

Service Standards on Obtaining Valid Consent in Sexual and Reproductive Health Services



The Faculty of Sexual and Reproductive Healthcare (FSRH) is the largest UK professional membership organisation working in the field of sexual and reproductive health (SRH). We support healthcare professionals to deliver high quality healthcare including access to contraception. We provide our 15,000 doctor and nurse members with NICE-accredited evidence-based clinical guidance, including the UKMEC, the gold standard in safe contraceptive prescription, as well as clinical and service standards.

The FSRH provides a range of qualifications and training courses in SRH, and we oversee the Community Sexual and Reproductive Healthcare (CSRH) Specialty Training Programme to train consultant leaders in this field. We deliver SRH focused conferences and events, provide members with clinical advice and publish *BMJ Sexual & Reproductive Health* – a leading international journal. As a Faculty of the Royal College of Obstetricians and Gynaecologists (RCOG) in the UK, we work in close partnership with the College but are independently governed.

The FSRH provides an important voice for UK SRH professionals. We believe it is a human right for women and men to have access to the full range of contraceptive methods and SRH services throughout their lives. To help to achieve this we also work to influence policy and public opinion working with national and local governments, politicians, commissioners, policy makers, the media and patient groups. Our goal is to promote and maintain high standards of professional practice in SRH to realise our vision of holistic SRH care for all.

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SERVICE STANDARDS ON OBTAINING VALID CONSENT IN SEXUAL AND REPRODUCTIVE HEALTH SERVICES

Changes introduced since review

- ▶ An update on explaining risk to patients in view of the 2015 Montgomery ruling.
- ▶ Advice and consent for multimedia and education purposes.
- ▶ Reference to a potential change in relationship with the ECtHR at the time of Brexit
- ▶ References have been updated.

Introduction

Consent is a person's agreement for a health professional to provide care.

"It is a general legal and ethical principle that health professionals must obtain valid consent before starting treatment or physical investigation or providing personal care. This principle reflects a person's right to determine what happens to his or her own body and is a fundamental part of good practice."¹

Patients have the right to dignity, privacy autonomy and confidentiality. Seeking consent is also a matter of common courtesy between health professionals and patients.

For consent to be valid, the person must:

- ▶ Have the mental capacity to make the decision.
- ▶ Have enough information and opportunity for discussion prior to making a decision.
- ▶ Be free from duress.

'Valid consent' is obtained by the person being informed of the nature and purpose of any proposed treatment and the likely outcome(s), including any significant possible adverse outcomes, and the likely result of not proceeding with the proposed treatment, so that the person can make an informed decision. Patients must be treated as individuals with their wishes respected at all times.

While there is no English statute setting out the general principles of consent, case law ('common law') has established that touching a person without valid consent may constitute the civil or criminal offence of battery. (In Scotland, this is known as assault). Further, if doctors and other healthcare professionals fail to obtain valid consent and the person subsequently suffers harm because of treatment, this may be a factor in a claim of negligence against the professional involved. Poor handling of the consent process may also result in complaints from patients. Case law on consent has evolved significantly over recent years.

The 2015 Supreme Court ruling on *Montgomery vs Lanarkshire Health Board* mandates shared decision-making, and the provision of standardised information to patients at all points in the care pathway; it establishes a duty of care to warn of "material risks". The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it. ²

Further legal developments may occur after this guidance has been issued, and health professionals must remember their duty to keep themselves informed of legal developments that may have a bearing on their practice. Legal advice should always be sought if there is doubt about the legal validity of a proposed intervention. While much of the case law refers specifically to doctors, the same principles will apply to other health professionals involved in examining or treating patients.

The Human Rights Act 1998³ came into force in October 2000, giving further weight in the UK to the rights enshrined in the European Convention on Human Rights (ECHR). Courts were expected to consider the case law of the ECtHR (European Court of Human Rights), as well as English case law (Scottish Common Law). The ECtHR protects the human rights of people in countries that belong to the Council of Europe. At the time of publication it has yet to be decided how the UK exit from the EU will impact on its relationship with the ECtHR.

Capacity and Incapacity

To give valid consent a patient must have mental capacity. This is a legal concept and relates to the way in which the patient arrives at a decision, rather than the appropriateness of their decision. ⁴

The law in England, Wales, and in Northern Ireland,^{1,4} presumes that adults (persons aged 18 years and over) have the capacity to make their own decisions unless there is reason to believe otherwise. The legal position concerning consent and refusal of treatment by those under the age of 18 is different from the position of adults where treatment is being refused. Young people aged 16 or over, but under 18, can give independent consent to their own treatment (but this can be overruled by a court order). Young people under 16 can give their own consent to treatment if they are judged capable of understanding what is involved; each case being judged on its own merits.

The law in Scotland presumes that people aged 16 and over have the capacity to make their own decisions. In Scotland, a young person under 16 can consent to, or refuse, any treatment if the qualified medical practitioner attending them believes that they can understand the nature and possible consequences of the treatment.⁵

The Mental Capacity Act 2005 ⁶ covering England and Wales, enshrines in statute what common law suggests regarding the care of those who lack capacity to consent. ⁶ It provides a statutory framework for people who may not be able to make their own decisions for example, because of a learning disability, an illness such as dementia or mental ill-health. It sets out who can take decisions, in which situations, and how they should go about this. It defines incapacity as an inability to make a decision for each intervention and states “A person is unable to make a decision if s/he cannot:

- ▶ Understand information relevant to the decision
- ▶ Retain that information for as long as necessary to make that decision
- ▶ Use or weigh that information, or
- ▶ Communicate the decision.”

It goes on to state “*before deciding that a person is incapable, all practical steps should be taken to assist the person to make his/her decision*”. This should include involving more specialist colleague(s). Guidance on how people should be helped to make their own decisions is given in Chapter 3 of the Mental Capacity Act (2005) Code of Practice. ⁶

In Scotland, the framework for regulating interventions into the property, financial affairs and personal welfare of adults with impaired capacity is set out in The Adults with Incapacity (Scotland) Act 2000. ⁷ Guidance on this Act and how it affects health professionals is also available. ⁷

Note

This document has been produced to assist health professionals working in the field of sexual and reproductive health service provision. Consequently, it has been assumed that colleagues working in these settings will not normally be involved in obtaining valid consent in the following situations:

- ▶ Removal of organs or tissue from patients who have been declared dead, whether for diagnostic, therapeutic or research purposes.
- ▶ Specialised subfertility practice covered by the Human Fertilisation and Embryology Act 2008.
- ▶ Organ transplantation.
- ▶ Withdrawing and withholding life-prolonging treatment.
- ▶ Permission to conduct a post-mortem examination.

To avoid multiple reference annotation, it should be noted that statement points not specifically referenced can be found in numerous documents already referenced.

1 Standard Statement on Training in Seeking and Obtaining Valid Consent

All staff should have training and ongoing support in seeking and obtaining valid consent.

- 1.1 Clinical and non-clinical staff should receive appropriate training in obtaining valid consent and keep up to date with any changes in the law.
- 1.2 All staff should receive training on national Child Protection procedures and be able to use local Child Protection/Safeguarding Children policies and protocols.
- 1.3 All staff should be aware of the guidance on protecting vulnerable adults in their region of work. Government guidance on this, “Safeguarding policy: protecting vulnerable adults” (July 2018) can be found [here](#).
- 1.4 All staff working with young people should be familiar with the latest Department of Health and Social Care Guidance (or equivalent guidance) on the care of under-18s.
- 1.5 All staff working with young people under 16 should be familiar with and use the Fraser Guidelines (or equivalent guidance) when assessing competence.
- 1.6 All staff should be trained in the legal requirements of current data protection guidance and regulations as they apply to health services.
- 1.7 All staff should receive Caldicott training.

2 Standard Statement on Process of Obtaining Valid Consent

All staff should be aware of the process of obtaining valid consent. This includes: purpose, process, assessment of capacity, provision of information and assessment of a patient's autonomy.

2.1 Purpose

- 2.1.1 All staff should be aware that people have a fundamental legal and ethical right to determine what happens to their own bodies.
- 2.1.2 Valid (verbal or written) consent should be obtained before examining, starting treatment or physical investigation or providing personal care for a patient.
- 2.1.3 The consent of a patient is required before any disclosure of information obtained during their healthcare, except in exceptional circumstances where disclosure is to protect the individual from serious harm or is in the public interest^{8,9}.
- 2.1.4 Health professionals should be aware that if they do not respect these principles, they may be liable both to legal action by the patient and action by their professional body.
- 2.1.5 Employing bodies should be aware that they may be liable for the actions of their staff if these principles are not respected.

2.2 Process

- 2.2.1 For consent to be valid the patient must:
 - ▶ Have the mental capacity to take the particular decision and
 - ▶ Have received sufficient information to make the decision along with time to reflect and an opportunity for discussion and
 - ▶ Not be acting under duress or undue influence from partners, family, friends, health professionals or other agencies.
- 2.2.2 Giving and obtaining consent is usually a process, rather than a one-off event. Patients can change their minds and withdraw their consent at any time.
- 2.2.3 A person may be competent to make some healthcare decisions, even if s/he is not competent to make others (i.e. consent is 'decision-specific'). For example, a young person may be deemed competent to consent to the provision of contraception but not necessarily to sex.

2.3 Assessment of Capacity to Consent

- 2.3.1 The health professional seeking to obtain valid consent must be sure that the person giving consent can understand, retain and use/weigh the information relating to the decision.
- 2.3.2 Adults (persons aged 18 years and over in England or aged 16 and over in Scotland) are assumed to be competent to give consent unless there is reason to believe otherwise (page 4).
- 2.3.3 No-one can give consent to examination or treatment on behalf of an adult who is deemed unable to give consent for him/herself (Standard 8).
- 2.3.4 Adults are presumed to have capacity to give or withhold consent to examination, investigation or treatment. Where any doubt exists the health professional should assess capacity (Appendix 1).
- 2.3.5 The assessment of capacity and the conclusions drawn from it should be recorded in the patient's notes.
- 2.3.6 An adult's incapacity may be temporary or long-standing and in these circumstances the law permits interventions, which are necessary in the patient's best interests.
- 2.3.7 Where the adult has never been competent, relatives, carers and friends may be well placed to advise on the patient's needs and preferences. It is advisable to involve a Consultant in Learning Disability Psychiatry and the multidisciplinary team in the decision-making process, and to document their involvement (see also Standard 8).
- 2.3.8 Under Section 8 of the Family Law Reform Act 1969,¹⁰ young people aged 16 and 17 years are entitled to consent to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic. As for adults, consent is valid only if it is given voluntarily, by an appropriately informed patient, capable of consenting to the intervention. However, unlike adults, the refusal of a competent person aged 16-17 years may in certain circumstances be overridden by either a person with parental responsibility or a court. This would not be the case in Scotland.
- 2.3.9 Young people aged under 16 who understand fully what is involved in the proposed procedure or treatment can give consent (although their parents, or someone with parental responsibility, should ideally be involved)^{4,10} (see also Standard 9.1). In Scotland, this is covered by the Age of Legal Capacity Act 1991.⁵
- 2.3.10 Where a young person is assessed as not competent to give consent, someone with parental responsibility must give consent on the young person's behalf (see also Standard 9.8).
- 2.3.11 If a competent young person consents to treatment, a person with parental responsibility cannot override that consent (see also Standard 9.1).

2.3.12 Health professionals should take all reasonable steps to facilitate communication with the patient, using interpreters or communication aids as appropriate. Equality and diversity issues, such as someone's ethnic background or disability, should also be considered in capacity assessment to eliminate the risk of misinterpreting indicators of cultural difference as incapacity and reduced cognitive function.¹¹

2.4 Provision of Information Prior to Obtaining Valid Consent

2.4.1 Patients should receive evidence-led, objective information, supplied in a way that they can understand, before they give or withhold consent to the proposed examination, diagnostic procedure or treatment. Quantification of risks, if known, may be supplied.

2.4.2 Information should be given regarding all "material risks" involved in a proposed treatment (i.e. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the health professional is or should reasonably be aware that the particular patient would be likely to attach significance to it.).²

Information should include:

The nature of the intended intervention

- ▶ The purpose of the treatment.
- ▶ The known risks, benefits and uncertainties of the treatment.
- ▶ The implications of not carrying out the procedure or treatment.
- ▶ The known risks, benefits and uncertainties of alternative interventions.

2.4.3 Information about anaesthesia should be given as well as information about the procedure.¹²

2.4.4 Patients need to know whether additional procedures are likely to be necessary as part of the procedure, and consent should be sought for any treatment to deal with problems that may arise during the primary procedure.

2.4.5 GMC guidance¹³ and MedFASH standards⁹ state that clinicians should do their best to find out about patients' individual needs and priorities when providing information about treatment options and that if the patient asks specific questions about the procedure and associated risks these should be answered truthfully.

2.4.6 If the health professional believes that to follow the guidance in the above paragraphs in full would have a deleterious effect on the patient's health, the GMC guidance states that this view, and the reasons for not following the guidance, should be recorded in the patient's notes.

2.4.7 If information about the treatment that is being proposed is offered to a patient and declined, it is also good practice to record this fact in the notes.

- 2.4.8 Patients should be treated with courtesy and respect and their dignity should be maintained always. Adequate privacy should be ensured for information giving. Patients should not be given essential information or asked to make decisions whilst undergoing intimate examinations.
- 2.4.9 Staff should seek to reinforce verbal information in a way that is appropriate and helpful to patients. This may include printed or written information, pictorial aids or links to relevant websites. Services should aim to provide translated versions of all modes of available information wherever possible.

2.5 Assessment of a Patient's Autonomy

- 2.5.1 To be valid, consent must be given voluntarily and freely, without pressure or undue influence being exerted on the patient either to accept or refuse treatment.
- 2.5.2 Health professionals must ensure that patients have reached their own decisions and understand that they can change their minds if they do not wish to continue with the treatment.
- 2.5.3 Health professionals should be alert to the possibility that pressure or undue influence can come from partners, family members or friends, as well as healthcare and social care professionals, and where appropriate should arrange to see the patient on their own to establish that the decision is truly that of the patient.
- 2.5.4 When an interpreter is needed, it is highly likely to be in the individual's best interests to use an independent party, rather than a friend or relative.
- 2.5.5 In environments where involuntary detention may be an issue (e.g. prison, mental health settings), staff should be careful to avoid the potential for treatments to be perceived as coercive, since coercion invalidates consent.

3 Standard Statement on Who Should Seek Consent

The clinician providing the treatment or investigation is responsible for ensuring that the patient has given valid consent before treatment begins.

- 3.1 Where verbal, non-verbal or written consent is being sought for examination, investigation, treatment or care, the health professional carrying out the procedure should seek consent from the patient. If the task of seeking written consent is delegated to another health professional, that professional must be able to perform the procedure in question, or have been suitably trained and qualified, have sufficient knowledge of the proposed investigation or treatment, and understands the risks involved, in order to be able to provide any information the patient may require.¹³
- 3.2 The clinician performing the procedure must ensure that valid consent has been obtained before treatment begins. If the clinician delegates, he/she is still responsible for making sure that the patient has been given enough time and information to make an informed decision, and has given their consent, before starting any investigation or treatment.¹³

4 Standard Statement on When to Obtain Consent

Staff should be aware that the process of seeking consent may take place at one time, or over a series of meetings and discussions. This should be documented appropriately.

All staff should be aware that:

- 4.1 A health professional can initiate a procedure immediately after discussing it with the patient, provided that the principles of obtaining valid consent (capacity, information and lack of duress) have been met.
- 4.2 For procedures where written consent is sought, health professionals should allow the patient sufficient time to absorb the information necessary for them to make their decision as well as provide them with an opportunity for discussion. NHS efficiencies, including booking directly into procedural clinics and admitting patients to hospital on the day of procedure, have the potential to eliminate or reduce the reflective period during which patients can consider their options. It is important to ensure that health professionals maximize a patient's ability to make decisions, by offering them further opportunities to discuss any proposed treatment in a clinic visit or phone call, should they wish to do so. ¹³
- 4.3 It is good practice to seek the patient's consent to the proposed procedure in advance and then check again, before the procedure starts, in order to ensure that the patient's consent still stands.
- 4.4 The timing of the process of seeking consent should be sufficiently close to the intervention for the patient to recall what they have been told about it. However, seeking consent when the patient may be feeling vulnerable is likely to be regarded as invalid.

5 Standard Statement on Method of Giving and Recording Consent

Valid consent may be given in a number of different ways but should be documented.

All staff should be aware that:

- 5.1 Legally, verbal and written consent are **equally** valid.
- 5.2 Consent may be implied (non-verbal) or expressed (verbal or written).
- 5.3 The form (implied or expressed) in which the patient consents should be documented in the patient's record.¹⁴
- 5.4 Implied consent (non-verbal) or verbal consent may be sufficient for certain procedures. Health care practitioners should consult FSRH guidance for specific procedures whilst considering recommended local practice.
- 5.5 It is good practice to obtain written consent for specific procedures such as:
 - ▶ A procedure that involves significant risks (e.g.abortion, sterilisation).
 - ▶ A procedure that involves general/regional anaesthesia or sedation.
 - ▶ Pelvic examination by medical students of anaesthetised women.
 - ▶ Participation in a research project or programme.
 - ▶ A procedure or treatment that is being offered that is of an experimental nature.¹⁵
 - ▶ Recording and use of multimedia images.
 - ▶ Disclosure of records.^{14,16}
- 5.6 For procedures involving significant risks, it is essential for health professionals to document clearly both a patient's agreement to the intervention and the discussions that led up to this agreement, including the provision of any patient information materials.
- 5.7 A signature on a consent form is not proof of valid consent but is evidence of the process of consent-giving and is not a binding contract. Patients may, if they wish, withdraw their consent after they have signed a form.
- 5.8 If consent has been validly given and documented, the lack of a completed consent form is no bar to treatment.

- 5.9 Completion of a consent form is in most cases **not** a legal requirement (exceptions include certain requirements of the Mental Health Act 1983 and of the Human Fertilisation and Embryology Act 2008).
- 5.10 A patient who has capacity to consent, but is illiterate, may be able to make a mark on a consent form to indicate that the consent-giving process has taken place. It is good practice for this mark to be witnessed by an appropriate adult, and for that fact that the patient has chosen to make their mark in this way to be recorded in the patient's notes.
- 5.11 If a patient has capacity to consent, and wishes to give consent, but is physically unable to mark the form, this fact should be recorded in the notes.
- 5.12 Explicit consent must be sought for the presence of medical students and other clinicians in training during consultations and in operating theatres as observers and assistants, and for students performing clinical examinations. This may be given verbally and documented accordingly.
- 5.13 Multimedia images taken through hysteroscopy and sonography are increasingly part of the patient record and should be stored on approved hospital data record systems in line with local policy. It is important to note that these images (laparoscopic and hysteroscopic findings, ultrasound pictures and X-rays) do not require additional consent for use as part of the care record, as consent for care purposes is implicit in the consent given for the procedure. If the image is to be used for education, then written consent must be obtained. Images of interest should not be taken with personal smartphones or duplicated and shared using screen capture methodology. [17](#)

6 Standard Statement on the Duration of a Patient's Consent

Staff should be aware that valid consent to an intervention remains valid for an indefinite duration unless it is withdrawn by the patient or the patient loses capacity to consent, in which case this should be clearly documented.

- 6.1 If a patient's treatment involves a series of visits it is good practice to confirm that the patient retains capacity and they still wish the intervention to proceed.^{13,17} This applies even if no additional information needs to be provided or further questions answered. A health professional involved in their care on the day should document that the patient still wishes to go ahead, and that all questions have been answered.
- 6.2 The health professional must ensure that patients are kept informed about the progress of their treatment, and are able to make decisions at all stages, not just in the initial stage. If the treatment is ongoing, clear arrangements should be in place to review decisions and, if necessary, to make new ones.
- 6.3 If new information becomes available regarding the proposed intervention (e.g. new evidence of risks or new treatment options) between the time when consent was initially sought, and the intervention is undertaken, a health professional should inform the patient and reconfirm their consent by repeating the process of seeking consent on the basis of this new information. Similarly, if the patient's condition has changed significantly in the intervening time, it will be necessary to obtain consent again, on the basis that the likely benefits and/or risks of the treatment may also have changed.
- 6.4 A patient with capacity is entitled to withdraw consent at any time, including during the procedure.^{13,17}

7 Standard Statement on Refusal of Treatment by Adults with Capacity

If an adult with capacity makes a voluntary and appropriately informed decision to refuse treatment this decision must be respected, except in circumstances defined by the Mental Health Act 1983.

All staff should be aware that:

- 7.1 If the process of seeking consent is to be meaningful, refusal must be one of the patient's options. A competent adult is entitled to refuse any treatment, except in circumstances governed by the Mental Health Act 1983. The refusal can be for any reason even if it is considered unwise by the health professional.
- 7.2 The Mental Health Act 1983¹⁸ [Mental Health (Care and Treatment) (Scotland) Act 2003]¹⁹ sets out circumstances in which patients detained under the Act may be treated without consent for their mental disorder. It has *no* application to treatment for physical disorders unrelated to the mental disorder, which remains subject to the common law principles set out in Standard 2 of this document.
- 7.3 Decisions taken by a patient, which are unusual, unexpected or not what the health professional would have chosen for him/herself, do not mean that the patient lacks capacity. It may highlight the need for further information or a clearer explanation. People are entitled to make decisions based on their own religious belief or value system even if it is perceived by others to be irrational, if the patient understands the consequences of their decision. However, if the decision appears to be based on a misperception of reality then the patient may not be able to comprehend and make use of the relevant information and hence may lack capacity to make the decision in question ⁴.
- 7.4 Where a patient has refused a particular intervention, the healthcare professional must continue to provide any other care to which they have consented. The healthcare professional should also ensure that the patient understands they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect their treatment choices, they should be advised accordingly ⁴.

8 Standard Statement on Treatment of Adults Who Lack Capacity

The Mental Capacity Act 2005 or Mental Health (Care and Treatment) (Scotland) Act 2003 should be referred to when caring for adults who lack the capacity to make their own decisions.⁵

- 8.1 A person lacks capacity if they have an impairment or disturbance that affects the way their mind or brain works and the impairment or disturbance results in the person being unable to make a specific decision. If a health professional has concerns that a patient may lack capacity and if they have considered the relevant circumstances, the Mental Capacity Act rules that the healthcare professional *must* perform the 2 Stage Functional Test ⁶ (Appendix 1).
- 8.2 As far as possible, health professionals should consider the person's past and present wishes and feelings (in particular if they have been written down) and any beliefs and values (e.g. religious, cultural or moral) that would be likely to influence the decision in question, or any other relevant factors that the person would be likely to consider if they were able to do so.^{4,6}
- 8.3 As far as possible health professionals should consult other people if it is appropriate to do so and consider their views as to what would be in the best interests of the patient, especially anyone previously named as someone to be consulted.^{4,19}
- 8.4 If the patient has appointed someone with a Lasting Power of Attorney (LPA) with authorization to consent to treatment on behalf of the patient in the event that they lose capacity, that person should be approached to seek their consent. If there is no LPA, treatment may be given if it is in the patient's best interests, as long as it has not been refused in a valid and applicable 'Advance Directive'. (See Mental Capacity Act 2005^{4,6} or Adults with Incapacity (Scotland) Act 2000).⁷
- 8.5 Independent Mental Capacity Advocates (IMCAs)²⁰ are not decision-makers for the person who lacks capacity. They are there to support and represent the person and to ensure that decision-making is done appropriately and in accordance with the Mental Capacity Act 2005.⁶
- 8.6 Where there is doubt about an individual's capacity or best interests, a court ruling should be sought. Doctors should seek legal advice where a woman lacks capacity to consent to a medical intervention which is nontherapeutic or controversial: for example, sterilization or abortion.¹³

- 8.7 The Mental Capacity Act 2005 Code of Practice ^{6,21} sets out a legal framework for involving people who lack the capacity to consent to taking part in research. The Act does not include clinical trials, which are covered by the Medicines for Human Use (Clinical Trial Regulations) 2004. ²²
- 8.8 Similarly, consent to research is covered by the Mental Health (Care and Treatment) (Scotland) Act 2003. ¹⁹
- 8.9 Patients may have an 'Advance Directive' specifying how they would like to be treated in the case of future incapacity. An advance refusal of treatment which is valid (made voluntarily by an appropriately informed person with capacity) and applicable to subsequent circumstances, in which the patient lacks capacity, is legally binding and must be respected. If there is doubt about the validity of an advance refusal a ruling should be sought from a court. ^{4,6}

9 Standard Statement on Consent to Treatment for Children and Young People

The process of obtaining valid consent to treat children and young people must be in accordance with current legislation and follow guidance from professional and employing bodies.[11](#), [25](#), [26](#)

- 9.1 The legal framework on consent, confidentiality and safeguarding (child protection) is covered by the General Medical Council publication, 0–18 Years: Guidance for All Doctors.[23](#) This document includes more detailed information covering each of the UK nations. In law; any competent young person in the UK can consent to medical treatment including contraception. Young people over 16 years of age, including those with a disability/impairment, are presumed to be competent to give consent to medical treatment unless otherwise demonstrated. For young people under the age of 16 years, however, competence to consent must be demonstrated. A young person must have sufficient understanding and maturity to understand fully what is proposed (England, Wales and Northern Ireland) or can understand the nature and possible consequences of the treatment (Scotland).[24](#)
- 9.2 In the United Kingdom, those under the age of 13 years are considered unable to legally consent to sexual activity.[23,24,25,26](#) In Northern Ireland, there is no statutory duty under criminal law to report to the police cases of sexual activity involving children under the age of 16 years unless the child is under 13 years or the other party is aged 18 years or over. In the Sexual Offences Scotland Act 2009 sexual activity with a male or female aged under 13 years is “rape of a young child”.
- 9.3 The assessment of a young person’s capacity to decide about contraception or medical treatment is a matter of clinical judgement guided by professional practice and local/national policy and is a legal requirement.[24](#) Assumptions should not be made about an individual’s capacity to consent based on age alone or disability.[4,23,27](#)
- 9.4 Following the case of *Gillick* in 1986, the courts have held that children and young people under 16 who have sufficient understanding and maturity to enable them to understand fully what is involved in a proposed intervention will also have the capacity to consent for treatment (Gillick Competence), in accordance with Fraser Guidance.[23,24,28](#) In England, Wales and Northern Ireland, in order to provide contraception to young people under 16 years of age without parental consent, it is considered good practice to follow the Fraser Guidelines/criteria (Appendix 2). In Scotland, although the Fraser Guidelines are sometimes used by health professionals, they have no authority in Scottish law. The primary legislation when determining ‘competency’ is the Age of Legal Capacity (Scotland) Act 1991,[5](#) whereby the only criterion is that the child understands the nature and consequence of the treatment.

- 9.5 A clinician should assess a young person's competence to consent to treatment by their ability to understand information provided, to weigh up the risks and benefits and to express their own wishes.
- 9.6 Competence to consent to treatment should be assessed and documented at each visit for all patients. [13,28](#)
- 9.7 As the understanding required for different interventions will vary considerably, a young person under 16 may have the capacity to consent to some interventions but not others (decision-specific consent). [23](#)
- 9.8 Where a child or young person lacks capacity to consent, consent would generally be given by a parent or other individual with parental responsibility or by the court. Those giving consent on behalf of young people must have the capacity to consent to the intervention in question, be acting voluntarily and be appropriately informed. The power to consent must be exercised according to the 'welfare principle'. Even where a child lacks capacity to consent, it is good practice to involve the child as much as possible in the decision-making process. [23](#)
- 9.9 The Children Act 1989 [29](#) sets out persons with parental responsibility.
These include:
- ▶ The child's parents if married to each other at the time of conception or birth.
 - ▶ The child's mother, but not the father if the parents were not married - unless the father has acquired parental responsibility via a court order or a parental responsibility agreement or the couple subsequently marry.
 - ▶ The child's legally appointed guardian.
 - ▶ A person in whose favour the court has made a residence order concerning the child.
 - ▶ A Local Authority designated in a care order in respect of the child.
 - ▶ A Local Authority or other authorised person who holds an emergency protection order in respect of the child.
- 9.10 Consent cannot be overruled by a person with parental responsibility if the young person is deemed to be competent according to the 'Fraser guidelines'. However, refusal of treatment can be over-ruled (except in Scotland) either by a person with parental responsibility for the child or by the court. In the UK (except for Scotland), the law on parents overriding a competent young person's refusal is complex. [11](#) Legal advice should be sought if treatment is considered to be in the best interests of the young person. [23](#)
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Note.

While no definitive guidance is provided as to when it is appropriate to over-rule a competent young person's refusal of treatment, it has been suggested that this should be restricted to occasions where the child/young person is at risk of suffering "grave and irreversible mental or physical harm". It may include a young person with capacity refusing an abortion then being over-ruled by a person with parental responsibility. In this scenario it would be recommended that health professionals seek a court ruling prior to undertaking the intervention. If the young person seeks advice or treatment in relation to an abortion and cannot be persuaded to inform her parent(s), every effort should be made to help them identify another adult (such as another family member or a specialist youth worker) to provide support. The putative father of a fetus cannot influence whether or not the partner requests an abortion. (Case law only).³⁰

10 Standard Statement on Consent Policies

All services should have a written policy on seeking and obtaining valid consent.

- 10.1 Service consent policies should be informed by and updated in line with latest national guidance (Department of Health and Social Care, England, Scottish Executive, The Welsh Office, Department of Health, Northern Ireland and the GMC).
- 10.2 Service consent policies should be in line with and endorsed by local NHS Trusts.
- 10.3 All staff should have read (and practice) according to the service's consent policy.

Further Guidance

The Department of Health and Social Care has issued a range of guidance documents on consent and these should be consulted for details of the law and good practice requirements on consent. Doctors and other health professionals must also be aware of any guidance on consent issued by their own regulatory bodies (e.g. GMC), Nursing and Midwifery Council (NMC), and the Royal Pharmaceutical Society of Great Britain.

The following guidance documents are available from the Department of Health and Social Care (August, 2009), and can be accessed on the Internet [here](#).

- ▶ Reference Guide to Consent for Examination or Treatment¹ provides a comprehensive summary of the current law on consent and includes requirements of regulatory bodies such as the GMC where these are more stringent.
- ▶ 12 Key Points on Consent: The Law in England. This one-page document summarises those aspects of the law on consent which arise on a daily basis and is available [here](#).
- ▶ Specific guidance, incorporating the law and good practice advice is available for health professionals working with children, with people with learning disabilities and with older people.
- ▶ Consent forms: ³¹
 - About the consent form
 - Consent Form 1 – patient agreement to investigation or treatment
 - Consent Form 2 – parental agreement to investigation or treatment for a child or young person
 - Consent Form 3 – patient/parental agreement to investigation or treatment (procedures where consciousness not impaired)
 - Consent Form 4 – form for adults who are unable to consent to investigation or treatment.

Guidance on the use of these consent forms can be found from the Department of Health [and Social Care], [here](#).

The Welsh Office has guidance on patient consent, available [here](#).

The Scottish Executive issued a document in June 2006 [NHS HDL (2006) 34] to assist health professionals working in NHS Scotland entitled *A Good Practice Guide on Consent for Health Professionals in the NHS Scotland* and this is available [here](#).

The Department of Health, Social Services and Public Safety in Northern Ireland has published a *Reference Guide to Consent for Examination, Treatment of Care* and this may be accessed [here](#).

Guidance on consent is also produced by the General Medical Council¹⁵, the Royal College of Obstetricians and Gynaecologists¹⁶ and the British Medical Association.³²

Specific guidance for nurses is provided in the NMC code and Royal College of Nursing (RCN) Principles of consent – Guidance for nurses, this can be found [here](#).

Appendix 1: Two Stage Functional Test

If there are doubts regarding a person's mental capacity the following test should be used and the results documented within the patient's records.

Stage 1

- ▶ Is there an impairment of, or disturbance in the functioning of a person's mind or brain? If so, is the impairment or disturbance sufficient that the person lacks the capacity to make a particular decision? If yes stage 2 should be performed.

Stage 2

- ▶ understand information provided
- ▶ retain that information
- ▶ balance or weigh that information as part of the decision-making process
- ▶ communicate their decision (by verbal, written, using sign language or any other means).

Where a person is unable to satisfy any one or more of the 4 criteria above, they will be regarded in law as lacking mental capacity to make the decision.

Appendix 2: Fraser Guidelines

The following questions should be considered by the health professional when considering a young person's ability to consent to contraception and documented appropriately in their records:

- ▶ The young person **Understands** the professional's advice.
- ▶ The young person cannot be persuaded to inform their **Parents**.
- ▶ The young person is likely to begin, or to continue having, **Sexual intercourse** with or without contraceptive treatment.
- ▶ Unless the young person receives contraceptive treatment, their physical or mental health, or both, are likely to **Suffer**.
- ▶ The young person's best **Interests** require them to receive contraceptive advice or treatment with or without parental consent.

U-P-S-S-I is a useful mnemonic to remember these five guidelines.

Appendix 3: Twelve key points on consent: the law in England

When do health professionals need consent from patients?

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

Can children consent for themselves?

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

Who is the right person to seek consent?

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

What information should be provided?

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

Is the patients consent voluntary?

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

Does it matter *how* the patient gives consent?

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

Refusals of treatment

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

Adults who are not competent to give consent

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

This summary cannot cover all situations. For more detail, consult the *Reference guide to consent for examination or treatment*, available from the NHS Response Line 08701 555 455 and at <https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition> .

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