

# Ethics briefings

## Research on incapacitated people

Proxy consent for the involvement of incapacitated adults in drug trials was discussed in a previous ethics briefing on the implementation of the *EU Clinical Trials Directive*.<sup>1</sup> In 2003, the BMA expressed concern about the piecemeal introduction of proxy decision making, prior to the introduction of more wide ranging mental incapacity legislation. In May 2004, this was echoed by the House of Lords in ongoing debate about the Medicines for Human Use (Clinical Trials) Regulations.<sup>2</sup>

It also became clear that the forthcoming Mental Capacity Act (formerly the Mental Incapacity Bill) would provide a proxy consent mechanism for strictly controlled research on incapacitated adults. In late 2003, a joint lords and commons committee scrutinising the draft incapacity bill recommended that “a clause be included to explore the causes and consequences of mental incapacity and to develop effective treatment for such conditions”.<sup>3</sup> The government accepted this proposal and consulted stakeholders about its potential scope and appropriate safeguards.

The act is expected to permit a range of research including studies on health and social care, subject to approval by research ethics committees. It may also amend the Human Tissue Bill to permit research on residual tissue taken from incapacitated people for diagnosis or therapy. Research must, however, relate to conditions affecting only incapacitated people in circumstances where there is no possibility of involving competent adults. Not only research expected to benefit the incapacitated individual, will be permitted: the act is also likely to allow research primarily intended to benefit others with the same condition, as long as it presents only minimal risk.

It remains to be seen, however, how the medicinal trials regulations and the capacity act create joined up rules in this first attempt to introduce legally recog-

nised proxy decision making in England and Wales.

## Challenges to confidentiality in England

It is a long established precept that doctors have a duty of confidentiality for identifiable patient data. Patients, however, also expect their information to be promptly available to any treatment providers when necessary for their care. Debate within the National Health Service (NHS) and within the British Medical Association has been intensifying about the proper uses of patient data. “Traditionalists” argue for tight control and restriction of disclosure unless patients consent, while “modernisers” call for better data sharing in order to guarantee the best service to patients. Both sides of the debate seek to promote patient interests, but define them rather differently.

The needs for tight control of information to maintain patient trust, and the desire for all care providers to have essential information on tap, are always likely to be in tension. Increasingly, however, emphasis appears to be on promoting effective data exchange in order to facilitate well informed patient care. Many factors contribute to the changing emphasis, but in England the National Programme for Information Technology (NPfIT) is crucial.

The NPfIT is an ambitious £6 billion programme with one of its key deliverables—the electronic care records service—raising ethical issues of consent and confidentiality. It essentially proposes that contemporaneous (not retrospective) patient data be placed on a national data spine by late 2004, with the full electronic care records service being phased in with completion expected in 2010. The database will be accessible to all NHS health care professionals. Apparently, patient consent to information featuring on the national data spine will be based on an opt out model following a public information campaign that clearly sets out the advantages, and the risks, of what is being proposed. It will be interesting to see how this is actually implemented in practice.

Patient autonomy will be promoted as individuals will be able to access their record on the central spine via the

“health space”—a “secure personal health organiser on the internet, at [www.nhs.uk/healthspace](http://www.nhs.uk/healthspace)”.<sup>4</sup> This will allow “people to make their preferences known to the clinical team. Preferences might include, for example, how they wish to be helped at a time of mental health crisis”.<sup>4</sup> It may also allow them to record wishes about organ donation and advance directives, and to note their religious beliefs.<sup>4</sup>

## Confidentiality and under 16s

The confidentiality aspects of the case of a 14 year old who arranged an abortion without her mother’s knowledge caused a furore in the UK in May this year.<sup>5</sup> The 14 year old had not disclosed her pregnancy to her mother until she was mid-way through a chemical abortion. The mother criticised the professionals who helped her daughter to have the abortion without informing her, and the law that permits this. It was claimed in the UK press that the 14 year old would have continued with the pregnancy had her mother known about the pregnancy sooner.

It is interesting to see that elements of good practice and ethics that appear well established—in this case, young people under 16 who are Gillick competent being able to seek confidential contraceptive and abortion advice<sup>6</sup>—continue to be open to challenge. It remains to be seen if this is a one off case or a manifestation of a more significant shift in public opinion on what young people, younger than 16, can expect to be kept confidential from their parents.

## HIV registry: Spain

Continuing the theme of confidentiality, the Spanish National Court ruled in May 2004 that a national Information System on New HIV Infections (SINVIH) should be abolished.<sup>7</sup> Established in 2000, the registry recorded data on HIV infected individuals, partly for epidemiological purposes, and had accumulated 70 000 personal files. Among other details, it included individuals’ initials, birth date and town of residency. Although HIV pressure groups were not opposed to an HIV registry as such, they argued that

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the database did not sufficiently protect individuals' identity. The national court agreed and ruled that "tabulated data...make possible the identification of a person with a high level of evidence". At the time of writing an appeal was expected.

HIV/AIDs registries are not unique to Spain, and can provide valuable epidemiological data. In the UK—for example, new diagnoses of HIV/AIDs are reported either to the Health Protection Agency Communicable Disease Surveillance Centre (CDSC) (England, Wales and Northern Ireland), the Scottish Centre for Infection and Environmental Health (SCIEH) (Scotland), or the Institute of Child Health (ICH) (paediatric infections). What is crucial, however, is that data held on these databases are secure and are pseudonymised.

## Criminalisation of HIV

Protection of identity is clearly vital when medical conditions are associated with some form of stigma. Unfortunately, this continues to be the case to some extent with HIV. We previously<sup>8</sup> highlighted the first case in England and Wales in 137 years of a person convicted of deliberately transmitting a disease, when an individual who failed to take precautions to prevent two of his female lovers becoming HIV infected or forewarning them, was found guilty of grievous bodily harm. Subsequently in May 2004, another man, Feston Konzani, was jailed for ten years for grievous bodily harm, for infecting three women with HIV by having unprotected sex with them.<sup>9</sup> In ruling at the Teesside Crown Court, judge Peter Fox QC stated: "The GBH which you inflicted falls into the category of the very worst sort for not only are the lives of these young women to be very substantially curtailed...you knew all along you had the infection and you knew you should have told them".<sup>10</sup>

## Maternal/fetal rights

### Scotland

In May 2004, the *breathe* project was launched in Glasgow to test routinely the carbon monoxide levels of consenting pregnant women, solely for the purpose of identifying whether they smoke.<sup>11</sup> It was proposed that women

identified as smokers would be offered a referral to a smoking cessation link midwife, whereby a smoking cessation "action plan" would be devised, including telephone support and counselling. Currently 27% of pregnant women in Glasgow are smokers. The Scottish Executive has, however, set a national target of reducing this number to 23% by 2005 and to 20% by 2010.

Although admirable in its aim of reducing the risks of prematurity and low birth weight for babies born to mothers who smoke, it is hard to see the advantage of such testing when women could simply be asked if they smoke. It will be interesting to see whether smokers who do not admit to smoking but consent to be tested, subsequently agree to participate in a smoking cessation programme.

### United States

In the run up to the 2004 American presidential elections, one potentially divisive issue will be the moral status attributed to embryos and fetuses, and the rights and protections stemming from this. One component in this dividing issue is the Unborn Victims of Violence Act 2004, also known as Laci and Conner's law, that was enacted on 1 April 2004.<sup>12</sup> The act essentially legislates that a person who causes the death of, or bodily injury to, a child in utero is guilty of an offence against the child if that person "had knowledge or should have had knowledge that the victim of the underlying offense was pregnant; or...the defendant intended to cause the death of, or bodily injury to, the unborn child." Concerns have been expressed that this is an initial strike at US abortion legislation,<sup>13</sup> although the act clearly states that:

Nothing in this section shall be construed to permit the prosecution—(1) of any person for conduct relating to an abortion for which the consent of the pregnant woman, or a person authorized by law to act on her behalf, has been obtained or for which such consent is implied by law; (2) of any person for any medical treatment of the pregnant woman or her unborn child; or (3) of any woman with respect to her unborn child.

## Euthanasia: Oregon, USA

A challenge to Oregon's Death with Dignity Act 1994 has been quashed.<sup>14</sup> The 1994 act allows terminally ill competent adults, resident in Oregon, to request medication for the purpose of "...ending his or her life in a humane and dignified manner...".<sup>15</sup> Attorney General John Ashcroft has long sought to restrict this, however, and in 2001 he issued a directive, known as the "Ashcroft directive", which essentially precluded doctors and pharmacists from prescribing lethal doses of drugs for the purposes of the act.

The United States Court of Appeals for the Ninth Circuit ruled, however, in May 2004, that Mr Ashcroft had exceeded his statutory authority by issuing the directive.<sup>16</sup>

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- 16 *State of Oregon v Ashcroft*, 02–35587.