proportion is likely to be much higher in people who remain on methadone in the long term. Historical practice, and the reluctance of many pharmacies to provide supervised consumption facilities, make routine supervised consumption of methadone difficult to provide.

In 2003 there were 167 drug related deaths in Britain where methadone was solely or partly involved.² Just over half of these deaths were due to diverted methadone—that is, methadone that had been sold to the victim on the black market. A total of 1 486 800 prescriptions for methadone were issued in 2003 (www.ppa.org.uk). This translates into an annual death rate of 112 deaths per million methadone prescriptions. In contrast, the risk of death from overdose of tricyclic antidepressants is estimated at 30 per million prescriptions.¹¹ Clearly, opiate dependent people are likely to have much higher levels of risk taking behaviour than recipients of antidepressants, but these figures indicate the relative risk of methadone compared with other drugs that are regularly cited in fatal overdose.

In 2003 310 700 prescriptions were issued for buprenorphine (www.ppa.org.uk). Buprenorphine has not been cited in any drug related deaths reported to coroners in England and Wales since it was licensed for the treatment of opiate dependence in 1999. The Medicines Control Agency adverse drug reactions database has received reports of seven deaths involving buprenorphine, (www.mca.gov.uk), although to what extent these cases were related to buprenorphine or to other factors (such as intercurrent cardiac illness or continued illicit drug use) is unknown.

The maximum licensed dose of buprenorphine is 32 mg, with a suggested maintenance dose of 16 mg/day. Trials have shown that even opiate-naïve individuals can tolerate doses of 32 mg of buprenorphine while “experiments on rhesus monkeys proved that buprenorphine does not cause any respiratory depression that requires intervention, even at very high doses (10 mg/kg).”¹² Pirnay et al reported a series of 34 deaths involving buprenorphine in France,¹² but buprenorphine was “clearly” responsible for only four of these; most deaths involved its intake with other drugs, especially benzodiazepines and antipsychotics.

Buprenorphine is as prone as methadone to diversion to the black market and it may have a higher propensity to be injected than oral methadone.^{5 8} This is

probably the main reason for the reluctance to use this drug in preference to methadone in some areas. Cost may be another reason; although buprenorphine has clearly been shown to be cost effective,¹³ it is about four times more expensive than methadone (www.BNF.org). Nevertheless, the safety of buprenorphine in overdose is a significant advantage over methadone, especially considering the continued failure to prevent diversion of these agents on to the black market.

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Treating non-competent patients

England’s new act imposes new obligations but also makes things clearer

One issue that faces every clinician is assessing a patient’s competence and thus the ability to give consent, whether for a blood test or major surgery. Doctors need an approach for cases where competence is in doubt. The Mental Capacity Act 2005, which comes into force in April 2007 in England and Wales, not only provides such an approach but also sets out clear legal requirements for both assessing competence (referred to as “capacity” in the act) and treating incompetent patients.¹

Generally the act applies to people aged 18 and above but may apply to 16 and 17 year olds whose

incompetence is likely to persist into adulthood. It applies to individual decisions, because an individual may lack capacity to make some sorts of decisions (such as consenting to complex surgery) but be competent to make others (such as consenting to ultrasound examination).

Under the act a person lacks capacity only if there is an impairment of, or a disturbance in, the functioning of the mind or brain, which can be either temporary (such as sepsis or drug induced) or permanent (such as dementia or learning difficulties). Once the impairment is established, there must also be a

failure of at least one of the following: (a) understanding the information relevant to the decision (which must be imparted in a manner he could realistically understand, such as via an interpreter); (b) retaining that information (even if only for a short period); (c) using or weighing that information; (d) communicating the decision (by any means). An unwise or irrational decision is not necessarily an incompetent decision, and inadvisable decisions such as a refusal of chemotherapy in treatable cancers are not by themselves evidence of incompetence.

These clear provisions mean that doctors must pay close attention to assessing capacity rather than relying on intuition or what the family says about a patient's ability to decide. It would also be prudent if they recorded the grounds for finding a person incompetent (or, where the patient is demented or confused, competent) in the medical notes.

Once a patient is found incompetent the act allows doctors to treat the patient in that patient's best interests (see below). However, this power will be overridden if there is a valid written and witnessed advance refusal for the procedure made when the patient was competent and 18 or older.

The act has changed the law on proxy decision making. A competent adult may appoint a "donee" of a lasting power of attorney specifically for medical decisions. The donee can then decide on behalf of the person should he or she become incompetent. However, if the decision involves withdrawing life sustaining treatment this must have been specified by the patient in writing prior to incompetence. In some circumstances a court may appoint someone to make decisions of behalf of the patient (a deputy)—for example a parent of a child with learning difficulties may apply to become a deputy as the child grows into adulthood.

Any decision made under the act, whether by a doctor, a donee, or a deputy, must be in the incompetent person's best interests. Although the act does not further define best interests, these are more than simply best medical interests and include emotional, social, and psychological benefits.²

The Mental Capacity Act has adopted a patient centred approach to determining best interests. The act requires that the patient, although incompetent, should participate as fully as possible in any decision (an incompetent person, for example, may be able to state they are in pain and want it to stop yet be unable to consent to a morphine injection). Furthermore, the doctor must consider the person's past and present feelings, wishes, and beliefs. For example, it may be unwise to intubate and ventilate an incompetent person who had previously said he would never want

to be admitted to an intensive care unit. Family members (other than donees or deputies) do not have the legal power to consent on behalf of their incompetent relative, but the act requires that their views on what is in the patient's best interests should be taken into account, along with those of others involved in the patient's care.

The act empowers the doctor to use restraint in dealing with incompetent adults if two conditions are satisfied. Firstly, the restraining act must be necessary to prevent harm to the patient, so restraint in taking blood may be necessary to monitor warfarin treatment. Secondly, the restraint must be proportional to the likelihood and seriousness of the harm. A wandering confused patient may be more appropriately restrained at night by ensuring the bed sides are up and by watchful nursing staff than by the use of sedation.

The act confirms previous law on which medical decisions require court authorisation.³ These are withdrawing artificial nutrition and hydration in the persistent vegetative state and sterilisation for purely contraceptive purposes. When healthcare professionals disagree among themselves or with family members over serious medical decisions legal advice, and possibly referral to court, is necessary.⁴ This should be done early rather than waiting for an emergency situation, a practice frowned on by the European Court of Human Rights.⁵

Almost every doctor will encounter situations covered by this act in their routine practice. Clinicians who have doubts about assessing competence or best interests should consult their seniors or colleagues or, failing that, the trust's lawyers. The act does protect doctors if reasonable steps have been taken in good faith to assess capacity and best interests.

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