Cluster trials

■ In most randomised controlled trials, individual patients are randomised to a treatment or control group, but sometimes this is undesirable or even impossible and groups (clusters) of people may be randomised instead. The need for these cluster randomised controlled trials is likely to increase in line with growing concern to evaluate the delivery of health services, public education, and policy on social care.

In cluster randomised controlled trials, informed consent for trial entry (that is, for randomisation) cannot be obtained individually. The question then is, under what, if any, circumstances are cluster trials ethical? The authors discuss why a cluster trial might be mounted, who has a duty of care to the people who form the cluster in question and should make the decision to participate on its behalf, and how this duty of care should be discharged.

Edwards SJL et al: Ethical issues in the design and conduct of cluster randomised controlled trials. Education and debate. *BMJ* 1999; 318: 1407-1409

Double intentions: relieve pain and hasten death

■ Following the acquittal of an English doctor, Dr David Moor, who had given a dying patient a lethal dose of diamorphine, two ethicists were invited to debate the issue at the centre of the case: that of giving a drug with the intention of relieving suffering even though it may hasten death. Professor Raanan Gillon argues that the difference between intending and foreseeing is all important, while Professor Len Doyal argues that the effect of this is to raise the moral character of a clinician above the best interests of his or her patients

Doyal L, Gillon R: When doctors might kill their patients. Editorial. *BMJ* 1999; 318: 1432-1433

Placental blood banking

■ Placental blood has gained new status as a potential source of hematopoietic stem cells for patients who would otherwise require a bone marrow transplant. With this new status have come new marketing strategies, as organisations approach hospitals and obstetricians, and pregnant women, for the collection, storage, and use of placental blood.

The author examines legal and social-policy issues regarding the collection, storage, and use of placental blood, including the hidden dangers of commercialising this "waste" product.

Some of the questions discussed are: Who owns placental blood? Who has rights to make decisions about its storage or disposal? What steps should be taken to preserve the privacy of the donor child and the mother? What are the implications of its use by physicians or hospitals collecting placental blood towards a research or commercial project, and what are the physician's responsbilities towards the mother in such cases? How should commercial companies marketing placental storage services be monitored?

The author notes that as market-based medicine matures and efficiency threatens to replace ethics as the touchstone of medical practice, we are likely to see more schemes to transform medical waste into profit. Such schemes are not necessarily bad, but unrestrained by law, they undermine important values, including autonomy and privacy.

Annas GJ: Waste and longing — The legal status of placental-blood banking. legal issues in medicine. *The New England Journal of Medicine* 1999 Vol. 340, No. 19

Research on the mentally ill

■ In the past 40 years, specific effective drug and psychological treatments have been developed for conditions such as depression, mania, psychosis, obsessions, panic, drug abuse, hyperactivity and Alzheimer's dementia. This progress has been based on the immense growth of both basic and clinical psychiatric research.

However, there has been concern about the ethical aspects of psychiatric research. How does one conduct ethical research on people, with a view to understanding and treating their illness, if their illness itself impairs their ability to provide informed consent? How do we proceed when these goals are in conflict, when conducting research on those who cannot themselves consent to participate in it is the route to improving their care?

The author discusses the US National Bioethics Advisory Commission's recently-issued recommendations on "the rights and welfare of human research subjects." He argues that the stricter regulations on the use of mentally ill patients for research will make research more cumbersome without any increased benefit or protection to its subjects.

Michels R: Are research ethics bad for our mental health? Soundings board. *The New England Journal of Medicine* 1999 Vol. 340, No. 18

Restrictions necessary

■ In a counter to Michel's argument, a member of the NBAC holds that the increased restrictions are absolutely necessary to protect research participants. A number of examples of unethical psychiatric research are cited, illustrating the author's point that current regulations do not ensure that researchers keep their subjects' best interests in mind, that they obtain informed consent from a guardian who has the potential participant's interests at heart.

Capron AM: Ethical and human-rights issues in research on mental disorders that may affect decision-making capacity. Sounding board. *The New England Journal of Medicine* 1999 340, No. 18