ETHICAL AND LEGAL ISSUES IN HEALTHCARE

'Capacity' and the pharmacist's judgement of the 'ability to decide'

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A man asks you, while collecting his mother's 'sleeping tablets', for directions as to how to crush tablets. Assume that your undergraduate training has equipped you with sufficient expertise in the pharmaceutical sciences to deal with any formulation or stability issues that might arise. Assume also that you can ensure the prescription meets all legal requirements, including specification of the appropriate 'form' of the drug to be supplied, in the event that tablets are to be crushed. Aware that there may be situations where a patient with swallowing difficulties might, on the advice of a speech and language therapist, require medicines to be prepared in liquids of a specific consistency, you note that the range of other medications taken by this patient indicates that there are no swallowing difficulties.

The question in your mind is whether the tablets might be intended to sedate a person and whether such sedation might be achieved without the knowledge of the patient, thereby putting his/her right to consent to or refuse a healthcare intervention at risk.

In order for consent to be 'valid', the patient must have capacity to make a healthcare decision, be appropriately informed and be free from influence. This discussion will focus on capacity, and the pharmacist's judgement of a patient's ability to make healthcare-related decisions for him/herself.

'Capacity' generally refers to the ability to perform a given task. In legal terms, capacity is used to refer to "a threshold requirement for persons to have the power to make enforceable decisions for themselves" (LRC 2005) and is "the pivotal issue in balancing the right to autonomy in decision making with the right to protection from harm". (BMA, 2004). A child or a vulnerable adult might be capable of buying groceries but might not be capable of understanding the implications of acquiring a bank loan.

Capacity to decide requires that the patient understands the relevant information and can also retain that information long enough to both make a decision and to see the action related to that decision completed. Capacity may be circumstance or issue-related. Consider a patient with schizophrenia, for whom the 'ward of court' process assigns medical staff decision-making authority for healthcare matters that arise during episodes of schizophrenia. He develops gangrene in his toe, for which conventional medical treatment would be to amputate below the knee. One such patient successfully sought a court injunction to prevent the proposed amputation on the basis that he'd rather die than have only one leg.[1] The courts deemed that, in this matter, he had capacity to make sustainable decisions for himself, regardless of whether medical opinion considered that decision unwise. Incapacity may also be 'temporary'. Consider a pregnant woman, due to deliver her baby by caesarean section, who has a needle phobia. Despite having consented to the procedure, the sight of a needle causes her to verbally withdraw consent. In this case the court judged that she became 'temporarily' incompetent to withdraw consent, and allowed the medical staff to proceed with the caesarean despite her protestations.[2] These two cases highlight that there may be specific situations where a patient temporarily loses decision-making capacity and that people may be able to make decisions in some areas but not others.

Circumstances under which individuals might be justifiably allowed to make healthcare decisions on behalf of another do arise, but they are rare. It is important to clarify just how (un)likely it would be that an average 'elderly relative' or nursing home resident could be deemed to lack the capacity to make healthcare decisions for him/herself and that it would be unlawful for carers to impose sedation on competent adults without involving them in the decision to do so.

Children are not deemed to have decision-making capacity. In Ireland one is generally considered to be a child until the age of 16 and an adult at 18, and between 16 and 18 one is deemed competent to consent to (but not refuse) a healthcare intervention as offered. Parents generally make such decisions on behalf of their children and it is rare that the authorities will challenge the right to act 'in the best interests' of one's own child.

The Mental Health Act 2001 (MHA) seeks to curtail and define the circumstances under which an adult's decision-making rights might be removed, such circumstances generally relating to mental illness, severe dementia or significant intellectual disability, or situations involving acquired brain injury (ABI) or fluency-related inability to communicate decisions. The Act specifically excludes instances of social deviancy, intoxication or addiction as justification for the curtailment of an individual's rights.

When a person does not have capacity to consent, a number of alternatives may be considered, including application of 'power of attorney', making the person a 'ward of court', the use of the 'best interests' principle or 'substituted judgements', or the introduction of guardianship, as envisaged in the Law Reform Commission (LRC) paper on vulnerable adults and the Mental Capacity and Guardianship Bill (2007). Both focus on a presumption of capacity unless proven otherwise and consider the practical and legal difficulties which arise where an adult is considered to be incompetent. While doctors and decision-makers may be appointed personal guardians under the Bill, and may avail of the insight and recommendations of family members and carers when deciding what might be in a patient's best interests, it is essential that pharmacists clearly understand that family members are generally not entitled to make decisions on behalf of patients.

Practitioners may have difficulty making assessments of capacity and the Bill seeks to protect practitioners from charges of negligence in the event that, having taken all due caution, they impose healthcare decisions on a patient who is afterwards deemed to have been competent. In addition the Minister for Health and Children will have the power to set up a working group to produce guidelines for medical professionals in relation to capacity to make healthcare decisions. Pharmacists would also certainly benefit from such guidelines.

Pharmacists in many branches of the profession face potential dilemmas with respect to the capacity of children and vulnerable adults. It is not unusual to find oneself dispensing to a 15-year-old without 'parental consent', and in the full knowledge that the teenager with whom you are engaged in a trusting healthcare practitioner-patient relationship does not wish for the aforementioned parents to be informed of the medication being taken. Vulnerable adults, such as those with intellectual disabilities, present with a range of abilities - some of which may well provide adequate capacity to decide to take, for example, oral contraceptives and who are as entitled as any patient to privacy regarding such decisions. Some people may have poor sight, sub-optimal hearing, literacy difficulties or physical disabilities. Some healthcare practitioners may require a reminder that none of these disabilities necessarily means there is a diminution of the person's capacity to make decisions.

I particularly remember one patient that regularly presented prescriptions while in an intoxicated state. If asked to judge whether he had capacity to make decisions at that point in time, my conclusion would have been 'negative'. To have refused him would risk, amongst other things, a charge of both cultural bias and a misuse of the 'position of power' a pharmacist holds in the medicines 'supply' process. In reality he was vulnerable. The circumstances and reasons why people misuse medicines remains a mystery to most practitioners, not least the issue of parasuicide, yet skills in the identification of those vulnerable to suicidal tendencies are not core to pharmacists' training.

Key points for pharmacists to consider include that fundamental beliefs about capacity are challenged and understood, that family members or carers are not generally entitled to make healthcare-related decisions for patients, that declining physical strength does not necessarily correlate with declining capacity to make healthcare-related decisions for oneself and that there is something unsettling about those situations where pharmacists dispense medication to patients of 'uncertain' capacity. However, the

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greatest dilemmas arise for pharmacists when we do not even meet the patients to whom we are responsible, thus denying the opportunity to professionally judge factors related to capacity at the point of dispensing. The range of potential 'carers' through whom pharmacists deliver patient care include family members, neighbours, HSE or privately employed 'home-help' and employees of nursing homes and other care facilities. While there may be occasions when sedation is appropriate, and consented to by the patient, pharmacists do not want to unwittingly collude in scenarios where a competent patient is given medication without his/her knowledge.

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References ~

1 Re C (adult: refusal of medical treatment) 1994.

2 Re MB (Caesarean Section) 1997. 2 FLR 426; 38 BMLR 175.

Other reading ~

British Medical Association and the Law Society Assessment of Mental Capacity: Guidance for Doctors and Lawyers (2nd) ed 2004).

Ireland, Law Reform Commission (2005) Law Reform Commission Consultation Paper on Vulnerable Adults and the Law: Capacity. LRC CP 37-2005. Dublin, Law Reform Commission.

The Mental Capacity and Guardianship Bill (2007).

Mental Health Act (2001).

PLEA: Association welcomes Irish Pharmacists interested in Ethics

The Pharmacy Law and Ethics Association was set up in England in 1998 and its objectives include the stimulation of debate on what constitutes ethical and responsible professional practice, and why, and to promote understanding at undergraduate level and beyond of the ethical basis for professional judgement.

Such objectives could be validly pursued in Ireland and, to this end, a branch of PLEA merits establishment. Pharmacists with a particular interest or qualification in Ethics and/or Law may join PLEA (gordon.appelbe@btopenworld.com).

A local branch could then develop.

PLEA founder members Joy Wingfield and Gordon Appelbe, and current editor of the PLEA newsletter, Alan Nathan, are very encouraging of this objective.

Ref: Appelbe, G., and Wingfield, J. (1998) The importance of law and ethics; Pharmaceutical Journal August 22nd. Vol 261, p286.