;
2. that he cannot persuade her to inform her parents or to allow him to inform the parents that she is seeking contraceptive advice;
3. that she is very likely to continue having sexual intercourse with or without contraceptive treatment;
4. that unless she receives contraceptive advice or treatment her physical or mental health or both are likely to suffer;
5. that her best interests require him to give her contraceptive advice, treatment or both without the parental consent”⁸⁵

Although this ruling was specific to contraceptive advice, the principles have been applied more widely to general areas of treatment and advice.

Criteria for judging ‘Gillick competence’⁸⁴ and the lower age range are not clear and practitioners are advised that “*legal capacity by a child varies according to the particular matter and maturity and understanding of the particular young person.*”⁸⁶ 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 competent’. This, however, may well depend on the nature of the procedure to be undertaken. It is important, therefore, for practitioners to recognise that they must exercise professional judgement in this regard each time they carry out a diagnostic examination or treatment procedure.

The 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*⁸⁷ allows a young person with no specified age range to consent on their own behalf to a medical procedure provided that, in the opinion of a qualified medical practitioner, they are capable of understanding the nature and possible consequences of the treatment.

Should a ‘Gillick (Fraser) competent’ child consent to a procedure, a parent cannot over-ride that consent. However, a parent can consent to a procedure should a ‘Gillick (Fraser) competent’ child

refuse. 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's Act*⁸⁸ for the procedure to be carried out in the best interests of the child.

Should a 'Gillick (Fraser) competent' child or young person consent to a procedure, this consent is only valid if it is given voluntarily. Undue pressure from family, carers or partners may influence decisions, therefore it is incumbent upon the practitioner to establish that the decision has been made by the individual.²⁰

SCoR recommendation 7 - consent and children:

If a child is competent to give consent for themselves, for either an examination or treatment, the healthcare professional 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.

In the event of a parent/carer or competent child subsequently refusing consent to the examination once in the clinical department, the practitioner will need to liaise with the requesting physician.

7.8 Student radiographer, assistant practitioner and trainee assistant practitioner involvement in consent procedures

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 practitioner.

The Department of Health's guidance²¹ also states that a patient's specific consent is not required for procedures undertaken by students if such procedures are part of the patient's normal care.

The Society and College of Radiographers¹³ 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.

The HCPC Guidance on Conduct and ethics for students⁸⁹ advises that the student should make sure that, before any intervention is carried out, the service user:

- is aware that a student will undertake the procedure;
- has given their permission for the intervention to be carried out by a student;
- has been given an explanation by the student about the procedure to be carried out;
- has been given an explanation of any risks associated with the procedure.

The task of gaining consent may be delegated by a supervising radiographer to the non-registered worker who is proven competent to do so following education and training. The radiographer retains the overall responsibility for the task and accountability for the decision to delegate. The person who has been delegated the task is responsible for their own actions.

Assistant practitioners in clinical imaging undertaking limited protocol-driven general radiology, ultrasound, and mammography examinations on the co-operative, communicative, and conscious adult patient, may take responsibility for obtaining patient consent in these limited contexts provided they are

proven competent to do so following education and training. Obtaining consent for radiotherapy is deemed to be beyond the scope of practice and role of the assistant practitioner in radiotherapy.⁹⁰

SCoR recommendation 8 - student radiographers' and trainee assistant practitioners' involvement in consent procedures:

Where a student may be present during an intimate procedure (e.g. transrectal/transvaginal ultrasound, mammography, prostate brachytherapy), 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 and the student should also obtain consent themselves.

Patients must be made aware of which students and how many will be present prior to the request for explicit verbal consent. In all situations where consent is sought from a patient for a student to perform a procedure or to be present during an examination or procedure that may be considered to be intimate, the healthcare practitioner must ensure that a patient can decline without fear of offence.

7.9 Consent for screening

7.9.1 National Screening Programmes

Asymptomatic screening for disease is seen as an important public health measure in effective clinical care 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 diagnosis.

The United Kingdom National Screening Committee (NSC)⁹¹ advises ministers in all four countries and resides within Public Health England, an executive agency of the Department of Health. Before any pathology or condition is accepted for national screening, there is a full evaluation against the NSC published criteria.⁹²

It should be noted that there may be variations in the screening programmes that operate across the four countries of the UK and practitioners should contact the relevant organisations for current advice.⁹³⁻⁹⁵

The diagnostic imaging and radiotherapy workforce may be directly involved with numerous national screening programmes.⁹⁶⁻¹⁰¹

PHE screening also has a useful blog on the issue of consent and mental capacity.⁶⁰

7.9.2 Asymptomatic screening outside the National Screening Programmes (Unregulated screening, private screening, health assessment).

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 (often known as health assessment). 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 reports by COMARE.¹⁰²

These screening services are generally provided by the independent sector. They may use CT or other procedures involving ionising radiation to do the assessments and because there is no specific referral (the person completes a questionnaire to get a 'risk score'), then the radiographers delivering the ionising radiation exposure must ensure that the person is fully aware of the risks as well as the benefits of the examination (including the radiation doses given).

Healthcare assessments may also be offered by companies using other imaging modalities, such as ultrasound, where ionising radiation considerations do not apply. Public Health England also provide advice on private screening.¹⁰³

SCoR recommendation 9 - consent for screening:

Individuals must be provided with full, accurate information on which to make an informed choice whether or not to participate in asymptomatic screening. This information should be based on the best current evidence available and include what they want to know as well as what they need to know. The purpose of screening, the uncertainties, and any associated risks should be included. The healthcare team involved in any National Screening Programme must regularly audit the information being disseminated to ensure that it remains current.

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. The healthcare professional responsible for the examination must gain explicit verbal consent after assessing the individual's understanding of the procedure and be prepared to provide further information and answer any 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.

In addition, healthcare professionals must use their professional judgement to note the physical and/or psychological behaviour of the attendee which may indicate an unwillingness to continue with the procedure and the right of the attendee to withdraw consent at any time should be respected.

7.10 Avoiding misunderstandings and use of chaperones

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.

The patient should be offered the security of having an impartial observer (a chaperone) present during an intimate examination and the patient has a right to request that one is present. For professional integrity and safety the healthcare practitioner should give equal consideration to their own need for a chaperone irrespective of the examination being undertaken or the gender of the patient. This applies whether or not the healthcare practitioner is the same gender as the patient. It is also good practice to be prepared to offer a chaperone even when the examination is not considered to be an intimate one.¹⁰⁴⁻¹⁰⁷ When using ionising radiation, the chaperone should not be in the room during exposure.

SCoR recommendation 10 - use of chaperones and consent:

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 or examinations deemed to be so by the patient.

Individual Trusts, Health Boards and other employers will also have their own intimate examination and chaperone policies to which healthcare practitioners should refer.

7.11 Consent and research

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 profession.¹⁰⁸

The Health Research Authority (HRA) provides advice and guidance, including research consent, for researchers working in the NHS. The Patient Information Advisory Group (PIAG) has provided information for patients about safeguarding information held about them and information about patients for health practitioners and researchers. Healthcare practitioners who are involved in research undertaken on human subjects are advised to keep abreast of the publications arising from these two offices.

Any research on human subjects that involves NHS patients and resources usually requires a written proposal be submitted to the appropriate research ethics committee (REC) covering details of the research to ensure that it accords with the accepted principles of ethical practice.

Healthcare practitioners must be aware that the tenets of obtaining consent to participate in a research programme are exactly the same as those for a diagnostic, treatment or care procedure.

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.

The Health Research Authority (HRA) has revised the previous National Research Ethics Service guidance on the design of participant information sheets and consent forms.¹⁰⁹

Practitioners undertaking medical or biomedical research involving the application of ionising radiation must be aware of *IR(ME)R*⁷⁰ 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) "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".

The *IR(ME)R* update Regulations⁷¹ includes definitions of "ethics committee" in relation to research exposures across the UK.

Due to the robust governance arrangements required of all research studies and the availability of specific guidance from HRA, it has been concluded that it is beyond the scope of this guidance to include

any further specific information related to patient consent requirements of research activities undertaken by members of the radiographic workforce.

N.B since the development of this document the Health and Care Professions Council (HCPC) has produced '*Confidentiality – guidance for registrants*' which contains sections on consent. For further information please go to: <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/consent>

8. Implementation strategies

The SCoR will disseminate this guideline through its networks. These include regular meetings of members and managers, conferences and study days.

To assist practitioners, patients and carers, the core group has developed:

- An executive summary document outlining the rationale and 10 key recommendations;
- A 'Remember ...' information sheet for health professionals (see Appendix 4);
- A presentation for use at conference and events (see Appendix 5);
- A poster and associated hand-outs for use at conference and events (see Appendix 6).

8.1 Impact measures and audit tools

All employing authorities are required to have governance arrangements in place that include locally developed audit tools for patient experience. These can be adapted to measure the impact of effective informed consent, if not already encompassing this aspect of patient care.

8.2 Organisational or financial barriers to implementation

The majority of the recommendations have no financial implications. There is a requirement that practitioners update themselves with the details of this refreshed guidance.

9. Recommendations for future research

Suggested areas of investigation include researching the patient or service users' perspectives to build a greater understanding of their wishes.

10. Dates of publication, process and timing of review and updating

Three-yearly review unless an earlier review is indicated. This may be required because of changes in policy, published evidence or case law to indicate a need for the practice guideline to be updated. Policy changes are monitored and reviewed by the SCoR team of professional staff.

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(All links last accessed 17 January 2020)

Please note: some sites need registration/log in for access to documents

. Glossary of terms

Anaesthesia – the use of gases or drugs given to individuals to artificially induce insensitivity to pain.

Assistant practitioners - non-registered staff trained to high standards to perform a specific range of clinical imaging examinations or treatment procedures. Assistant practitioners' work is delegated under the supervision of a registered radiographer or radiologist taking responsibility for the episode of care.

Asymptomatic screening - the medical screening of those showing no apparent symptoms of disease.

Brachytherapy - a type of internal radiotherapy, in which radioactive material is placed within the body using specially designed equipment. Radioactive sources are sited to a known location inside the patient for a specific time to deliver the required dose of radiation. This is often used for the treatment of patients with cancer of the cervix, uterus, oesophagus and prostate.

Clinical imaging - the technique and process of creating visual representations of the interior of a body for clinical analysis and medical intervention. Imaging techniques encompass the fields of radiology, nuclear medicine and digital imaging and image-guided intervention.

Clinical Oncologist - A doctor trained in the diagnosis and treatment of cancer using radiotherapy and/or chemotherapy. They work closely with surgeons, clinical radiologists, pathologists and medical oncologists deciding and defining the best treatments for a patient's cancer. They plan and prescribe radiation and other therapy and liaise with psychologists, complementary therapy specialists etc. in the wider treatment of cancer and its effects. They also ensure that patients who cannot be cured are kept symptom-free.

CT examination - a computerised tomography (CT) scan uses X-rays and a computer to create detailed images of the inside of the body.

Diagnostic procedure – a type of test carried out to help diagnose a disease or condition.

External beam radiotherapy - this is delivered by using radiation sources from outside the body. The types of treatments most frequently used are using linear accelerators delivering high energy megavoltage x-rays.

Interventional radiological procedures - a term used to describe a range of techniques which use radiological image guidance (X-ray fluoroscopy, ultrasound, computed tomography [CT] or magnetic resonance imaging [MRI]) to accurately target treatment.

Ionising radiation - electromagnetic radiation in the form of x-rays or radioactive substances used for diagnosis of health conditions and treatment of cancer.

Mammography - the use of low-energy X-rays to examine the human breast for screening and diagnosis.

Nuclear medicine - a branch of medical imaging that uses small amounts of radioactive material to diagnose and determine the severity of or treat a variety of diseases, including many types of cancers.

Palliative radiotherapy – the use of radiotherapy with the aim of relieving symptoms such as pain, in order to improve the quality of the patient’s life in advanced stages of disease.

Peer-professional assessment - an evaluation of scientific, academic, or professional work by others working in the same field.

Plaintiff – a person who brings a case against another in a court of law.

Psychometrics – the science of measuring mental capacities and processes.

Radical radiotherapy – the use of radiotherapy with the intent to destroy the cancer and cure the patient.

Radiologists (diagnostic radiologists) - doctors who have made a special study of radiology. They carry out the more complex investigations and are responsible for analysing the images. They also perform procedures under imaging guidance to obtain samples for pathology and for treating some conditions.

Radiographers - regulated professionals with the Health and Care Professions Council (HCPC). They are entitled to hold one of the protected titles Radiographer, Diagnostic Radiographer or Therapeutic Radiographer. Radiographers undertake a broad portfolio of either diagnostic examinations or radiotherapy procedures and can work at levels of practice ranging from practitioner through to advanced, and to highly specialised consultant roles. **Diagnostic radiographers** work in areas that include X-ray, Ultrasound, Fluoroscopy, Computerised Tomography (CT), Magnetic Resonance Imaging (MRI), Nuclear Medicine (NM), Angiography and Mammography. **Therapeutic radiographers** are responsible for the planning and delivery of accurate radiotherapy treatments using a wide range of technical equipment and the care of cancer patients before, during and after receiving their radiotherapy.

Radiotherapy – the use of ionising radiation, usually high energy x-rays, to treat disease. Radiotherapy is mainly used to treat malignant disease (cancer). It is sometimes used to treat benign tumours and some benign diseases.

Treatment pathway - one of the main tools used to manage the quality of healthcare services. This approach allows standardisation of the care processes.

Triaging - deciding and establishing the order of a patient’s management.

Ultrasound – the use of high-frequency sound waves to create images of the inside of the body.

Appendix 1 - Names of guideline core and stakeholder groups

Core Group

Kumud Titmarsh - Associate Professor

Dr Julie Woodley - Senior Lecturer; Allied Health Chair of HAS Faculty Research Ethics Committee

Steven La Pensee - Member of SCoR PPLG

Linda Samuels - Member of SCoR PPLG

Nigel Thomson - SCoR Professional Officer

Sarah James - SCoR Professional Officer and Core Group Lead

Stakeholder Group

Loryn Caulfield - Consultant Therapeutic Radiographer in Gynaecological Oncology

Helen Cooper - Advanced Practice Lead.

Heather Dias - Specialist Macmillan Radiographer

Charles Sheldrake - Senior Radiography (Nuclear Medicine)

Rachel Mullen - Radiotherapy Team Leader

Lorraine Whyte - Practice Education Radiographer

Toni Hennings - Radiotherapy Manager

Tracey Slatter - Senior Lecturer

Kerry Howe-Bush - Ultrasound Manager

Lucy Davidson - Colorectal Specialist Radiographer

Christina Summers - Deputy Radiography Manager

Nsenam Obot - Radiographer

Aarthi Ramlal - Principal lecturer and programme leader

Linda Bedford - Macmillan Consultant radiographer for Palliative Radiotherapy and Pre-treatment

Louise Mifsud - Course Leader DipHE Radiographic Studies, Lecturer in Diagnostic Radiography

Marie Pagett - Radiotherapy Lecturer and Pre-Treatment Radiographer

Ben Stuttard - Diagnostic Radiographer

Maria Murray - SCoR Professional Officer for Scotland and UK Radiation Protection Lead

Appendix 2 - Summary and critique of articles

Allan J.²⁸ - Informed consent.

Allan, a partner in a law firm, wrote this piece as part of the Royal College of Physicians continuing medical education series. He set out the legal underpinning for consent and pointed out that practising without consent could actually result in a charge of battery. The professional standard as opposed to the patients' standard is debated and although this piece predates the *Montgomery v. Lanarkshire Health Board Case*,²⁹ the need for patient specific consent processes is raised. The article advocates adherence to the GMC principles²⁷ and recommends that all consent is documented.

Appelbaum PS.³⁰ - Assessment of patients' competence to consent to treatment.

This case study report is in one of the most prestigious medical journals currently published. It focusses on a 75 year old woman with diabetes mellitus and peripheral vascular disease who refuses surgical intervention for a gangrenous ulcer, as this would involve a below knee amputation. There was some question regarding the patient's mental state and whether she was competent to make this decision. The article analyses legally relevant criteria associated with decision-making capacity and provides a list of suggested questions that clinicians could utilise in the assessment of capacity (see Table 3).

Table 3: Legally relevant criteria for decision-making capacity and approaches to assessment of the patient. (Appelbaum,³⁰ p. 1836)

Criterion	Patient's Task	Physician's Assessment Approach	Questions for Clinical Assessment*	Comments
Communicate a choice	Clearly indicate preferred treatment option	Ask patient to indicate a treatment choice	Have you decided whether to follow your doctor's [or my] recommendation for treatment? Can you tell me what that decision is? [If no decision] What is making it hard for you to decide?	Frequent reversals of choice because of psychiatric or neurologic conditions may indicate lack of capacity
Understand the relevant information	Grasp the fundamental meaning of information communicated by physician	Encourage patient to paraphrase disclosed information regarding medical condition and treatment	Please tell me in your own words what your doctor [or I] told you about: The problem with your health now The recommended treatment The possible benefits and risks (or discomforts) of the treatment Any alternative treatments and their risks and benefits The risks and benefits of no treatment	Information to be understood includes nature of patient's condition, nature and purpose of proposed treatment, possible benefits and risks of that treatment, and alternative approaches (including no treatment) and their benefits and risks
Appreciate the situation and its consequences	Acknowledge medical condition and likely consequences of treatment options	Ask patient to describe views of medical condition, proposed treatment, and likely outcomes	What do you believe is wrong with your health now? Do you believe that you need some kind of treatment? What is treatment likely to do for you? What makes you believe it will have that effect? What do you believe will happen if you are not treated? Why do you think your doctor has [or I have] recommended this treatment?	Courts have recognized that patients who do not acknowledge their illnesses (often referred to as "lack of insight") cannot make valid decisions about treatment Delusions or pathologic levels of distortion or denial are the most common causes of impairment
Reason about treatment options	Engage in a rational process of manipulating the relevant information	Ask patient to compare treatment options and consequences and to offer reasons for selection of option	How did you decide to accept or reject the recommended treatment? What makes [chosen option] better than [alternative option]?	This criterion focuses on the process by which a decision is reached, not the outcome of the patient's choice, since patients have the right to make "unreasonable" choices

While this article obviously has a medical focus, it underlines the need for an assessment of capacity in all informed consent processes.

Boyd K.³¹ - The impossibility of informed consent?

Professor Kenneth Boyd analyses the difficulties and (in his opinion) impossibility of obtaining true informed consent. He sets out how the debate in this area has developed from a very paternalistic (“Doctor knows best”) attitude to a position where patient autonomy is regarded as paramount. He demonstrates that informed consent should be regarded as a process not an individual event and questions whether a patient can be truly autonomous without being in possession of very complex medical knowledge. Ultimately, he concludes that the partnership model for gaining consent will probably be the most useful to clinical practice.

Capron AM.³² - The real problem is consent to treatment not consent to research.

Capron, a world-renowned professor of Bioethics, raises the issue that while informed consent for research has been well regulated and documented, this is not the case for obtaining consent to treatment. He debates that the risk benefit analysis and the alternative treatment options are heavily regulated in research but “clinical judgement” seems to be sufficient in medical practice. Although a philosophical piece, it advocates greater understanding and openness with the informed consent process.

Caulfield L.³³ - Radiographer-led consent.

Caulfield, a consultant therapeutic radiographer at the Churchill hospital in Oxford, presents a case study that sets out how radiographers in her department were being trained to take consent from vault brachytherapy patients, with the aim of improving the patient experience. Oncologists would traditionally have undertaken this role, but this new approach may afford a better continuity of care for the patient. The radiographers undertake training so that they are able to best advise the patient and answer all their queries as part of the consent process. This radiographer-led service should also free up valuable clinic time for doctors. Caulfield recognises that radiographers must have sufficient understanding of the process, the risks and benefits and alternatives, to be able to obtain fully informed consent as they have a duty of care towards the patients. This article demonstrates how the radiographers promote patient autonomy whilst improving the service and potentially reducing waiting lists. This article illustrates that a medical practitioner does not necessarily need to lead consent for treatment.

Colyer H.³⁴ - Informed consent for Radiotherapy: Our responsibility.

This reference was included in the original *Consent to imaging and radiotherapy treatment*¹⁰ but, at the time, it was in press. It was subsequently published in the Radiography profession’s leading journal, and remains one of the best quality articles focussing specifically on consent in radiotherapy. This empirical work reports on a survey of all UK cancer centres and seeks to investigate whether these departments adhere to the Department of Health’s 2001 guidance on *Good Practice in Consent*.²² The survey shows there was wide adherence, but the article concludes that radiographers need greater awareness and more input into this process so that a more patient-centred service can be delivered.

Farrell AM. and Brazier M.³⁵ - Not so new directions in the law of consent? Examining Montgomery v Lanarkshire Health Board

This paper examines the UK Supreme Court decision in the *Montgomery v. Lanarkshire Health Board Case*.²⁹ This case dealt with consent and information disclosure. Nadine Montgomery took action on behalf of her son who developed cerebral palsy as a result of being starved of oxygen during a difficult birth. Mrs Montgomery was small in stature and diabetic which meant that she was more likely to give

birth to a larger baby. It also meant that she faced a 9-10% risk of her child's shoulders possibly becoming stuck in the birth canal (shoulder dystocia). In her evidence, Mrs Montgomery stated that if she had been told about the risk of shoulder dystocia she would have opted for a caesarean section.

Although an obstetric case, it has far-reaching consequences for healthcare in general as it moves towards a more patient-focused approach to informed consent. It signalled the need for consent tailored to "the specific patient" and the disclosure of risks that are important to that specific patient.

Ferral H.³⁶ - The Importance of the informed consent for Interventional Procedures.

This paper suggests that the informed consent process should include a clear understanding of the patient's health condition, explanation of the procedure, discussion of benefits, risks and alternatives to the procedure and focusses upon interventional radiologic procedures. The author advocates that the degree of difficulty of the procedure should influence the depth of information given to the patient and there should be a clear explanation of what realistically can be expected as an outcome of the procedure and the related complications.

Lamont S, Jeon Y, Chiarella M.³⁷ - Assessing patient capacity to consent to treatment: an integrative review of instruments and tools.

The authors examine research evidence to support the effectiveness of instruments or tools designed to assess capacity to consent to treatment. They support that capacity assessment is a significant priority within the informed consent process. They carried out a systematic review to identify all available tools and discovered 19 tools published within a 5-year period which they then assessed against criteria, including: psychometric properties; instrument implementation; patient population; and instrument versus clinical judgement. They concluded that only a small number of instruments were reliable and valid and conceded that many were unlikely to capture specific patient-centred nuances. They also suggested that the instruments should support but not replace clinical judgement, as the assessment of capacity can be a complex process. While this research has a mental health nursing focus, the complex issue of capacity needs to be addressed for all healthcare treatment.

Olufowote JO.³⁸ - A Dialectical perspective on Informed consent to treatment: An examination of Radiologists' Dilemmas and Negotiations.

The author carried out a series of focus groups where radiologists were asked to discuss their experience of informed consent to treatment (ICT). The transcripts of the discussions were analysed and it was found that radiologists experienced four primary tensions. These tensions were identified as: (a) the tension between simple and complex ICT; (b) between radiologist and patient control; (c) between standardised and idiosyncratic practice (involving struggles between documentation and conversational processes), and between vague and detailed language use; and (d) between withholding and disclosing alternatives. This study also highlights the need for guidance and training in this area and although conducted in the USA, it is very likely that the findings could be transferred to practice within the UK, although the UK does have more comprehensive professional guidance in certain areas.

Portelli JL, McNulty JP, Bezzina P, Rainford L.³⁹ - Radiographers' and radiology practitioners' opinion, experience and practice of benefit-risk communication and consent in paediatric imaging.

The aim of this study was to investigate radiographers' and radiology practitioners' experiences relating to the communication of risk and benefit as part of the consent process in paediatric imaging. Practitioners in a large teaching hospital in Malta were surveyed and it was concluded that there is a high degree of variation in practice in this area. Issues often arose when trying to give information and reassurance to both parents/guardians and to the patients themselves. They advocate that improved dialogues relating to this area should be fostered and identify a need for training. Whilst this study was conducted outside the UK, it is likely that the findings would be transferable.

Sokol DK.⁴⁰ - Update on the UK law on consent.

The author, a practising barrister, produced this observational piece in one of the most widely read medical journals in order to raise awareness of the implications of the *Montgomery v. Lanarkshire Health Board Case*.²⁹ He examines the ruling, which advanced the legislation away from the more traditional Bolam-⁴¹ based approach. He advocates that law-abiding doctors should ask themselves the following questions:

Does the patient know about the material risks of the treatment I am proposing?

- *What sort of risks would a reasonable person in the patient's circumstances want to know?*
- *What sorts of risks would this particular patient want to know?*

Does the patient know about reasonable alternatives to this treatment?

Have I taken reasonable care to ensure that the patient actually knows all this?

Do any of the exceptions to my duty to disclose apply here?

Have I properly documented my consent process?

Sokol⁴⁰ (p1)

These questions do provide a very simple framework with relation to the process of providing individual patient-centred consent.

Appendix 3: Summary of guidance from professional bodies, networks and associations

Association of Surgeons of Great Britain and Ireland⁴² - Issues in professional practice-Informed Consent.

This evidence has been included as it is a typical example of how professional bodies have collated available evidence from the Department of Health, BMA, GMC, and legal cases, and produced guidance specific to the association's membership. It starts with a definition of consent then sets out the legal principles that underpin the process. It outlines the issues related to those patients with capacity and proceeds to those who lack capacity. It also covers end of life issues, organ donation, anaesthesia and research. It is set out in a very logical format, but is effectively a collection of previously published advice.

British Medical Association²⁶ - Consent Toolkit

This is a web-based resource, divided into 13 sections and allows the reader to click directly on the section of interest. It follows a very succinct Q&A style and provides general advice, but also advice on more specialised areas, such as: emergency treatment, children and young people, teaching and serious communicable diseases. It also provides an extensive list of contacts for various associations, societies and professional bodies who issue further guidance. Although aimed at a medical audience it provides clear guidance on many aspects of the consent process.

British Nuclear Medicine Society⁴³ - Consent issues in Nuclear Medicine.

This guidance was published by the British Nuclear Medicine Society (BNMS) in order to set out their position on consent, and how and when this process should be undertaken. They provide bullet point guidance on general issues, then more specific guidance for nuclear medicine procedures. The resource is only supported by five references, but two of those references include Paling (2003) who suggested strategies for communicating risk to patients. While specific to nuclear medicine, the notion of communicating risk in a way that a patient can understand is regarded as paramount to the informed consent process. (The notion that all risk is communicated by showing how many people out of a thousand would be affected is suggested by Palin⁴⁴ as being a clear indication.)

Department of Health²² - Good practice in consent implementation guide: consent to examination and treatment.

This document was published prior to the *Mental Capacity Act*.¹⁶ It provides extensive guidance in this area and suggests a model consent to examination policy that could be adapted and adopted by all Trusts in the UK. It also includes a succinct "12 key points on Consent" and templates for consent forms. It also provides a valuable reminder that the patient's perspective on consent may be very different from the healthcare practitioners and this is summarised in Figure 2, which forms an appendix to the main document.

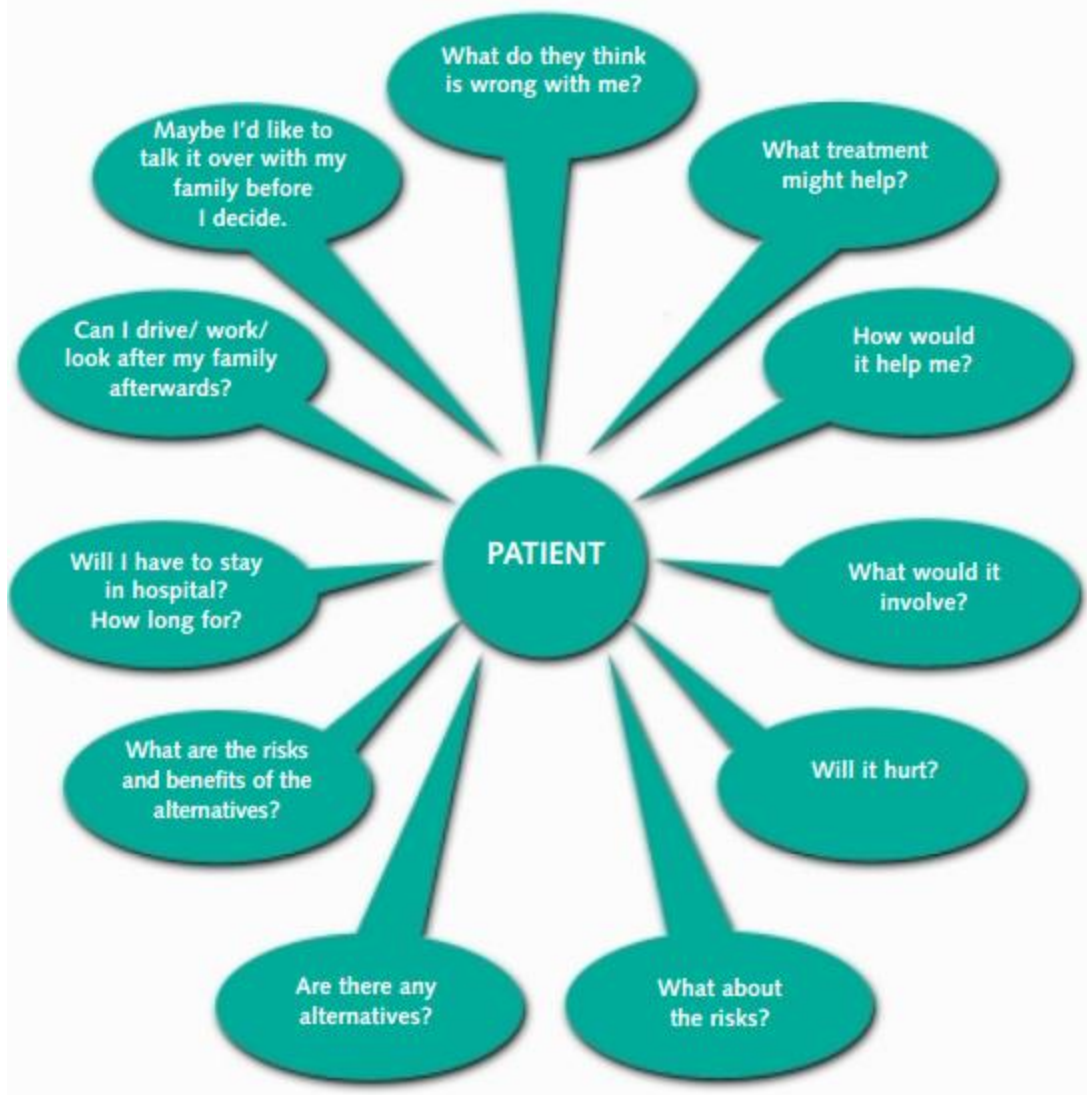


Figure 2: Seeking Consent: remembering the patient’s perspective DoH,²² p. 32

This highlights some of the issues that may be important to the patient but could possibly be overlooked in the consent process.

Department of Health²⁰ - Reference guide to consent for examination or treatment (second edition)

This superseded the Department of Health 2001²² guidance and includes the implications for the consent process necessitated by the publication of the *Mental Capacity Act*.¹⁶ It provides comprehensive advice regarding the ethical and legal principles underpinning the consent to treatment process. It is divided into five key areas, which include: seeking consent; adults without capacity; children and young people; withdrawing and withholding life-sustaining treatment; and exceptions to the principles.

Department of Health²¹ - Information to assist in amending consent forms.

This document also superseded the Department of Health 2001²² guidance and highlights the amendments to consent documentation necessary as a result of the implementation of the *Mental*

Capacity Act.¹⁶ It provides suggested phrases to be included in written consent forms and considers best interests and capacity.

European Society of Radiology⁴⁴ - Patient communication, confidentiality and consent: radiology policy and practice in Europe. A survey by the European Society of Radiology.

This article focuses on communication and confidentiality between the patient and Radiologist, specifically the ramifications of the Picture Archiving and Communications System (PACS). A survey of Radiology departments was conducted, which highlighted that policies regarding access and storage of patient data (including consent documentation) do not seem to have kept pace with electronic storage systems and that Europe lacks a unified approach in this area. The move away from paper-based systems means that any updated guidance should include provision for electronic methods in the consent process.

General Medical Council²⁷ - Consent: Patients and doctors making decisions together.

This is probably the most widely referred-to source for guidance in this area. It forms the basis to all professional bodies' specific guidance and is a comprehensive 64 page summary of the key issues in consent to treatment. Its main premise is to set out that consent to treatment should be a shared process. It advocates that discussions regarding consent should be tailored to individual patients according to:

- f. *their needs, wishes and priorities*
- g. *their level of knowledge about, and understanding of, their condition, prognosis and treatment options*
- h. *the nature of their condition*
- i. *the complexity of their treatment*
- j. *the nature and level of risk associated with the investigation or treatment.*

GMC, ²⁷p. 11

It considered all the legal precedents and advocated personalised individual consent even prior to the *Montgomery v. Lanarkshire Health Board Case*.²⁹

Medical Protection Society⁴⁵ - Essential guide to Consent: Advice for the United Kingdom.

This guidance was issued by the medical profession's leading legal defence society. It sets out the three main components of valid consent: capacity; information; and voluntariness. It deals with complex issues like fluctuating capacity, consent by proxy and implied and express consent. It also includes some medical-based consent scenarios to illustrate the practical application of the legal basis of consent to treatment.

Royal College of Radiologists⁴⁶ - Standards for patient consent particular to radiology. Second edition.

This guidance was based on the 2008 GMC publication²⁷ but is adapted for a Radiology readership. It covers the basics of consent but again advocates the need for documentation of the process especially discussions around risk and benefit. It also includes: guidance on intimate examinations in radiology; the consent for the use of imaging in teaching and training; and the consent to screening and research. Its basis again is on informed decision making after the sharing of appropriate information.

Royal College of Surgeons⁴⁷ - Consent: Supported Decision-Making: A guide to good practice.

This very recently published guidance takes into consideration the implications of the *Montgomery v. Lanarkshire Health Board Case*²⁹ while still heavily influenced by the GMC (2008) guidance. It also proposes a 10 step overview of the consent process which takes into consideration the need for adherence to legal and ethical principles, as per Table 4.

Table 4: Royal College of Surgeons,⁴⁷ p. 20-22

Step	Task	Comments
1	Explain the diagnosis to the patient.	Ensure that the information is given in a format that the patient can understand. Explain the prognosis if untreated.
2	Explain the options for treatment.	Explain the risks and benefits of various treatment options side by side and ensure that not having any treatment is included amongst the options. Describe the likelihood of success of the various options and the impact that treatments will have on the patient's life.
3	Explain the consent and decision-making process so the patient understands what is expected of them.	Ensure that the patient understands that they are expected to make a supported decision, and their rights within this process. Do not assume that the patient will be familiar with the concept of supported decision-making and check whether they have a supporter.
4	Time for deliberation and homework for the patient.	Where relevant, surgeons should allow sufficient time for patients to deliberate on available options and to consider their goals and wishes in terms of their treatment. This may include reading further information or accessing online resources to provide them with more information on their condition and treatment options.

5	Discuss the patient's wishes, needs, views and expectations regarding any treatment they might undertake.	It is important not to make assumptions regarding what a 'good' outcome from treatment would look like for the patient. Different patients will have different life priorities and different views regarding what the best available outcome might be or what risks are acceptable to them. Sufficient time is given to ensure that the patient's views are understood and respected.
6	Discuss trade-offs with the patient in light of their needs, goals and expectations.	Explain how different options will or will not achieve their goals and any potential impact that the options will have.
7	Provide any relevant information not already covered, or any emerging information that may have altered the conditions surrounding the various options for treatment.	Is there any further information that would have a bearing on the decision that the patient is being asked to make that has not already been discussed and/or understood by the patient? If so, ensure that these factors are explained and if necessary go back to an earlier stage in the process and repeat in light of the new knowledge. This is of particular importance in cases where the process has spanned a period of time where changes may have occurred in the patient's condition or around the risks and benefits of any of the treatment options available.
8	Has the patient understood?	Prior to any decision it is imperative that the person seeking consent is satisfied that the patient has understood the information that they have been given and that any decision they make will be made independently and from an informed position.
9	Respect the patient's decision.	You must always respect the decision made by an adult patient with capacity.
10	The signing of the form and maintaining a decision-making record.	The consent form as part of the decision-making record should be signed at the end of the discussion, provided the patient has made a decision. The patient should be given a copy of the form to review and retain. Details about the discussion with the patient and copies of any information given to the patient should be included in the patient's notes.

Treatment should only be given once valid consent has been obtained. Prior to undertaking any intervention, the person providing the treatment should be satisfied that the consent obtained for the procedure is still valid.

Society and College of Radiographers¹¹ - Patient advocacy.

This publication sets out the radiographer's role as an advocate. In general terms this guidance is key for all decision making and consent to treatment. It states that radiographers should safeguard patients' rights and conserve their best interests in acting as an advocate. It also suggests that patient autonomy should be protected and maintained.

Society and College of Radiographers¹² - Patient identification, confidentiality and consent: further guidance.

This short briefing paper was published in response to an HCPC case whereby a paramedic was sanctioned for posting a radiographic image on a social networking website. While not specifically focussing on consent to treatment, it does, however, set out that the consent of the patient should be gained before sharing any patient information with relatives or carers who may accompany the patient and this may be a consideration in the consent to treatment process.

Society and College of Radiographers¹³ - Student radiographers and trainee assistant practitioners: verifying patient identification and seeking consent.

This short briefing paper outlines the student's role in identification and consent. It is permissible for a non-registered healthcare practitioner to carry out these duties, but only if a supervising radiographer has delegated that duty, and is assured that they have the skills and knowledge to undertake the process. It also sets out that any patient should be made aware that a supervised student is carrying out their examination. The student position will need to be included in the updated documentation.

Society and College of Radiographers¹⁴ - Consent and Adults with impaired capacity.

This guidance was published following enquiries from members regarding patients with impaired capacity and took into consideration the *Mental Capacity Act*.¹⁶ It outlines the five key underpinning principles from the Act, which are:

- A presumption of capacity - every adult has the right to make his or her own decisions and must be assumed to have capacity to do so unless proved otherwise;
- The right for individuals to be supported to make their own decisions - people must be given all appropriate help before anyone concludes that they cannot make their own decisions;
- The individuals must retain the right to make what might be seen as eccentric or unwise decisions;
- Best interests - anything done for or on behalf of people without capacity must be in their best interests ;
- Least restrictive intervention - anything done for or on behalf of people without capacity should be the least restrictive of their basic rights and freedoms.

It also advocates the documentation of these decisions.

UK Clinical Ethics Network⁴⁸ - Ethical Issues – Consent: A summary of the ethical and legal considerations in patient consent.

This web-based publication was produced as a resource primarily for members of clinical ethics committees but it does provide a short summary of the ethical and legal underpinnings to the consent to treatment process and suggests some references that are mainly ethical analyses of the issue of consent to treatment.