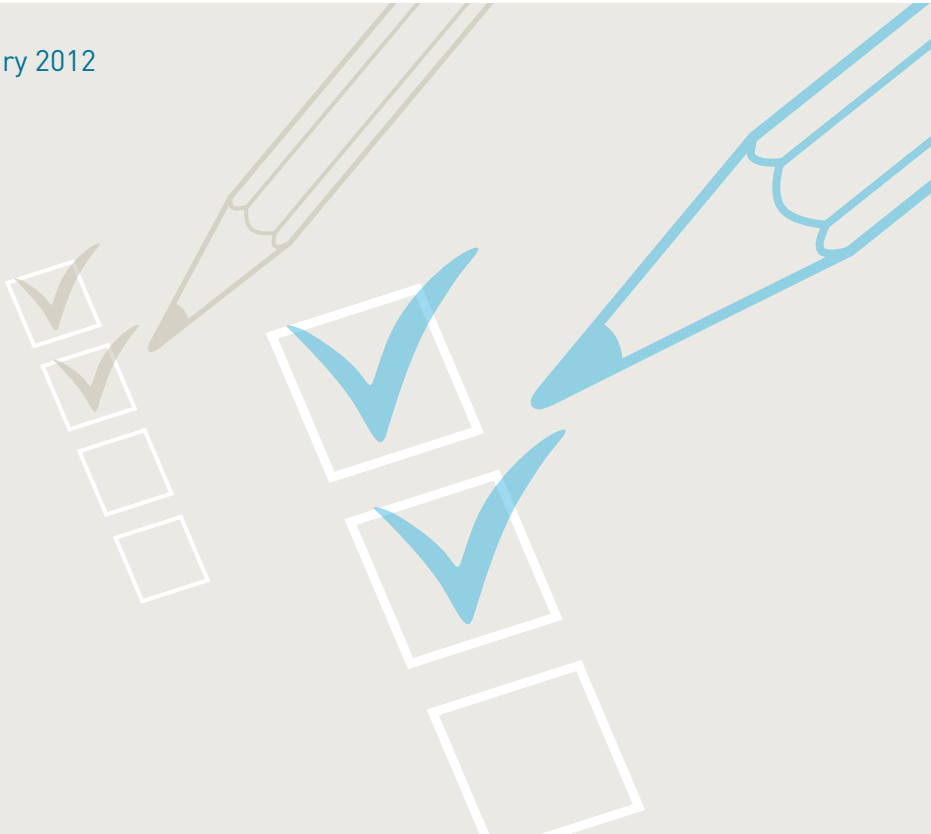


Guidance on consent

February 2012



The General Pharmaceutical Council is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in England, Scotland and Wales. As part of our role, we set the standards which govern the practice of pharmacists and pharmacy technicians.

About this guidance

This guidance should be read alongside the **standards of conduct, ethics and performance** which all pharmacists and pharmacy technicians must apply to their practice. This document gives guidance on standard 3.6 of the standards of conduct, ethics and performance, which says:

- You must get consent for the professional services you provide and the patient information you use.



The status of this guidance

This document gives guidance to pharmacy professionals on how to meet the standard of consent. The guidance is not intended to cover every situation and it does not give detailed legal advice. However, it reflects the current law in Great Britain.

Pharmacy professionals work in many different settings, so how relevant this guidance is to you may vary depending on your role and the type of patient contact that you have. You should use your professional judgement in applying this guidance in your own practice. You must make sure that you keep up to date and comply with the law, and with any NHS or employment policies for consent that apply to your particular area of work.

You must make sure that all staff members you are responsible for are aware of this guidance and are appropriately trained in all areas that are relevant to their duties.

If you are not sure about how the law applies in a specific situation, you should always ask for advice from appropriate professional colleagues, your employer, your professional indemnity insurance provider, your professional body or other pharmacy organisation, or get independent legal advice.

We have produced more guidance to help pharmacy professionals apply our standards of conduct, ethics and performance. You can find this on our website. In particular, when reading this guidance you should also see our 'Guidance on patient confidentiality'.

1 Consent

1.1 What is consent?

- 1.1.1 The Oxford English Dictionary defines 'consent' as 'to express willingness, give permission, agree'.
- 1.1.2 Patients have a basic right to be involved in decisions about their healthcare. The process of obtaining consent is a fundamental part of respect for patients' rights.
- 1.1.3 Obtaining consent is also essential in forming and maintaining effective partnerships between you and your patients.
- 1.1.4 You have a professional and legal duty to get a patient's consent for the professional services, treatment or care you provide, or to use patient information.
- 1.1.5 You must know and comply with the law and the good practice requirements about consent which apply to you in your day-to-day practice.

1.2 Types of consent

1.2.1 There are two types of consent:

- explicit (or 'express') consent: when a patient gives you specific permission to do something, either spoken or written
- implied consent: when a patient indicates their consent indirectly, for example by bringing their prescription to you to be dispensed. This is not a lesser form of consent but it is only valid if the patient knows and understands what they are consenting to. If you are not sure whether you have implied consent, you should get explicit consent.

1.2.2 You must use your professional judgement to decide what type of consent to get. You should take into account legal requirements, NHS service requirements, and policies where you work that may set this out.

1.2.3 When appropriate, you should record the fact that the patient has given explicit consent and what they have consented to.

1.3 Obtaining consent

1.3.1 For consent to be valid the patient must:

- have the capacity to give consent
- be acting voluntarily – they must not be under any undue pressure from you or anyone else to make a decision
- have sufficient, balanced information to allow them to make an informed decision
- be capable of using and weighing up the information provided.

1.3.2 The information you provide to the patient must be clear, accurate and presented in a way that the patient can understand. For example, you must consider any disabilities, or literacy or language barriers.

1.3.3. You should not make assumptions about the patient's level of knowledge and you should give them the opportunity to ask questions.

1.3.4 You are responsible for making sure that a patient has given valid consent. You must use your professional judgement to decide whether you should get consent from the patient yourself, or whether this task can be properly delegated. If you do delegate the task you must make sure that you delegate it to a competent and appropriately trained member of staff.

- 1.3.5 Getting consent is an ongoing process between you and the patient. Consent cannot be presumed just because it was given on a previous occasion. You must get a patient's consent on each occasion that it is needed, for example when there is a change in treatment or service options.
- 1.3.6 Patients with capacity are entitled to withdraw their consent at any time.

2 Capacity

2.1 What is capacity?

- 2.1.1 In England and Wales, under the Mental Capacity Act (2005), a person lacks capacity if at the time the decision needs to be made, they are unable to make or communicate the decision, because of an 'impairment or disturbance' that affects the way their mind or brain works.
- 2.1.2 In Scotland, under the Adults with Incapacity (Scotland) Act (2000), a person lacks capacity if they cannot make decisions or communicate them, or understand or remember their decisions, because of a mental disorder or physical inability to communicate in any form.

2.2 Assessing capacity

- 2.2.1 You must base an assessment of capacity on the patient's ability to make a specific decision at the time it needs to be made. A patient may be capable of making some decisions but not others.
- 2.2.2 In general, to make an informed decision the patient should be able to:
- understand the information provided
 - remember the information provided
 - use and weigh up the information provided, and
 - communicate their decision to you (by any means).
- 2.2.3 You must not assume that because a patient lacks capacity on one occasion, or in relation to one type of service, that they lack capacity to make all decisions.
- 2.2.4 A patient's capacity to consent may be temporarily affected by other factors, for example fatigue, panic, or the effects of drugs or alcohol. The existence of these factors should not lead to an automatic assumption that the patient does not have the capacity to consent. Instead you should use your professional judgement to make a decision based on the individual circumstances.
- 2.2.5 You must not assume that a patient lacks capacity based just upon their age, disability, beliefs, condition, or behaviour, or because they make a decision you disagree with.

- 2.2.6 You must take all reasonable steps to help and support patients to make their own decisions or to be as involved as they can be in a decision. For example:
- time the discussion for when the patient’s understanding may be better
 - use appropriate types of communication, simple language or visual aids
 - get someone else to help with communication such as a family member, support worker or interpreter.
- 2.2.7 If you are unsure about a patient’s capacity you must get advice from other healthcare professionals or people involved in their care.
- 2.2.8 If you are still unsure you must get legal advice.
- 2.2.9 Any advice you get or assessments carried out should be properly recorded, along with the outcome.
- 2.2.10 You can find more guidance on how people should be helped to make their own decisions, and how to assess capacity, in the Codes of Practice that accompany the Mental Capacity Act (2005) and Adults with Incapacity (Scotland) Act (2000).

2.3 Adults with capacity

- 2.3.1 Every adult is presumed to have the capacity to make their own decisions (that is, they are competent) and to give consent for a service or treatment unless there is enough evidence to suggest otherwise.

2.4 When a competent adult refuses to give consent

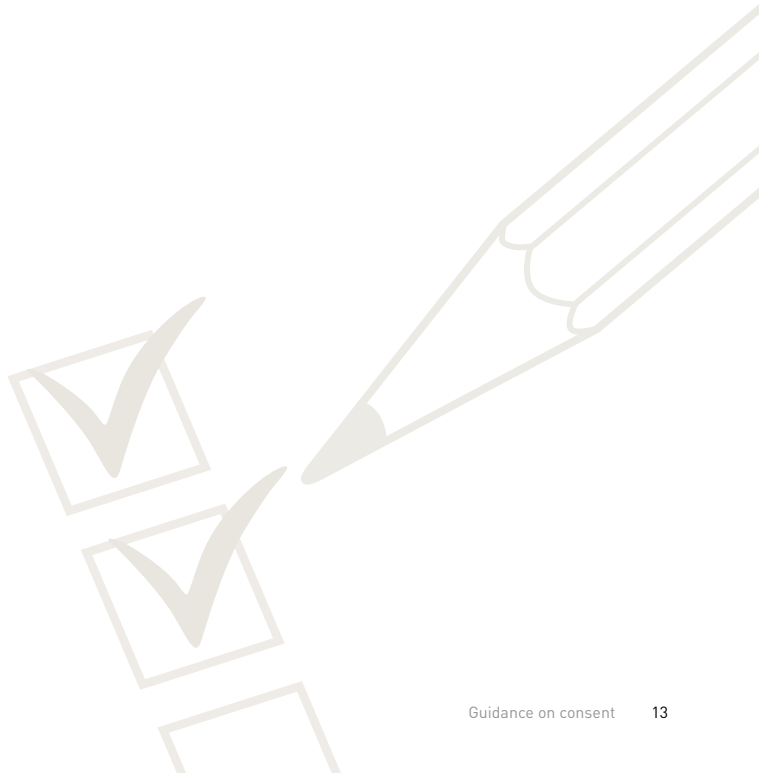
- 2.4.1 If an adult with capacity makes a voluntary, informed decision to refuse a service or treatment you must respect their decision, even when you think that their decision is wrong or may cause them harm. This does not apply when the law says otherwise, such as when compulsory treatment is authorised by mental health legislation¹.
- 2.4.2 You should clearly explain the consequences of their decision but you must make sure that you do not pressure the patient to accept your advice.
- 2.4.3 You should make a detailed record if a patient refuses to give consent. This should include the discussions that have taken place and the advice you gave.
- 2.4.4 If you believe that the patient is at risk of serious harm due to their decision to refuse a service or treatment, you must raise this issue with appropriate healthcare or pharmacy colleagues or people involved in their care, and your employer (if applicable). Consider getting legal advice if necessary.



¹ Mental Health Act 2003 (as amended by the Mental Health Act 2006), and the Mental Health (Care and Treatment) (Scotland) Act 2003.

2.5 Adults without capacity

- 2.5.1 If the patient is not able to make decisions for themselves, you must work with people close to them and with other members of the healthcare team.
- 2.5.2 The Mental Capacity Act (2005) and Adults with Incapacity (Scotland) Act (2000) set out the criteria and the processes to be followed in making decisions and providing care services when a patient lacks the capacity to make some or all decisions for themselves. They also grant legal authority to certain people to make decisions on behalf of patients who lack capacity.
- 2.5.3 If you believe that a patient lacks capacity to make decisions for themselves, consult the Codes of Practice that accompany the Mental Capacity Act (2005) or Adults with Incapacity (Scotland) Act (2000). These set out who can make decisions on the patient's behalf, in which situations, and how they should go about this.



2.6 Young people and children

- 2.6.1 The capacity to consent depends more on the patient's ability to understand and consider their decision than on their age.
- 2.6.2 In this guidance a young person means anyone aged 16 or 17 and a child means anyone aged under 16. However, people gain full legal capacity in relation to medical treatment at a different age in Scotland than in England and Wales.
- 2.6.3 As with any patient, a young person or child may have the capacity to consent to some services or treatments but not to others. Therefore it is important that you assess maturity and understanding individually, and bearing in mind the complexity and importance of the decision to be made.
- 2.6.4 If a person with parental responsibility is required to provide consent, you may need to get legal advice if:
- you are in any doubt about who has parental responsibility for the individual, or
 - the views of those that have parental responsibility differ.
- 2.6.5 Young people and children should be involved as much as possible in decisions about their care, even when they are not able to make decisions on their own.

2.7 Young people with capacity

- 2.7.1 Young people are presumed to have the capacity to make their own decisions and give consent for a service or treatment, unless there is enough evidence to suggest otherwise.
- 2.7.2 To decide whether a young person has the capacity to consent to a service or treatment, use the same criteria as for adults (see section 2.2 'Assessing capacity').
- 2.7.3 You should encourage young people to involve their parents in making important decisions. However, you should respect a competent young person's request for confidentiality.

2.8 Children with capacity

- 2.8.1 Children are not presumed to have the capacity to consent. They must demonstrate their competence.
- 2.8.2 A child can give consent if you are satisfied that the treatment is in their best interests, and that they have the maturity and ability to fully understand the information given and what they are consenting to. In this case you do not also need consent from a person with parental responsibility.

2.9 When competent young people and children refuse to give consent

England and Wales

- 2.9.1 In some circumstances, the courts can override the refusal of consent of a young person or child. You should get legal advice if needed on this issue.
- 2.9.2 The law is complex when a competent young person or child refuses to give consent for a treatment or service and someone with parental responsibility wants to override their decision. You should get legal advice if you are faced with this situation.

Scotland

- 2.9.3 When a young person or child has capacity to make a decision, then the law² says that their decision should be respected. This applies even if the decision differs from your view, or from the views of those with parental responsibility.
- 2.9.4 However, this position has not yet been fully tested in the Scottish courts, and nor has the issue of whether a court can override a young person's or child's decision. You should therefore get legal advice if you are faced with this situation.

²The Age of Legal Capacity (Scotland) Act 1991.

2.10 Young people without capacity

England and Wales

- 2.10.1 A person with parental responsibility for a young person can give consent on behalf of that young person to investigations and treatment that are in the young person's best interests.

Scotland

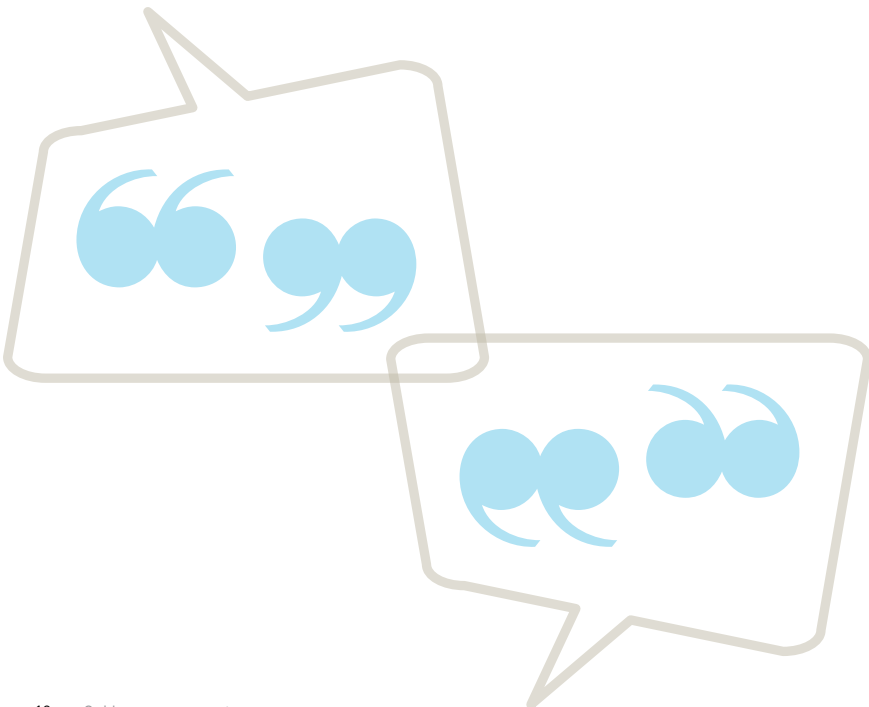
- 2.10.2 The rights of a person with parental responsibility to make decisions on behalf of a child ends when the child reaches the age of 16.
- 2.10.3 Young people who do not have the capacity to consent should be treated as though they are adults and in line with the Adults with Incapacity (Scotland) Act (2000).

2.11 Children without capacity

- 2.11.1 When a child lacks capacity to give consent, any person with parental responsibility for that child, or the court, can give consent on their behalf.

3 Advance decisions

- 3.1 People who understand the implications of their choices can say in advance how they want to be treated if they later suffer loss of mental capacity.
- 3.2 An unambiguous advance refusal for a treatment, procedure or intervention which is voluntarily made by a competent, informed adult is likely to have legal force.
- 3.3 An advance refusal of treatment cannot override the legal authority to give compulsory treatment under the mental health laws.
- 3.4 Any advance decision is superseded by a competent decision by the person concerned, given at the time consent is sought.



England and Wales

- 3.5 Advance decisions are covered by the Mental Capacity Act (2005). For an advance refusal of treatment to be legally valid, it must meet certain criteria set out in the Mental Capacity Act (2005).
- 3.6 If an advance decision does not meet these criteria, it is not legally binding but can still be used in deciding the patient's best interests.
- 3.7 You must follow an advance decision if it is valid and applicable to current circumstances.

Scotland

- 3.8 The Adults with Incapacity (Scotland) Act (2000) does not specifically cover advance decisions. However, it says that health professionals must take account of the patient's past and present wishes, however they were communicated.
- 3.9 It is likely that you would be bound by a valid and applicable advance decision. However, there have been no specific cases yet considered by the Scottish courts. If in any doubt, get legal advice.

4 Emergencies

- 4.1 In an emergency, if you cannot get consent, you can provide treatment that is in the patient's best interests and is needed to save their life or prevent deterioration in the patient's condition (this applies to children, young people and adults).
- 4.2 There is an exception to 4.1 above if you know there is a valid and applicable advance decision to refuse a particular treatment. For more information see the relevant incapacity legislation and its Code of Practice, or ask your professional indemnity insurance provider or a legal advisor.

5 Other sources of information

England and Wales

Mental Capacity Act 2005

www.legislation.gov.uk/ukpga/2005/9/contents

Mental Capacity Act Code of Practice

www.publicguardian.gov.uk/mca/code-of-practice.htm

Scotland

Adults with Incapacity (Scotland) Act 2000

www.legislation.gov.uk/asp/2000/4/contents

Scottish Government site for the Act

www.scotland.gov.uk/Topics/Justice/Civil/awi

More information

If you would like copies of this document in Welsh, please go to www.pharmacyregulation.org/standards/guidance where you can download a PDF. If you are seeking this document in other formats, please contact our communications team:
Email: communications@pharmacyregulation.org

If you have questions or comments about the content of this guidance, please contact our Standards Team:

Standards Team
General Pharmaceutical Council
25 Canada Square
London
E14 5LQ

Phone: 020 3713 8000
Email: standards@pharmacyregulation.org

We have also produced guidance on other topics that you may find useful:
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General Pharmaceutical Council
25 Canada Square
London
E14 5LQ
Phone: 020 3713 8000
www.pharmacyregulation.org

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