

Professional Standards and Guidance for Patient Consent

About this document

The Code of Ethics sets out seven principles of ethical practice that you must follow as a pharmacist or pharmacy technician. It is your responsibility to apply the principles to your daily work, using your judgement in light of the principles.

The Code of Ethics says that you must **'Show respect for others'**. In meeting this principle you are expected to:

- Respect and protect the dignity and privacy of others.
- Obtain consent for the professional services, treatment or care you provide and the patient information you use.

You have both a professional and a legal duty to obtain a patient's consent for the professional services, treatment or care you provide, or patient information you use. This document expands on the principles of the Code of Ethics to explain your professional responsibilities when obtaining consent. It is designed to meet the Society's obligations under the Pharmacists and Pharmacy Technicians Order 2007 and other relevant legislation.

This document does not give detailed guidance on legal requirements, but you must ensure you comply with relevant legislative requirements and with any NHS policies that may apply to your work. The law relating to consent is complex and differs across the United Kingdom. If you are in doubt about your responsibilities, you should seek legal or specialist advice.

Status of this document

Principle 6.6 of the Code of Ethics states that you must comply with legal requirements, mandatory professional standards and accepted best practice guidance.

This document contains:

- Mandatory professional standards (indicated by the word ‘must’) for all registered pharmacists and pharmacy technicians; and
- Guidance on good practice (indicated by the word ‘should’) which you should follow in all normal circumstances.

If a complaint is made against you the Society’s fitness to practise committees will take account of the requirements of the Code of Ethics and underpinning documents, including this one. You will be expected to justify any decision to act outside its terms.

1. CONSENT

STANDARDS

The Oxford English Dictionary defines consent as ‘permission or agreement’. Consent is a person’s agreement to receive a professional service or treatment appropriate for them and will be based on both their preferences and values and the information with which they have been provided. Patients have a basic right to be involved in decisions about their healthcare and the process of obtaining consent is fundamental for patient autonomy.

The consent you obtain must be valid. For consent to be valid the person must be:

- capable of making that particular decision,
- acting voluntarily, that is, they must not be under pressure from you or anyone else to make a particular decision,
- provided with sufficient information to enable them to make the decision,
- capable of using and weighing up the information provided during the decision-making process.

Obtaining consent is an on-going process not a single event. You must seek a patient’s consent on each occasion that it is necessary, for example due to a change in circumstances, rather than simply at the beginning of a process.

2. OBTAINING CONSENT

2.1 Providing sufficient information

STANDARDS

To provide valid consent patients must be given sufficient information to enable them to make an informed decision. Information must be clear, accurate and presented in a way that patients can easily understand. The information you provide may vary depending on the purpose for which consent is being obtained, the complexity of the information being provided and the needs of the individual patient. You must give consideration to the type of information patients are likely to want and need. This may be influenced by their personal beliefs.

Information the patient is likely to want includes:

- the service or activity they are being asked to consent to.
- the benefits to themselves of providing consent.
- the risks involved in providing consent.
- the implications of not providing consent.
- the alternatives that may be available to them.

You must provide information on the potential risks associated with the patient's decision, particularly serious adverse outcomes, even if the likelihood of them happening is very small. If you provide insufficient information the patient's consent may not be valid.

2.2 Presenting information to patients

STANDARDS

You must communicate information in a manner that is appropriate for the individual patient. Before speaking to the patient you need to consider whether the patient suffers from a disability (e.g. poor sight or hearing) or whether there is a language barrier. To ensure that patients are able to provide valid consent these must be overcome. You must consider whether patients need time to absorb the information they have been given and offer them an opportunity to come back later with questions.

GOOD PRACTICE GUIDANCE

- Use of visual aids, written material or the assistance of a translator or patient representative may assist you in ensuring that the patient understands the information they are being given.

2.3 Responding to questions

STANDARDS

Part of the patient's decision-making process may involve asking questions and the patient must be given the opportunity to do so. You must respond to questions and concerns openly and honestly, and must not mislead the patient in order to obtain consent.

2.4 Confirming patients' understanding

STANDARDS

You must be satisfied that patients have understood the information provided to them, and that patients are fully aware of what they are consenting or refusing consent to.

GOOD PRACTICE GUIDANCE

- Asking the patient a few simple questions is one way you could satisfy yourself that the patient has understood the information.

2.5 Who obtains consent?

STANDARDS

Generally, the person treating the patient, or providing a professional service for them should obtain consent. You must use your professional judgement to decide whether it is appropriate to delegate the task to another member of staff. There may be occasions when you judge this to be acceptable, for example, when a patient is providing consent to be part of a prescription collection service. Alternatively, if you are a pharmacist prescriber, it is more likely to be appropriate to obtain consent yourself.

Where the task of obtaining consent is delegated to a member of staff you still have overall responsibility for it. You must be satisfied that the member of staff is suitably trained and competent. Failure to do so may cause patients to lack confidence in the information with which they are being provided.

2.6 Patients' right to change their mind

STANDARDS

Patients are entitled to change the decision they have made with regard to providing consent. You must not assume that because patients have consented to a particular treatment or service in the past they will consent to it again. This may work both ways and patients could decide to give consent where they have initially refused. Patient choice must be respected. Patients must not be placed under pressure to make a decision, nor must they be pressured into accepting the advice provided by you or anyone else.

2.7 Standard operating procedures

STANDARDS

The process of obtaining consent must be taken into account when developing standard operating procedures for pharmacy services.

Procedures must cover:

- which activities within the pharmacy require patient consent.
- which activities require the pharmacist to obtain consent.
- which members of staff may obtain consent on your behalf.
- the information that should be provided.
- the type of consent required, e.g. implied, written or verbal.

(See Section 3)

2.8 Presence of a third person

STANDARDS

Where you would like a third person to observe your practice, for example a pre-registration trainee listening to a private consultation, you must seek the consent of the patient. You must inform the patient who the third person is, in what capacity they are working and what activities they will be undertaking, for example, observing or taking notes. You must give the patient the opportunity to refuse the presence of a third person. Where a third person is privy to confidential information they must be made aware that they are under the same duty of confidentiality as you are. This must also be made clear to the patient.

GOOD PRACTICE GUIDANCE

- If a patient requests that a third person of their choice is present, you should be clear about the information they are content to discuss in the third persons' presence.

3. FORMS OF CONSENT

STANDARDS

Consent may be obtained in the following ways:

- **Explicit consent**
 - verbally – the patient orally indicates their consent, e.g. by saying yes or no.
 - in writing – the patient signs a document stating they provide consent e.g. signing a declaration to receive a collection and delivery service, or a medicines use review.
- **Implied Consent** - the patient indicates their consent without writing or speaking, for example, a patient who brings their prescriptions to you for dispensing.

You must use your professional judgement when deciding which method you use to obtain consent; this may vary depending on the activity for which consent is being sought. You must be careful about relying on a patient's apparent compliance as an indication of his or her understanding or agreement.

Obtaining the signature of the patient provides evidence that consent was given, however it does not prove that the patient gave valid consent as the signature does not prove that they made an informed decision. It is the validity of the consent that is critical and even a signed consent form can be subject to dispute.

GOOD PRACTICE GUIDANCE

- Written consent should be obtained when you are providing services that require physical examination or diagnostic testing.

4. CAPACITY

4.1 Assessing capacity to provide consent

STANDARDS

As part of your assessment of capacity for both adults and children to provide consent, you must consider whether the patient:

- is able to retain the information you provided;
- has understood the information you provided;
- has understood the implications of their decision;
- is able to communicate their decision to you.

If you are unsure about a patient's capacity to make a decision you must seek specialist advice from another colleague or healthcare professional with relevant experience. If the patient's capacity remains in doubt you must seek legal advice.

4.2 Adults with capacity

STANDARDS

You must assume that every adult has the capacity to provide consent unless they have demonstrated otherwise.

In order for a patient to be considered capable of providing consent they must be able to understand and retain the information being given.

You must not assume that a patient who asks questions lacks capacity. Additionally patients do not lack capacity simply because they do not accept professional recommendations.

As part of the process of providing consent requires the patient to understand and retain the information they are being given, a patient may be considered capable of making some decisions but not others.

You must remember that a patient's capacity to provide consent may be temporarily affected by other external or associated factors e.g. the information they are being given may cause them to become anxious or agitated therefore temporarily influencing their ability to provide consent. However, anxiety on its own is not evidence that a patient lacks capacity.

4.3 Adults without capacity

STANDARDS

You must use your professional judgement, taking into account relevant legislation, such as those parts of the Mental Capacity Act 2005 that are now in force and the Adults with Incapacity (Scotland) Act 2000, when determining whether a patient is considered to have the capacity to provide consent.

There are provisions in certain circumstances for third parties to provide consent on behalf of an adult without capacity, as outlined in the Mental Capacity Act: <http://www.dca.gov.uk/menincap/legis.htm>.

Arrangements also exist in the Adults with Incapacity (Scotland) Act 2000 for proxy consent to be given where the person lacking capacity will benefit from the treatment.

Where you consider a patient lacks capacity to provide consent, you must record the discussions that have taken place and the reasons for your conclusion.

4.4 Children with capacity

4.4.1 Children aged 16 and over

STANDARDS

Children aged 16 or over are considered to have the capacity to provide consent unless they have demonstrated otherwise. Therefore, in many respects they must be treated as adults.

The standards as set out above for adults with capacity apply equally to children aged 16 and over (also see Section 5.2).

4.4.2 Children under 16

STANDARDS

England and Wales

There is no set age at which a person under the age of 16 has the capacity to provide consent.

Children under the age of 16 must be assessed to determine whether they are capable of making decisions about their healthcare and therefore provide consent. The courts have stated that a person under the age of 16 can give consent if he or she has ‘sufficient understanding and intelligence to enable him or her to understand fully what is proposed.’ (Gillick v West Norfolk and Wisbech Area Health Authority [1985] 3 All ER 402 (HL))

Where a child with capacity under the age of 16 provides consent to medical services this cannot be over-ridden by a person with parental responsibility.

Scotland

Where a qualified medical practitioner attending a child under the age of 16 is of the opinion that the child is capable of understanding the nature and possible consequences of the procedure, the child can provide consent. Parental consent to treatment will only be relevant if the medical practitioner feels that the child does not have sufficient understanding.

GOOD PRACTICE GUIDANCE

- It is good practice for you to encourage children to involve their parents in the decisions they make about their healthcare, but where the young person has capacity parental authority is not needed. Indeed, the young person can reasonably expect that their discussion with you will be kept confidential.
- The Society has produced guidance on child protection which outlines when you should consider speaking with other professionals who are involved in the child’s care, for example, their doctor.

4.5 Children without capacity

STANDARDS

Where a child lacks capacity, any person holding parental rights and responsibilities can give or refuse consent. Where there is no such person, a person who has the care and control of the child for the time being can give consent provided this person does not already know that the child's parent would refuse to do so.

5. REFUSAL OF CONSENT

5.1 Adults

STANDARDS

An adult with capacity may refuse treatment even if that refusal results in harm. The exception to this is where a person is being treated under mental health legislation or the Public Health Act

You must respect a patient's decision to refuse treatment, even when you think their decision is wrong.

If a patient without capacity has clearly indicated in the past, while capable, that they would refuse treatment in certain circumstances (an 'advance refusal/directive'), and those circumstances arise, you must abide by that refusal.

Where a patient refuses to provide consent a record of this must be made together with a record of the discussions that have taken place.

5.2 Children

STANDARDS

In England and Wales, where children under 16 years and young people aged 16 and 17 refuse to give consent their decision may, exceptionally, be over-ridden by a person with parental responsibility or alternatively the courts, where this is considered to be in the child or young person's best interests. Where a person with parental responsibility refuses to give consent on a child's behalf the courts may intervene.

However, in Scotland the decision of a young person aged 16 or 17 cannot be overridden either by parents or by a court. Legislation also supports the right of a young person under the age of 16 with capacity to refuse consent to medical treatment on their own behalf.

6. EMERGENCIES

STANDARDS

Treatment may be provided without patient consent in an emergency when necessary to save a life or prevent deterioration in the patient's condition. The exception to this is where an advance refusal exists that you know about or is drawn to your attention. The Mental Capacity Act Code of Practice must be consulted for further information.

An example of when this may arise is where a patient suffers from anaphylactic shock and an Epipen is administered for the purpose of saving a life.

GOOD PRACTICE GUIDANCE

- Emergency situations may be more prevalent within the hospital setting and you should ensure that you have read any relevant policy regarding patient consent.

Guidance that supports this document

We have produced documents or guidance bulletins on the following which should be considered in conjunction with these standards:

- Code of ethics for pharmacists and pharmacy technicians
- Professional standards and guidance for patient confidentiality
- Child protection
- Protection of vulnerable adults

You can download these documents and more copies of this document from our website (www.rpsgb.org) or you can telephone us on 020 7735 9141.

Other sources of Society advice

Further information or advice on the professional or legal obligations of the pharmacy profession can be obtained by contacting the Society's legal and ethical advisory service on 020 7572 2308 or by e-mail ftp@rpsgb.org.

Other useful sources of information:

- Mental Capacity Act: <http://www.dca.gov.uk/menincap/legis.htm>
- Mental Capacity Act Code of Practice:
<http://www.dca.gov.uk/menincap/legis.htm>
- Department of Health: www.dh.gov.uk
- A Good Practice Guide on Consent for Health Professionals in NHS Scotland: http://www.sehd.scot.nhs.uk/mels/HDL2006_34.pdf
- Adults with Incapacity (Scotland) Act 2000:
<http://www.opsi.gov.uk/acts.htm>