

resources.¹² However, benefit sharing agreements under the Convention are negotiated locally, between contracting individuals (“I want your plant, what do you want in return?”). This market model does not sit comfortably with human health needs. Merely expanding the convention to cover human genetic resources might serve as “window dressing” for national governments and detract from efforts to make them regard health and health research as a state priority and the best economic investment they could make.^{13–15} Instead the research community should make a concerted effort in cooperation with national governments to devise a legally binding framework for sharing the benefits of human genetics research that is based on equity, justice, and the spirit of the convention.

Doris Schroeder *reader in ethics and acting head of centre*
(dschroeder@uclan.ac.uk)

Miltos Ladikas *international development officer*

Centre for Professional Ethics, University of Central Lancashire,
Preston PR1 2HE

Udo Schuklenk *professor and head of centre*

Centre for Ethics, Public Policy and Corporate Governance, Glasgow
Caledonian University, Glasgow G4 0BA

Carolina Lasén Díaz *environmental lawyer*

9 rue des Veaux, 67000 Strasbourg, France

Anita Kleinsmidt *acting head*

University of Witwatersrand, Faculty of Health Sciences, Bioethics
Division, Johannesburg, South Africa

Fatima Alvarez-Castillo *professor in social sciences*

University of the Philippines, Department of Social Sciences, Diliman,
Quezon City 1101, Philippines

Dafna Feinholz *chair, Latin American Federation of
Ethical Review Committees*

National Commission of Bioethics, 01900 Mexico DF, Mexico

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Is methadone too dangerous for opiate addiction?

The case for using a safer alternative, buprenorphine, is strong

Methadone is an effective treatment for heroin addiction, and it remains the mainstay of drug treatment for opiate dependence in the United Kingdom.¹ The lethal dose of methadone is estimated at 50 mg for an opiate-naïve adult.² Nevertheless, many authorities recommend that methadone doses should be gradually increased to maintenance doses of 80–120 mg¹—that is, twice the lethal dose for non-users. The greatly increased risk to users from methadone, particularly black market methadone, thus remains a major concern. Buprenorphine is a partial agonist that has a lower potential for causing respiratory depression than many other opioids, including methadone and heroin.³ It is increasingly used in the United Kingdom to treat opiate dependence, with guidelines for clinical management in primary and secondary care summarised by Ford et al⁴ and Taikato et al.⁵ It is time it replaced methadone as the mainstay of drug treatment for opiate dependence.

A long running debate continues between proponents of long term maintenance treatment with metha-

done and the proponents of detoxification (in which the dose of a substitute drug is reduced over time to achieve abstinence from all agents). An expert US panel concluded, “although the drug free state represents an optimal treatment goal, research has demonstrated that the state cannot be achieved or sustained by the majority of persons dependent on opiates.”⁶ Without digressing further into this debate, we point out that that buprenorphine is at least as effective as methadone in both maintenance and detoxification.^{7–9}

One mechanism to reduce the diversion of methadone on to the black market is to insist that these drugs are taken in the presence of a pharmacist rather than being given “to take away.” Repeated advice to this effect is provided by the UK Department of Health and the Home Office.¹⁰ We have recently contacted 120 of the 140 community drug teams in England and Wales to ask what proportion of new patients on methadone undergo supervised consumption. We found that at least 25% of people who start prescriptions for methadone are still prescribed methadone to take away. This

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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-naive 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).”¹³ 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.

Jason Luty *honorary consultant psychiatrist in the addictions*
(sl006h3607@blueyonder.co.uk)

Cambridge and Peterborough Mental Health NHS Trust, Taylor Centre, Southend on Sea, Essex SS4 1RB

Colin O’Gara *clinical research fellow in the addictions*
National Addiction Centre, Institute of Psychiatry, London, SE5 8BB

Mohammed Sessay *staff grade in addiction psychiatry*
Merton Community Drug Team, Department of Addictive Behaviour, St George’s Hospital Medical School, London SW17 0RE

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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