SCoR
THE SOCIETY & COLLEGE OF RADIOGRAPHERS

Obtaining consent

"The principle that a person must give permission before they receive any type of medical treatment, test or examination".[1]

Seeking patient consent prior to undertaking an examination or treatment is a fundamental ethical and legal requirement of you as a practitioner.

It is also a common courtesy and establishes an appropriate relationship of trust between you and the patient.

The principle of gaining consent demonstrates your 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".[2]

The Final Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry[3] recommendations included the principle that the NHS and its staff must prioritise patients' needs at all times, as well as being honest, transparent, and candid.

You must place the needs and values of patients and carers at the forefront of your service delivery.

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 you are aware of the issues surrounding the process of gaining consent from patients.

"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".[4]

10 recommendations

The Society and College of Radiographers has developed 10 recommendations, based on an extensive systematic review, to assist you in ensuring you have undertaken an informed consent.

1 Legal issues

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. 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 usually referred to diagnostic imaging or radiotherapy departments for diagnostic procedures or treatment. The referring clinician may have given some explanation of procedures, but it is essential that you also obtain and/or confirm consent. The SCoR recognises the time pressures radiographic practitioners are operating under and thereby recommends your department adopts a consent process to ensure a valid informed consent has actually been achieved.

2 Advocacy

You need to ensure that you support and encourage a patient's autonomy and rights. Sometimes patients may not have 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', acting as an advocate for their care choices, or concerns about the service they find themselves accessing. You need to recognise your patient advocacy responsibilities and ensure you have the knowledge and skills to be able to perform this function.

3 Shared decision making

Consent is not a once-only decision but a process or journey that happens gradually over time. Nor is it a rigid process; it must be personalised to suit the individual patient. It is also not good practice for a procedure to be described verbally immediately before it is undertaken. If you are using a list of tick boxes as an aid to facilitate the consent process, you should still ensure that the process is personalised to meet an individual's need.

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. Consent principles must apply to all patients and where a patient has a diagnosis that may affect their capacity to consent, you must not automatically assume that the patient is 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. It is important that you keep up to date and comply with the codes of practice that apply to your work place.

5 Communication of risk and benefit

It is incumbent on you to find out an individual patient's priorities and concerns and tailor the information accordingly. You 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 they understand that they may change their minds at any time and withdraw their consent if they do not wish to continue. Information should be given to the patient at a reasonable time before the procedure. This allows the patient time to read the information, and then be given the opportunity to ask questions. You should not pass judgement on a competent patient's decision to refuse an examination at any stage and you must respect a patient's own lifestyle priorities and choices. You will also need to explain risks that may arise as well as the benefits of undergoing imaging and treatment when using ionising and non-ionising radiation. The 2013 BSS EU Directive5 (to become UK law by Feb 2018) states that patient information must also include radiation doses for each specific examination. Therefore, from 2018, you will also be required to give an explanation to a patient about the radiation dose they will receive.

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. Any refusal or withdrawal of consent by a patient 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, including dates and times. You must check your employing authority's policy which covers obtaining written consent for intimate and invasive examinations and procedures. You may be responsible for obtaining written informed consent for specified examinations and/or treatments. These responsibilities will be detailed in your individual scope of practice, as defined in your job description.

7 Consent and children

If a child is competent to give consent for themselves, for either an examination or treatment, you should seek consent directly from them. In the event of a parent/carer or competent child subsequently refusing consent to the examination/treatment once in the clinical department, you will need to liaise with the requesting physician.

8 Student radiographers and trainee assistant practitioners' involvement in consent procedures

Where a student may be present during an intimate procedure (eg 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. You 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 being asked to give 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, you must ensure that a patient can decline without fear of offence.

9 Consent for screening

Individuals must be provided with full, accurate information from which they can make an informed choice of 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. 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. You 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 for consideration of the new information before consenting.

10 Use of chaperones and consent

You might find it useful to consider the issue of chaperoning together with consent. 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 which are deemed to be so by the patient. Your Trust, Health Board and other employer will have their own intimate examination and chaperone policies to which you should refer.

Remember …

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?

(as proposed by Sokol[6])

Conclusion

The overview of the consent process adapted from The Royal College of Surgeons[7] may also be useful in modifying and producing your local consent policies.

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.*

References

1. *NHS Choices. Consent to treatment. 2016. Available: http://www.nhs.uk/Conditions/Consent-to-treatment/Pages/Introduction.aspx*
2. *Lord Goff in Re F (Mental Patient: Sterilisation): HL 4 May 1989 2 AC 1 (p 73).*
3. *UK Government. (Chair – Robert Francis QC) The Final Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry. London: TSO; 2013. Available: http://webarchive.nationalarchives.gov.uk/20150423112024/http://www.midstaffspublicinquiry.com/report*
4. *Department of Health. Good practice in consent implementation guide: consent to examination or treatment. London: DH; 2001. Available: http://www.health.wa.gov.au/mhareview/resources/documents/UK_DOH_implementation_guide.pdf*
5. *Council of European Union. BSS EU Directive 2013. Official Journal of the European Union. 2014. Available: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2014:013:0001:0073:EN:PDF*
6. *Sokol DK. Update on the UK law on consent. BMJ 2015; 350:h1481.*
7. *Royal College of Surgeons. Consent: Supported Decision-Making: A guide to good practice. London: RCS; 2016. Available: https://www.rcseng.ac.uk/library-and-publications/college-publications/docs/consent-good-practice-guide/*

A pdf of this information leaflet and accompanying poster may be downloaded at www.sor.org/practice/obtaining-consent

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