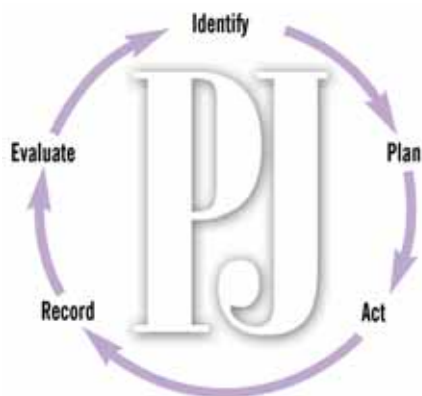


Consent: the heart of patient respect

In the second article of a series discussing the 2007 Code of Ethics for Pharmacists and Pharmacy Technicians, Joy Wingfield looks at the new requirements concerning consent and the capacity to consent



In their traditional role as suppliers of medicines, pharmacists have not had to pay a great deal of attention to the nature of consent — pharmacy customers volunteer information and often invite examination when they ask for advice on over-the-counter medicines. After seeing a GP and having first consented to treatment by medication patients also implicitly consent, by bringing in their prescription, to the use of their personal data for dispensing. In hospital, pharmacists reasonably assume that patients have consented to be there and have accepted whichever treatment they are offered. However, many new roles for pharmacists, such as diagnostic testing, performing medication reviews or medicines use reviews, running long-term treatment clinics and prescribing, require more significant interventions in patient care and access to records in GP surgeries and elsewhere. In such situations, consent cannot simply be assumed — pharmacists must ensure positive steps have been taken to secure valid consent.

For the first time, the code of ethics has explicit references to the need for consent and the Royal Pharmaceutical Society has provided additional standards and guidance concerning consent to address possible complications (see later). Why this emphasis? Securing consent is often promoted to health care students as a safeguard against being sued for assault and battery. (In law, a non-consensual intervention, any form of touching without permission, could constitute “battery”.) However, there are much better reasons for regarding consent as an essential part of successful health care. The securing of consent for any health intervention, whether or not it involves physical contact, is essentially the embodiment of respect for the patient’s autonomy. If you were the patient, you too would want at least the option of knowing what is wrong with you, what treatments might be available, what the pros and cons of such treatments might be, etc — in other words, you would want the opportunity to be

Identify knowledge gaps

1. Panel 1 (below) contains examples of situations that pharmacists have encountered. Can you identify which aspects of consent might be at issue?
2. How should you proceed when dealing with patients who may be unable to make their own decisions?
3. When can patients legally refuse to take their medicines?

Before reading on, think about how this article may help you to do your job better. The Royal Pharmaceutical Society’s areas of competence for pharmacists are listed in “Plan and record”, (available at: www.rpsgb.org/education). This article relates to “being a pharmacist” (see appendix 4 of “Plan and record”).

in control of your own treatment as far as possible. Furthermore, patients manage their conditions better if they fully understand, have agreed to and have confidence in their treatment. This is the basis of concordance in pharmaceutical care.

The key principle in the code of ethics underpinning consent is principle 3, “Show respect for others”, and this is amplified in statement 3.6: “Obtain consent for the professional services, treatment or care you provide and the patient information you use.”

In addition, principle 4, “Encourage patients to participate in decisions about their care”, reflects the role of capacity and consent in ensuring informed decisions (see statements 4.1, 4.6 and 4.7), exercising good communication skills (statement 4.2) and recognising the

Panel 1: Applying ethics to real-life situations*

- At the surgery where you undertake supplementary prescribing, they have standard clinical management plans for patients. The receptionist tells you: “For diabetics we just add in the patient’s name and then set up the appointment”.
- On a children’s ward you are advised by colleagues not to mention the use of unlicensed paediatric medicines to parents because they are “worried enough already”.
- The leaflet drafted by the marketing department for your pharmacy says: “When you complete your lifestyle check with us we will automatically send you details of new services to manage your weight.”
- In your meeting with the contracting manager for a chain of care homes, he says: “We want monitored dosage systems for all new admissions — much easier for our care assistants. We always do this, OK?”
- You are carrying out a medicines use review and the patient says: “I assume this only relates to this particular prescription. You don’t see all my medical records, do you?”
- Because of threatened violence and abuse of staff, you are asked to draw up an agreement for substance misusers to sign before receiving their daily supply.

* Suggested answers can be found at: www.pjonline.com/CPD



ElenaBorodiykina/Dreamstime.com

A competent adult always has the right to refuse treatment, to change his or her mind and withdraw consent or to refuse further treatment to which he or she may have previously consented

right to refuse treatment (statement 4.5) as well as their application to disclosure of information (statements 4.3 and 4.4), which is the subject of the final article in this series.

But what does consent really mean?

Because consent is an everyday word — unlike autonomy and battery, for example, — pharmacists may reasonably believe that they know what it means. However, the question of whether or not proper consent has been obtained has been the subject of many court cases and much learned discussion and debate. Most of the arguments turn on three legal tests:

- Whether or not the patient was capable of giving consent (termed having “capacity”)
- Whether or not the patient was under any pressure or incentive to give consent
- Whether or not the patient was fully informed before taking the decision to give consent

Capacity is a legal term and definitions of who is considered to have capacity and when have varied over the centuries. The best synonym is probably “competence” and the pertinent question is: when does an individual have legal competence to, for example, enter into a contract to sell goods or, in this case, give consent to treatment? The answer has changed over time. For example, until the mid 19th century, married women were classed (alongside children and those with mental disorders) as being incompetent to enter into legal transactions.

Today, we describe patients as “having the capacity” or “lacking the capacity” to give consent to treatment or make decisions about their health care. The law also prescribes quite closely when capacity should be assumed.

Assuming that patients have capacity, pharmacists need to establish that they are fully informed and are making their decision of their free will

Adults over the age of 18 years, having achieved the age of majority, are presumed to have capacity. In addition, contrary to popular belief, no one can give consent on behalf of a competent adult. Equally, infants, patients who are unconscious and, in some circumstances, those who have mental disorders (including dementia) might lack the capacity to take decisions about some or all of their health care. This may involve issues such as consenting to medication or surgery, disclosure of health information or making decisions in relation to health care provision. In all of these situations it is the patient — not the doctor, not the relatives and not the carer — who must be the first choice when seeking consent.

Until relatively recently, assessment of a patient’s capacity was largely down to the judgement and experience of the physician. However, the past few decades have seen clarification of the legal boundaries, first from precedents derived from court cases and then in statutory legislation, constraining such professional judgement. In particular, the Mental Capacity Act 2005 (and, earlier, the Adults with Incapacity [Scotland] Act 2000) has established principles and safeguards to protect the interests of vulnerable adults (see Panel 2, p414).

The fully informed patient

Assuming that patients have capacity, pharmacists need to establish that they are fully informed and are making their decision of their free will. It is arguable whether or not a patient is ever truly fully informed about any health care intervention. Given the uncertainties of prospects of a cure or remission, the variable likelihood of medication side effects and the unpredictability of individual patient response, treatment is always a question of possible benefits versus risks. Nevertheless, pharmacists should aim for a patient who is as fully informed as possible, and this is what the courts will wish to see demonstrated in the decision-making by pharmacists.

It follows that the efforts made to achieve full information may depend on the seriousness of the intervention. Clinical trials, for example, have possibly the highest hurdles to meet. For example, participation by otherwise healthy adults in such trials needs: the most careful presentation of information and elucidation of the risks; lengthy periods for questions to be resolved; time to consider options and to change one’s mind; and meticulous checking of the subject’s understanding of every aspect of the trial. And all these should be captured in a detailed written consent form and signed by all parties.

Such a process might well be regarded as the gold standard of consent but is neither necessary nor achievable for everyday pharmacy practice. For example, in an emergency there may simply be insufficient time to explore fully every aspect of the information that might be relevant.

For consent to be valid in relation to the provision of information, the Society’s profes-

sional standards and guidance for patient consent draws on the words in a now landmark court case¹ saying that the patient must be “provided with sufficient information to enable them to make the decision” and “capable of using and weighing up the information during the decision-making process”.

The standards and guidance then outline the probable steps needed to reach this position:

- Sufficient information (ie, clear, accurate and presented at a level that the patient can understand) is provided
- The presentation of information in a way that covers, where relevant, details of exactly what the treatment or service entails, the benefits, risks and alternatives, including not having the treatment or service at all
- Efforts are made, where necessary, to overcome disabilities, such as poor sight or hearing or a language barrier
- The patient is given time to absorb the information and ask questions, to which responses should be given open and honestly
- Understanding is confirmed, ideally by asking the patient to put into words what they believe they are consenting to

Consideration should be given as to who is equipped to obtain consent. On occasions, it may be acceptable for a trained member of staff to obtain consent; on others, such as independent prescribing, the pharmacist may be best placed to secure informed consent. It should be noted that just as the patient's capacity to give consent may vary over time, any change in circumstances, or new or additional treatments, may make it necessary to seek consent on more than one occasion rather than just at the beginning of the process.

The right to refuse

A competent adult always has the right to refuse treatment, to change his or her mind and withdraw consent or to refuse further treatment to which he or she may have previously consented. Conversely, a patient may subsequently give consent to something he or she has previously refused, in which case care may be needed to explain any consequences a delay may have caused. The court decision mentioned above also states that for consent to be valid, the patient must be “acting voluntarily”. That means the patient must not be under pressure from others to make a particular decision.

Although the average pharmacist may think this consideration is unlikely to be an issue, patients in pain or under stress can all too easily adopt passive roles in order not to be “an awkward customer” or not to “upset the doctor”. Along with other health professionals, pharmacists should be alert to this possibility, especially in patients who are vulnerable due to their condition or circumstances. They should be prepared to enquire



Consent may be implied, explicit or recorded

whether patients in prison or in care homes, for example, have given valid consent to their treatment or care.

Consent should always be sought if a third person (eg, a preregistration trainee) wishes to be present to observe an interaction. The patient should be told who the person is, why he or she is there and what he or she will be doing. Any patient can refuse to allow the third person to be present.

Finally, the form of consent is flexible. It may be implied, for example, by the patient who brings you his prescription or who proffers his thumb for a blood sample. It can be explicit but not necessarily written down — the patient may simply say “yes” or “no”. Or it may be explicit and recorded as with an agreement to receive a collection and delivery service or enter a clinical trial. What matters is that all the components of valid consent have been addressed.

As with so many aspects of pharmacy practice, the development of standard operating procedures can ensure that all of the above points are itemised and formalised in the minds of all staff offering services or treatments to patients, customers or clients.

Vulnerable patients

All adults may experience periods of temporary lack of capacity at some time. The most obvious example is being unconscious. I have said above that no one may lawfully give consent on behalf of a competent adult so if a 23-year-old motorcyclist is admitted unconscious from head injuries, for example, does this mean nothing can be done? Well, no: a body of law has developed to assist in taking decisions about the medical treatment of unconscious patients. This is often described as the doctrine of “necessity and best interests” and recognises a situation where there is a need to act urgently to save life or prevent deterioration in a patient's mental or physical well being.

The health professional must decide that intervention is necessary and then take whatever action he or she judges to be in the patient's best interests. Although it is acceptable to seek information from relatives, carers and friends to ascertain what would have been the patient's wishes, it is the health professional who is taking the decision in the absence of consent from the patient; it is not for the relatives, etc, to give consent on the patient's behalf.

What of periods of diminished capacity in adults, such as may arise with a mild stroke, a bout of mental illness or in the early stages of dementia? Capacity to take decisions and give consent may come and go; it may vary according to the nature of the decision. Adults may develop difficulties in managing their financial affairs, for example, but remain able to express preferences for particular foods or their clothing, or retain the ability to manage their own medication. Residents in care settings may need support for the physical activities of daily life but otherwise expect full autonomy in other aspects of their lives.

A patient's capacity to give consent may vary over time and it may be necessary to seek consent on more than one occasion

Panel 2: Concepts in the Mental Capacity Act*

Principles

- There is a presumption that every adult has capacity.
- Individuals have the right to be supported to make their own decisions.
- Individuals retain the right to make what might be seen as eccentric or unwise decisions.
- Interventions for people without capacity must be the least restrictive possible.
- Anything done for or on behalf of people without capacity must be in their best interests — not yours or the organisation's (see below).

Determining best interests

- Best interests must not be determined merely on the basis of age, appearance or behaviour.
- When determining best interests, the patient should be permitted and encouraged to decide as much as he or she can.
- A determination of best interests must assess whether the patient will have capacity in the future and, if possible, delay decisions until then.
- When determining best interests, the patient's past and present wishes and feelings (especially if written down) must be considered.
- A determination of best interests must take into account, if practicable and appropriate, views of persons with an interest in the patient's welfare.
- In relation to life-sustaining treatment, what is in the patient's best interests must not be motivated by a desire to bring about his or her death.

* Adapted from J Wingfield and D Badcott. *Pharmacy ethics and decision making*. London: Pharmaceutical Press; 2007.

For some patients, perhaps with severe dementia or mental illness, the lack of capacity may eventually become permanent. In others, perhaps with learning disabilities, the lack of capacity is not total but is permanent. Other patients still, perhaps with neurological injuries or disease, may be in a position to anticipate their impending lack of capacity (or the ability to express it) and want to set down their wishes in the form of an "advance directive". In all these cases, the principles set out in Panel 2 should be followed and the standards and guidance supplementing the code of ethics expect pharmacists to record discussions and reasons for any conclusion that a patient lacks capacity to make their own decisions.

Children

Capacity in children is a bit of a movable feast. "Young people" over the age of 16 years (but below the age of 18) are considered generally to have capacity to consent to health care but, in England and Wales (but not in Scotland), their guardians, or the courts, can override that consent and refuse treatment on their behalf where that is considered to be in that young person's interests.

Professional standard 4.4.2 says that "children under the age of 16 years must be assessed to determine whether they are capable of making decisions about their health care and, therefore, provide consent". However, most pharmacists will be familiar with the concept of so-called Gillick competence and the ruling of Lord Fraser in the famous 1980s case² concerning the provision of contraceptive advice. The courts held that a person under the age of 16 years can give consent if he or she has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed".

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Although the original ruling related only to doctors and contraceptive advice the principle of making an individual assessment of level of understanding and ability to grasp the benefits and risks of a proposed intervention in older children is now widely adopted by all professionals in health care. Generally speaking, it would be wise to involve any adolescent in decisions about their health care and, in our society, even pre-teens may expect some input to decisions about their care.

This article has been confined to exploring consent to treatment and decisions about health care. The final article of this series, to be published on 10 November, will look at the provisions of the new code of ethics relating to confidentiality, the application of consent principles to the disclosure of confidential information and the related concepts of privacy and maintenance of professional boundaries.

References

1. Re C (adult: refusal of treatment) [1994] 1 All ER 819 (Fam Div); [1994] 1 FLR at 33E; [1994] 1 WLR 290
2. Gillick v West Norfolk and Wisbech Area Health Authority [1985] 3 All ER 402 (HL)

Resources

- The document "Professional standards and guidance for patient consent" was sent to every registered pharmacist and pharmacy technician with the 21 July issue of *The Journal*. It is also available at www.rpsgb.org.

Action: practice points

Reading is only one way to undertake CPD and the Society will expect to see various approaches in a pharmacist's CPD portfolio.

1. Reflect on the capacity of your patients and customers to take decisions. Are you always dealing with mature adults? How often do you deal direct with children or adolescents? Are your patients sometimes unconscious or suffering from learning disabilities or psychiatric disorders? Write down what issues might arise in achieving fully informed consent with those who use your services..
2. Read thoroughly the professional standards and guidance for patient consent supporting the 2007 code of ethics. Explain the content to pharmacy staff and invite questions to check your understanding.
3. Visit the Department of Health website: www.dh.gov.uk and search on "consent". Under the consent key documents, look at the guidance for patients and write down three examples of how you will now change your practice to reflect that guidance.

Evaluate

For your work to be presented as CPD, you need to evaluate your reading and any other activities.

Answer the following questions:

What have you learnt?

How has it added value to your practice? (Have you applied this learning or had any feedback?)

What will you do now and how will this be achieved?