FSRH The Faculty of Sexual & Reproductive Healthcare

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

2022 | FSRH

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 goldstandard 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 workto influence policy and public opinion working with national and local governments, politicians, commissioners, policy makers, the media and patient groups. Our goal is topromote and maintain high standards of professional practice in SRH to realise our vision of holistic SRH care for all.

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Published by the Clinical Standards Committee

Faculty of Sexual & Reproductive Healthcare

of the Royal College of Obstetricians and Gynaecologists

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First Published: June 2007

Review dates: June 2011, July 2014, July 2018, 2022

Next review date: 2025

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This standard should be used in conjunction with the following guidance and standards to support best clinical practice:

- https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent
- https://www.nhs.uk/conditions/consent-to-treatment/
- https://www.rcog.org.uk/en/guidelines-research-services/guidelines/clinical-governance-advice-6/
- https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/good-practice-guides/consent/
- https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf
- https://www.rcn.org.uk/(pub-006047.pdf)
- https://www.pharmacyregulation.org/sites/default/files/guidance_on_consent_08.09.14_0.pdf
- FSRH CEU method specific clinical guidelines
- FSRH clinical standards:
  - Record Keeping
  - Confidentiality
  - Quality Standard for Contraceptive Services
  - Risk Management
  - FSRH/BASHH Standards for Online and Remote Providers of Sexual and Reproductive Health Services
  - FSRH Key Principles for Intimate Clinical Assessments Undertaken Remotely in Response to Covid 19 (August 2020)

All service providers should be able to audit their services against current standards.

To avoid multiple reference annotations, it should be noted that statement points not specifically referenced can be found in previously referenced documents

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

Changes introduced since review

- Incorporates updated GMC[1] and FSRH guidance[2],[3],[4]
- Covers remote consultation and use of images in addition to face-to-face consultations
- References updated and added as footnotes

Introduction

This standard provides best practice guidance for healthcare professionals working in Sexual and Reproductive Health to support the delivery of safe, effective, patient-centred, and equitable care and avoid legal challenges. It should be used in all face to face and remote settings providing such care and in conjunction with published guidance from other professional bodies. It includes obtaining consent for examinations, use of images and for procedures. The consent process must be tailored to each patient individually and must fully support their decision-making in partnership with the clinical team. This standard only provides guidance relating to routine clinical practice.

When taking consent, the focus should be on the patient. Health professionals need to understand the concerns and wider circumstances of the individual patient before imparting advice. Patients need comprehensible information tailored to the individual about their options before they can reach a valid decision.

Patients should have a personalised explanation of the likely benefits, risks and effectiveness of each option including the risks and benefits of not proceeding. The amount of information provided will vary according to factors such as the patient's risk factors, the risks associated with the procedure and the patient's own wishes. The issuing of leaflets or factsheets does not replace a dialogue. Any questions from patients should be responded to honestly and as fully as the patient wishes.

[1] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent
[2] https://www.fsrh.org/standards-and-guidance/documents/fsrh-service-standards-for-consultations-june-2020/
[3] https://www.fsrh.org/standards-and-guidance/documents/fsrh-key-principles-for-intimate-clinical-assessments/

[4] https://www.fsrh.org/standards-and-guidance/documents/fsrh-statement-pain-associated-with-insertion-of-intrauterine/

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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 staff and non-clinical staff should have training in obtaining valid consent and keep up to date with any changes in the law and accepted best practice.

1.2 All staff must receive training on national child protection and safeguarding procedures and be able to use local policies and protocols.

1.3 All staff must be aware of the current Government guidance on protecting vulnerable adults.[5]

1.4 All staff working with young people must 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 must use the Fraser Guidelines (or equivalent guidance) when assessing competence.

1.6 All staff must be trained in the legal requirements of current data protection regulations as they apply to health services.

1.7 All staff should receive Information Governance training.

[5] https://www.gov.uk/government/publications/safeguarding-policy-protecting-vulnerable-adults

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2 Standard Statement on Process of Obtaining Valid Consent

All staff responsible for obtaining valid consent must understand the process and follow the seven principles of decision making and consent set out in GMC guidance

2.1 The consent process may vary according to the specific circumstances, but should be proportionate to the decision, risk involved and the patient's circumstances.

2.2 Clinicians and health professionals involved in obtaining consent should read and refer to GMC guidance.

2.3 The form of consent given should be documented in the clinical notes (non-verbal, verbal or written).

2.4 Verbal consent should be obtained to proceed with all non-face to face consultations as it is not always possible to rely on implied consent in these circumstances.

2.5 A written consent form may be a useful prompt and help to standardise record keeping but is not a substitute for a meaningful dialogue with the patient about the proposed intervention and is not an essential requirement for all procedures

2.6 Patients should be given accessible, relevant information about the proposed procedure and what is involved, including the risks and benefits. This should be supported by written information (or other aids such as online resources) where appropriate. The potential significance of the risks to the patient must be explored.

2.7 The patient must be given enough time and space for the discussion and to consider their decision.

2.8 The patient must understand that they can withdraw consent at any point during the procedure. The patient must understand what the procedure will involve and that they are able to say no or stop at any point.

2.9 Consent must be obtained for intimate examinations and no essential information giving or decision making should be made during an examination.

2.10 Adequate privacy should be ensured for information giving and the patient should be given the opportunity to be seen alone.

2.11 When an interpreter is needed an independent interpreter should be used rather than a family member or friend.

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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 Delegation of part of the consent process to other team members may be appropriate within a multidisciplinary team.

3.2 Any clinician involved in the consent process must be working within their competence, have the relevant training and skills and a full understanding of the procedure involved, including risks, benefits, and alternative options. They must be able to ask for further advice or support from appropriate colleagues if necessary.

3.3 If part of the decision-making process has been delegated, the clinician performing the procedure must check that the patient has received all the information they need to make their decision, that they have had time to consider it, that their expectations are realistic and that their consent is still valid before any intervention

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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

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, provision of appropriate, objective information, assessment of the patient's needs and priorities and lack of duress) have been met.

4.2 Clinicians must 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. It is important to ensure that the patient's ability to make decisions is supported by offering them further opportunities to discuss any proposed treatment in a clinic visit or phone call, should they wish to do so.

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, 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, consent obtained when the patient may be feeling vulnerable could be regarded as invalid.

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5 Standard Statement on Method of Giving and Recording Consent

Valid consent may be given in several different ways, but the process and decision must be documented

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.

5.4 Implied consent (non-verbal) or verbal consent may be sufficient for certain procedures.

5.5 The patient's agreement to the intervention and the discussions that led up to this agreement must be clearly documented, including the provision of any supporting material or use of interpreters.

5.6 A signature on a consent form is evidence of the process of consent-giving but is not proof of valid consent. Patients may withdraw their consent after they have signed a form. Reasonable adjustments may need to be made if the patient has additional needs such as difficulty reading or writing.

5.7 If consent has been validly given and documented, the lack of a completed consent form should not prevent treatment provision.

5.8 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).

5.9 Explicit consent must be sought for the presence of clinicians-in-training during consultations and for any clinical examinations done by them, regardless of whether the patient is conscious or sedated. This consent may be given/taken verbally but should be documented accordingly.

5.10 Consent must be obtained to make a recording that forms part of the investigation of a condition. All clinicians must explain why this is relevant to their care, the form the recording will take and that it will be stored securely. If the image is of an intimate nature the clinician should confirm consent to view the image and even share the image (e.g. if a second opinion is requested).

5.11 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 is not required provided images are anonymised and that the patient

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cannot be identified. Images of interest should not be taken with personal smartphones or duplicated and shared using screen capture methodology.

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

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. This applies even if no additional information needs to be provided or further questions answered. The health professional involved in their care on the day must document that the patient wishes to go ahead.

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 obtained, and the intervention is undertaken, a health professional should inform the patient and repeat the process of seeking consent based on this new information. Similarly, if the patient's condition has changed significantly in the intervening period, 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.

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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

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 1983 [6] and Mental Health (Care and Treatment) (Scotland) Act 2003][7] set out circumstances in which patients detained under the Acts may be treated without consent for their mental disorder. It has *no* application to treatment for physical disorders unrelated to the mental disorder.

7.3 People are entitled to make decisions based on their own belief or value system if they understand the consequences of their decision, even if it is perceived by others to be irrational. However, if the decision appears to be a result of an inability to comprehend or process the relevant information, they may lack capacity to make the decision in question.

7.4 Where a patient has refused a particular intervention, the clinician must continue to provide any other care to which they have consented. The patient must understand they are free to change their mind and accept treatment if they later wish to do so. Where delay may affect theirtreatment choices, they should be advised accordingly.

[6] Mental Health Act 1983. https://www.legislation.gov.uk/ukpga/1983/20/contents
[7] https://www.legislation.gov.uk/asp/2003/13/contents

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8 Standard Statement on Treatment of Adults Who Lack Capacity

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

8.1 If a health professional has concerns that a patient may lack capacity an assessment must be performed [8] (see Appendix 1).

8.2 The patient's past and present wishes and feelings (if they have been written down) and any beliefs and values (e.g., religious, cultural, or moral) that may influence the decision in question should be considered.

8.3 If appropriate, other people close to the patient or other professionals that know them well should be consulted and their views considered.

8.4 It may be necessary to involve an independent advocate, a mediation service, independent clinical expert, or local ethics committee. A case conference may be required.

8.5 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. It may be appropriate to provide treatment if it is in the patient's best interests, if it has not been refused in a valid and applicable 'Advance Directive' or Adults with Incapacity (Scotland) Act 2000) [9]

[8] Mental Capacity Act (2005) Code of Practice. https://www.legislation.gov.uk/ukpga/2005/9/contents
[9] Scottish Executive. Adults with Incapacity (Scotland) Act 2000. https://www.legislation.gov.uk/asp/2000/4/contents

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

The process of obtaining valid consent to treat children and young peoplemust be in accordance with current legislation and follow guidance from professional and employing bodies

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[10]. 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. However, competence to consent for young people under 16 must be demonstrated. A young person must have sufficient understanding and maturity to understand fully what is proposed (England, Wales, and Northern Ireland) or able to understand the nature and possible consequences of the treatment (Scotland)[11].

9.2 In the United Kingdom, those under the age of 13 years are considered unable to legally consent to sexual activity. 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.

9.4 In England, Wales, and Northern Ireland, to provide contraception to young people under 16 years of age without parental consent, it is considered good practice to follow the Fraser Guidelines[12] 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.

[10] https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/0-18-years

[11] https://www.gov.scot/publications/children-young-people-scotland-act-2014-national-guidance-part-12/pages/3/

[12] https://learning.nspcc.org.uk/child-protection-system/gillick-competence-fraser-guidelines

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9.5 Competence to consent to treatment should be assessed and documented by a clinician at each consultation.

9.6 A person under 16 may have the capacity to consent to some interventions but not others.

9.7 Where a child lacks capacity to consent, it is good practice to involve the child as much as possible in the decision-making process. 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.

9.8 The Children Act 1989[13] sets out persons with parental responsibility.

9.9 Consent cannot be overruled by any other person if the young person is deemed to be competent. If a 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.[14].

[13] https://www.legislation.gov.uk/ukpga/1989/41/section/2

[14] https://www.legislation.gov.uk/ukpga/1967/87/contents

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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 WelshOffice, Department of Health, Northern Ireland and the GMC).

10.2 All staff should have read the consent policy in their service and practise in accordance with its guidance.

10.3 Staff involved in the consent process should maintain their knowledge and remain up to date with any relevant changes in guidance.

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