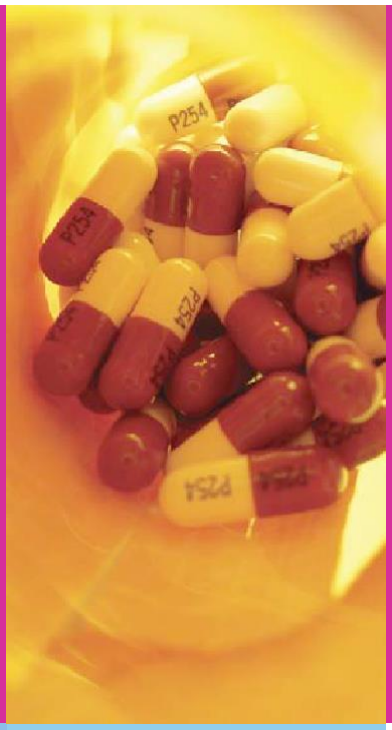
Issue: March 2016



PROFESSIONAL STANDARDS AND GUIDANCE FOR PATIENT CONSENT

Pharmaceutical Society of Northern Ireland

PROFESSIONAL STANDARDS AND GUIDANCE FOR PATIENT CONSENT

CONTENTS

STATUS OF THIS DOCUMENT

This guidance is addressed to pharmacists but may also help patients and the public understand what to expect of their pharmacist when making decisions about their care in relation to obtaining patient consent.

Standard 2.1.12 of the Code states that a pharmacist must adhere to all relevant legislation, standards and guidance.

This document contains:

- mandatory professional standards (indicated by the word 'must' or 'have to') for all registered pharmacists;
  and
- guidance on good practice (indicated by the word 'should', 'may', 'might', 'would', 'will' or 'could') which should be followed in all normal circumstances.

Serious or persistent failure to follow this guidance will put the pharmacist's registration at risk. The pharmacist must, therefore, be prepared to explain and justify his[1] actions.

If a complaint is made against a pharmacist, the Pharmaceutical Society of NI's, Fitness to Practise committee will take account of the requirements of the Code and underpinning documents, including this one. The pharmacist will be expected to justify any decision to act outside the terms set down in these documents.

ABOUT THIS DOCUMENT

The Code sets out the five mandatory principles of ethical practice that a pharmacist must follow. It provides a framework for professional decision-making and it is the pharmacist's responsibility to apply these principles to daily work situations, using his professional judgement. The guidance is not meant to be exhaustive, nor can it be.

The Code states that a pharmacist must **"obtain patient consent."**

1 'Pharmacist' appears with masculine pronoun and is understood to refer to male/female gender.

In adhering to this principle, a pharmacist is expected to:

- obtain appropriate consent from patients for the treatment and/or professional service provided, taking particular care to act in accordance with law where you suspect that a patient lacks or may lack capacity to consent;
- respect the right of the patient to refuse to take their medicines or to receive treatment or care;
- ensure you record, where appropriate, patient consent, either in writing or electronically, before providing a professional service and at appropriate intervals during the service provision.

This document expands on the principles of the Code to explain the pharmacist's professional responsibilities when obtaining patient consent.

This document does not cover a pharmacist's responsibility to protect or disclose personal information about a patient. Refer to "*Standards and Guidance for Patient Confidentiality*."

This document does not give detailed guidance on legal requirements. The pharmacist must adhere to relevant legislative requirements and Health Service policies that may apply to his work. As the law relating to decision-making and consent, particularly for a patient who lacks ability, varies across the United Kingdom, a pharmacist needs to understand the law as it applies in Northern Ireland.

This guidance takes account of, and is consistent with current law in Northern Ireland.

If the pharmacist is in doubt about his responsibilities, he should seek legal or specialist advice.

PARTNERSHIP

A pharmacist must work in **partnership** with a patient to manage his/her treatment and care. A relationship with a patient should be based on openness, trust and good communication. The patient has a right to be involved in decisions about his/her treatment or care. Obtaining patient consent should be viewed as an important part of the process of discussion and decision-making.

1 CONSENT

Consent should be seen as a person's agreement to receive a professional service or treatment appropriate for him/her, based on his/her preferences and values and the information with which he/she has been provided. A patient

has a basic right to be involved in decisions about his/her healthcare and the process of obtaining consent is fundamental to patient autonomy.

The following principles are essential for patient consent to be valid. The patient has to be:

- capable of taking that particular decision ('*competent*');
- acting voluntarily: not under pressure or duress from the pharmacist or anyone else;
- provided with enough information to enable him/her to make the decision.

Where treatment or care is not immediately necessary seeking consent is an ongoing process rather than a single act. The discussion of available options prior to making a decision should be seen as part of the consent process. The pharmacist must seek a patient's consent on each occasion that is necessary, such as after a change in circumstances, not only at the beginning of a process.

2 OBTAINING CONSENT

2.1 PROVIDING SUFFICIENT INFORMATION STANDARDS

To provide valid consent a patient must be given sufficient information to enable him/her to make an informed decision. Information must be clear, accurate and presented in a way that a patient understands. The information the pharmacist provides 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. The pharmacist must give consideration to the type of information the patient is likely to want and need: this will be influenced by the patient's individual circumstances, views, beliefs and values.

The patient should be encouraged to ask questions if he/she does not understand or if he/she wants more information. In particular, he/she will need information about:

- the benefits and risks of the proposed intervention;
- what the intervention will involve;
- the actual and possible implications of not having the intervention; and
- the alternatives that may be available.

The pharmacist 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 the pharmacist provides insufficient information the patient's consent may not be valid.

2.2 PRESENTING INFORMATION TO A PATIENT

STANDARDS

The exchange of information between the pharmacist and a patient is central to good decision-making. The pharmacist must communicate information in a manner that is appropriate for the individual patient. How much information the pharmacist shares with a patient will vary, depending on his/her individual circumstances. The pharmacist should tailor his approach to discussion according to:

a) the patient's needs, wishes and priorities;
b) the patient's level of knowledge about and understanding of his/her condition and his/her treatment options; and
c) the nature of the patient's condition.

Before speaking to the patient the pharmacist also needs 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 a patient is able to provide valid consent these difficulties must be overcome (see Good Practice Guidance below). The pharmacist should explore these matters with the patient, listen to his/her concerns, ask for and respect his/her views, and encourage him/her to ask questions.

GOOD PRACTICE GUIDANCE

- Use of visual aids, written material or the assistance of a translator or patient representative: these may assist the pharmacist in ensuring that the patient receives and understands the information given.

2.3 RESPONDING TO QUESTIONS

STANDARDS

The pharmacist should check whether the patient has understood the information he/she has been given, and whether or not he/she would like more information before making a decision. The pharmacist must make it clear that the patient can change his/her mind about a decision at any time. The pharmacist must not mislead the patient in order to obtain consent.

2.4 CONFIRMING A PATIENT'S UNDERSTANDING

STANDARDS

The pharmacist must consider how fully the patient understands the details of the proposed treatment/intervention: this involves checking responses to

questions to elicit the patient's level of understanding, rather than simply accepting an answer at face value. This is more important than how the patient's consent is expressed or recorded.

GOOD PRACTICE GUIDANCE

- By asking the patient a few simple questions the pharmacist could satisfy himself that the patient has understood the information.

2.5 WHO OBTAINS CONSENT?

STANDARDS

Generally, the individual treating the patient, or providing a professional service to him/her should obtain consent. The pharmacist must use his professional judgement to decide whether it is appropriate to delegate the task to another member of staff. There may be occasions when the pharmacist judges this to be acceptable, for example, when a patient is providing consent to be part of a prescription collection service. Alternatively, it is more appropriate for a pharmacist to obtain consent if he is a pharmacist prescriber and will be prescribing for the patient.

Where the task of obtaining consent is delegated to a member of staff the pharmacist still has overall responsibility for it. The pharmacist must be satisfied that the member of staff:

- is suitably trained and competent;
- knows enough about the planned treatment or service;
- understands the risks involved;
- is able to provide the patient with sufficient and accurate information on which to base their decision;
- follows the principles explained in this document.

Failure to do so may cause the patient to lack confidence in the information with which he/she is being provided.

2.6 A PATIENT'S RIGHT TO CHANGE HIS/HER MIND

STANDARDS

A patient is entitled to change his/her mind and withdraw consent at any point. The pharmacist must not assume that because a patient has consented to a particular treatment or service in the past he/she will consent to it again. This may work both ways and a patient could decide to give consent after he/she has initially refused. Patient choice must be respected. A patient must not feel pressured into making a decision by the pharmacist 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;
- how consent is recorded in the patient's absence, for example, delivery of prescriptions;
- which members of staff may obtain consent on the pharmacist's 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 the pharmacist would like a third person to observe his practice, for example, a pre-registration trainee listening to a private consultation, he must seek the consent of the patient.

The pharmacist must make the following points clear to the patient:

- inform the patient who the third person is, in what capacity he/she is working and what activities he/she will be undertaking, for example, observing or taking notes;
- give the patient the opportunity to indicate whether or not they would like the presence of a third person;
- reassure the patient that refusal to allow the presence of a third person will not compromise their standard of care in any way;
- emphasise that where a third person is privy to confidential information he/she must be aware that he/she is under the same duty of confidentiality as the pharmacist.

GOOD PRACTICE GUIDANCE

- If a patient requests that a third person of his/her choice is present, the pharmacist should be clear about the information the patient is content to discuss in the third person's presence.
- Record request for and patient's decision to provide consent, where practicable, on PMR.

3 FORMS OF CONSENT

STANDARDS

Legally, it makes no difference whether a consent form is signed, or whether consent is given verbally or non-verbally. It is the validity of the consent that is critical.

- *Explicit consent*
  - verbally – the patient orally indicates his/her consent, for example, by saying yes or no,
  - in writing – the patient signs a document stating he/she provides consent, for example, signing a declaration to receive a collection and delivery service, or a medicines use review.
- *Implied consent* – the patient indicates his/her consent without writing or speaking, for example, a patient who brings his/her prescriptions to your pharmacy for dispensing or attends a clinic for an appointment.

The pharmacist must use his professional judgement when deciding what form of consent to accept; this may vary depending on the activity for which consent is being sought. A consent form is only a record, not proof that genuine consent has been given and that an informed decision was made.

GOOD PRACTICE GUIDANCE

- Consent should be recorded where appropriate when the pharmacist is providing services, which require physical examination or diagnostic testing or where treatment or care is complex.
- Giving and obtaining consent is usually a process, not a '*one-off*' event. A patient can change his/her mind and withdraw consent at any time. If there is any doubt, the pharmacist should always check that the patient still consents to his caring for or treating him/her.

4 CAPACITY

4.1 ASSESSING CAPACITY TO PROVIDE CONSENT

STANDARDS

For an adult or child aged 16 and over to have the capacity (be competent) to take a decision, he/she must be able to:

- understand and retain information material to the decision, especially as to the consequences of having or not having the intervention in question;
- use and weigh up this information in the decision-making process; and
- communicate his/her wishes.

4.2 ADULTS WITH CAPACITY STANDARDS

In the first instance, the pharmacist must assume that every adult has the capacity to provide consent. This includes adults with a disability such as visual impairment. The pharmacist must only regard a patient as lacking capacity once it is clear that, having been given all appropriate help and support, he/she cannot understand, retain, use or weigh up the information needed to make that decision, or communicate his/her wishes.

The pharmacist must not assume that a patient lacks capacity to make a decision solely because of his/her age, disability, appearance, behaviour, medical condition (including mental illness), his/her beliefs, his/her apparent inability to communicate or the fact that he/she makes a decision that he, the pharmacist, disagrees with.

The pharmacist must remember that a patient's capacity to provide consent may be temporarily affected by his/her emotional/mental state and other external or associated factors, for example, the information he/she is being given may cause him/her to become anxious or agitated therefore temporarily influencing his/her ability to provide consent. However, anxiety on its own is not evidence that a patient lacks capacity.

4.3 ADULTS WITHOUT CAPACITY STANDARDS

In Northern Ireland, there is currently no legal provision for someone else to consent to treatment on behalf of a patient without capacity. Decision-making for a patient without capacity is governed by the common law, which requires that decisions must be made in a patient's best interests.

In August 2007, the Bamford Review[2] produced a final report to conclude a four-year independent review of the effectiveness of current policy and service provision relating to mental health and learning disability, and of the Mental Health (Northern Ireland) Order 1986. The report recommends that there should be a single comprehensive legislative framework for the reform of mental health legislation and for the introduction of capacity legislation in Northern Ireland.

2 The Bamford Review of Mental Health and Learning Disability (Northern Ireland), 2007.

The Mental Health (NI) Order 1986, Article 69 of this order in Council provides for treatment for mental disorder to be given to a patient in certain circumstances without his/her consent. www.opsi.gov.uk/SI/si2004.
Where the pharmacist considers a patient lacks capacity to provide consent he must record the discussions that have taken place and the reasons for his conclusion.

4.4. CHILDREN WITH CAPACITY

The definition under Children (Northern Ireland) Order 1995, Article 2, states that:

"*Child……..means a person under the age of 18*".

A person aged 18 years or over can always give consent for him/herself unless he/she is deemed not competent. This includes children with a disability such as visual impairment.

In 1986, the Gillick judgement[3] stated that children under 16 who '*had sufficient understanding and intelligence to enable him or her to understand fully what is proposed*' could consent to treatment a doctor thought in their best interests. Parents need not be involved in the decision to treat. The BMA handbook on '*Consent, rights and choices in health care for children and young people*', (December 2000), provides guidance on how to assess when a child is competent to give consent.

When a child lacks capacity to give valid consent, everything possible should be done to foster that capacity. If the child is still unable to give consent, he/she should be kept fully involved and his/her views considered in any decisions that are taken.

If a child is competent to give consent for him/herself, the pharmacist should seek consent directly from him/her.

The legal position regarding '*competence*' is different for a child aged over and under 16.

3 The Gillick judgement (Gillick v West Norfolk and Wisbech Area Health Authority [1985], established the principle that in the absence of an express statutory rule, all parental authority 'yields to the child's right to make his/her own decisions when he/she reaches a sufficient understanding and intelligence to be capable of making up his/her own mind on the matter requiring decision'.

4.4.1 CHILDREN AGED 16 AND OVER
STANDARDS

A child aged 16 or over is considered to have capacity to provide consent unless he/she has demonstrated otherwise. Therefore, for the purposes of decision-making about medical treatment and care, he/she must be treated as adults.

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

4.4.2 CHILDREN UNDER 16
STANDARDS
NORTHERN IRELAND

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

A child under the age of 16 must be assessed to determine whether he/she is capable of making decisions about his/her 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*.' (sometimes known as "*Gillick competence*"). In other words, there is no specific age when a child becomes competent to consent to treatment: it depends both on the child and on the seriousness and complexity of the treatment being proposed.

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

GOOD PRACTICE GUIDANCE

- Competent children may consent to medical treatment and may ask that their parents are not involved at all. The pharmacist should seek to persuade them to involve their parents, but must respect their decision if they refuse. Indeed, the young person can reasonably expect that his/her discussion with the pharmacist will be kept confidential.

4.5 CHILDREN WITHOUT CAPACITY
STANDARDS

Where a child is not competent to give consent for him/herself, the pharmacist should seek consent from a person with '*parental responsibility*'. This will generally, but not always, be the child's parent. Legally, the pharmacist only

needs consent from one person with parental responsibility, although it is necessary to consult the child as well as involving those close to the child in the decision-making process.

The Children (Northern Ireland) Order 1995 and Family Law (Northern Ireland) Act, 2001 sets out who has parental responsibility.
www.opsi.gov.uk/legislation/northernireland/acts/acts2001/nia_20010012

5 REFUSAL OF CONSENT

5.1. ADULTS

STANDARDS

An adult with capacity may refuse treatment even if that refusal results in harm to him. The exception to this is where a person is being treated under mental health legislation or the Public Health Act[4].

The pharmacist must respect a patient's decision to refuse treatment, even when the pharmacist thinks his/her decision is wrong or irrational. The pharmacist should explain his concerns clearly to the patient and outline the possible consequences of his/her decision. The pharmacist must not however, put pressure on a patient to accept his advice. If the pharmacist is unsure about the patient's capacity to make a decision, he must follow the guidance in Part 4.3.

If a patient without capacity has clearly indicated in the past, while capable, that he/she would refuse treatment in certain circumstances (an '*advance refusal/directive*'), and those circumstances arise, the pharmacist 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. Where possible the patient should sign the record.

4 "*A person must not willingly cause a health hazard, or act in a manner that the person knows, or ought to know, will cause a health hazard.*" From Bill 23 – 2008, Public Health Act.
"***health hazard***" means
(a) a condition, a thing or an activity that:
(i) endangers, or is likely to endanger, public health, or
(ii) interferes, or is likely to interfere, with the suppression of infectious agents or hazardous agents, or
(b) a prescribed condition, thing or activity, including a prescribed condition, thing or activity that:
(i) is associated with injury or illness, or
(ii) fails to meet a prescribed standard in relation to health, injury or illness.

5.2 CHILDREN STANDARDS

In Northern Ireland, the decision of a competent child to **accept** treatment cannot be over-ridden by a person with parental responsibility. However the courts have said that, exceptionally, if the child **refuses** treatment, those with parental responsibility may consent on his/her behalf, and treatment can lawfully be given. This power to over-rule a competent child's refusal should be used very rarely, bearing in mind both the consequences of forcing treatment on a child who has refused it and the consequences of non-treatment in this particular case. At all times the pharmacist should be guided by the **best interests** of the child.

Where a child is refusing treatment which his or her parents want to accept, and the consequences of refusal are potentially very serious, consideration should be given to seeking a court ruling on what would be in the best interests of the child. Courts have the power to over-rule the decisions of both children and those with parental responsibility. Where the consequences are less serious, the pharmacist should do all he can to help the child and his/her parents reach agreement.

Similarly, there may be differences of opinion between parents and children who are not deemed competent. While, legally, the consent of the person with parental responsibility is sufficient for health and social care professionals to proceed, it is clearly good practice to do everything possible to reach agreement. In many cases, it may be possible to delay treatment until the child is content for it to go ahead. Again, the pharmacist should always be guided by the child's best interests.

6 EMERGENCIES STANDARDS

Treatment may be provided without patient consent in an emergency when it is necessary to save a life or prevent deterioration in the patient's condition. An example of when this may arise is where a patient suffers from anaphylactic shock and an adrenaline injection is administered for the purpose of saving a life.

The exception to this is where an advance refusal exists that the pharmacist knows about or is drawn to the pharmacist's attention. The Mental Health (Northern Ireland) Order 1986 must be consulted for further information.

GOOD PRACTICE GUIDANCE

- Whilst emergency situations may be more prevalent within the hospital setting, the pharmacist should ensure that he has read any relevant policy regarding patient consent within the workplace. This allows for all workplaces who may be covered by company policies, including, industry and community pharmacies.

GUIDANCE THAT SUPPORTS THIS DOCUMENT

The organisation has produced documents on the following which should be considered in conjunction with these standards:

- The Code – standards of conduct, ethics and performance for pharmacists 2016
- Professional Standards and Guidance for Patient Confidentiality.

These documents are available from our website (www.psni.org.uk).

Other useful sources of information:

- Reference Guide for Consent for examination, treatment or care (Department of Health, Social Services & Public Safety, Northern Ireland, 2003).
- www.dhsspsni.gov.uk/protchildrenvulnerableadults
- DHSSPS Code of Practice on Protecting the Confidentiality of Service User Information (January 2009).
- *Children and young people tool kit*. BMA Ethics. December 2010. British Medical Association (editor).

ACKNOWLEDGEMENT

GMC