Counselling for thalassaemia

■This audit of the counselling process for couples in the UK whose pregnancies were affected by a major thalassaemia sought to measure how and when genetic risk was identified for each couple, and whether and when prenatal diagnosis was offered. The findings: standard practice of prenatal screening and counselling for haemoglobin disorders was not followed in a large proportion of the couples interviewed, resulting in a number of couples giving birth to a child with thalassaemia major. If they had been offered prenatal diagnosis, some of these couples would have terminated their pregnancies. Although antenatal screening and counselling for haemoglobin disorders are standard practices in the United Kingdom, they are delivered inadequately and inequitably. An explicit national policy is needed, to make early prenatal diagnosis available to all couples.

Modell B et al: Informed choice in genetic screening for thalassaemia during pregnancy: audit from a national confidential inquiry *BMJ* 2000; 320: 337-341

Screening for cystic fibrosis

■Practical methods are now available for population screening of neonates for cystic fibrosis. Though the prognosis for the disease has not yet improved with diagnosis and treatment from birth, this is expected to happen eventually. The authors discuss ethical reasons in support of neonatal diagnosis and early treatment.

Dodge JA and Ryley HC: Screening for cystic fibrosis *Archives of Diseases in Childhood;* Vol 57: 774-780

When to stop a trial

■ The research process includes a thorough evaluation of existing evidence along with a meta-analysis of earlier studies to confirm the need for the research project. Once started, a randomised clinical trial can come to a halt for a number of reasons. The authors describe their experience stopping a large international trial because of external evidence that emerged after the trial began.

The trial evaluated the antenatal use of thyrotropin releasing hormone combined with corticosteroids in women at risk of preterm labour. Researchers had reviewed earlier trials and were also aware of other ongoing trials. After recruitment started, one of the investigators peer-reviewed a journal submission on one of the other trials, which indicated that the drug affected babies' developmental scores, and the results of two other trials were also found to be disappointing. An updated meta-analysis suggested the hormone would have little benefit, if at all; even confirming this would require a much larger sample size than planned.

On the basis of their experiences, the authors suggest that principal investigators of clinical trials follow relevant information from other studies, including unpublished confidential information. Meta-analysis is useful for incorporating ongoing trial data with existing and emerging evidence. Finally, a data monitoring committee must review internal and external information, but the decision to modify or stop a trial must come from a separate steering committee.

Brocklehurst Peter et al: Role of external evidence in monitoring clinical trials: experience from a perinatal trial *BMJ* 2000;320:995-998

Treating for fun

■ This comment from a group of expatriate doctors in Nepal refers to the phenomenon of "medical tourism" in developing countries - western health professionals holding ad hoc clinics in rural parts of developing countries, without a local licence to practice, an understanding of the local culture, prevalent illnesses. "If an unregistered Nepali doctor on holiday in the United Kingdom offered general medical consultations in a shopping centre there would be a public and professional outcry." Medical tourism done by individual 'do-gooders' as well as through organised groups, in both cases without the consent or involvement of the local system.

Bishop Rachel A and Litch James A : Medical tourism can do harm Personal views *BMJ* 2000;320:1017

The academic - industry nexus

■This editorial on the growing ties between academic medical institutions and the pharmaceutical industry notes that the listing of authors' financial ties, for an article in the journal, was so long that it could not be printed in full. Ties range from grant support to consultancies, royalty agreements, listed authorship, gifts and equity interest in the companies. Harvard Medical School recently relaxed guidelines on such financial ties, ostensibly to prevent the loss of star faculty members to other schools.

The writer makes a forceful argument against this trend, and against the various arguments used to justify it. The academic-industry link does not improve the quality of research, but it does give the companies more credibility. Nor does it enable these centres to fulfil their mission of education, research and clinical care. Medical students and house officers learn to rely too much on drugs and devices, and begin a long and cosy relationship with the industry. Research becomes biased toward drugs and devices which have a market value, and less on the causes and mechanisms of disease. Finally, financial ties can influence the outcome of research studies. And the money spent on influencing researchers through industry-sponsored trips, gifts, conferences and the like are added to the prices consumers pay for drugs and devices.

The author calls for a change in these practices. The academic medical community should adopt stronger conflict-of-interest guidelines, not dilute them further.

Angell, Marcia: Is academic medicine for sale? *The New England Journal of Medicine,* May 18, 2000; 342(20).

Commercial research organisations

■This interview-based report discusses another trend, that of the growing use

by the pharmaceutical industry, of commercial research organisations (CROs) for drug trials.

With the new emphasis on chronic diseases, drug research needs long, large and multi-centre trials for statistical validity. Drug companies find that the teaching and clinical responsibilities of academic medical centres slow down the research process. Companies can contract with CROs for everything from study design onwards. They recruit patients through academic centers as well as community physicians, and may subcontract some of the work to site management organisations. Fighting to regain their lost market shares, academic centres are transforming themselves into research networks to compete with the commercial drug-trial sector.

The industry now writes trial protocols themselves. Important studies which might reduce drug sales are vetoed. Studies are designed with samples, dosages and end points all to favour their products. Data are controlled by the commercial organisation rather than the principal investigators. The results are written by a ghost writer, and the listed authorship often includes people who did not analyse the data or write the manuscript. Industry controls to a greater or lesser extent the publication of results, delaying unfavourable results, sometimes suppressing them altogether from publication.

Bodenheimer Thomas: Uneasy Alliance - Clinical Investigators and the Pharmaceutical Industry, *The New England Journal of Medicine,* 2000 May 18; 342.

HIV and getting pregnant

■This essay discusses the options of an HIV-positive man and his HIV-negative partner, who wish to have a child. At present, there is no recognised method to inseminate an HIV-seronegative woman with the ejaculate of an HIV-seropositive man and be certain that the woman will not seroconvert. There is no recognised technique for washing the sperm or extracting the HIV or treating the ejaculate to render it noninfective, though an Italian group reports the use of such a technique, and a test group of 10 discordant couples will soon be studied in the US using a similar technique with *in vitro* fertilization.

Should they risk unprotected sex since the man has had an undetectable viral load for years? Should they consider adoption, or insemination by an HIV-negative donor?

This case study discusses and quantifies the known risks, and concludes that "the odds that Linda won't become infected and their child will be born healthy". In fact, the couple conclude that "the consequences of an unwanted outcome are so dire and so irreparable that… the risk is not worth it." However, this article proposes that such couples be given complete information in order that they can make their own choices.

Ball Susan C: Addressing the issue of childbearing in heterosexual couples discordant for HIV. *The AIDS Reader* 2000; 10:144-145.

Race and health care

■This editorial comments on an article in the same issue of the journal which found that blacks and Latinos were less likely than whites to get common prescription medications because pharmacies in non-white areas didn't stock opioids, apparently fearing theft and illicit drug use, and claiming that there was little demand. Blacks are likely to be refused morphine-based pain-killers when prescribed them. They are likely to be inadequately treated for cancer-related pain, though they have a higher incidence of and death rate from cancer than other groups. (In the next issue of the journal, a review of medical records on poor patients in the US with acute myocardial infarction needing reperfusion therapy found that white patients were more likely to receive this potentially life-saving therapy than were blacks.)

A growing body of evidence points to inferior medical care for black Americans, even if they are on an equal economic footing with whites. These findings have been confirmed in many other studies looking at pain relief, curative surgery for cancer, likelihood of renal transplantation, diagnostic work-ups for coronoary artery disease…These remain true regardless of socioeconomic status, insurance coverage, or access to care. The common thread is a racial bias on the part of medical care providers.

The writer recommends awareness campaigns among medical trainees and professionals, and establishing and monitoring standards of medical care.

Freeman HP and Payne R: Racial Injustice in Health Care, *The New England Journal of Medicine* 2000; 342:Canto JG et al: Relation of Race and Sex to the Use of Reperfusion Therapy in Medicare Beneficiaries with Acute Myocardial Infarction, *The New England Journal of Medicine* 2000; 342:1094-1100.

Religion and end of life care

■What should doctors do when a patient in intensive care is declared brain stem dead, but is still alive according to their family's religious beliefs? Two paediatric intensive care specialists, supported by a former rabbi, describe how they kept their patient, an orthodox Jew, on mechanical ventilation without monitoring, antibiotic treatment, resuscitation in the event of an arrhythmia, endotracheal suction or renal support, until she died from "natural" causes. Their message: families should not be pressurised on this subject, and consulting religious authorities can arrive at compromises acceptable to both religious beliefs and those of the medical staff.

On the other hand, two ICU specialists argue that there are also the interests of the medical and paramedical staff and the community at large. Continuing treatment may be using the individual as a means to achieve the family's ends. It can go on for months, and provoke staff resentment about the apparent misuse of scarce resources or the compromise of the patient's dignity. Third, this logic should require respecting those of all religious groups, even if they are unacceptable to medical practice.

Finally, the question of organ transplant raises a number of difficult issues. Respecting this religious

perspective would exclude cadaveric organ donation, making organ transplant more difficult for religious-ethnic groups which do not recognise brain stem death. Also, should transplantation be made available to groups whose religious beliefs prevent them from donation? If not, should they be offered the more expensive option of renal dialysis — when they have effectively rejected the cheaper option of transplant on non-medical grounds?

Inwald D, Jakobovits I, Petros, A: Fisher M, Raper RF:Brain stem death: managing care when accepted medical guidelines and religious beliefs are in conflict *BMJ* 2000;320:1266-1268

Clinical response to intersex disorders

■ "What is the relation among anatomy, sexual identity, and sexual practices? The authors of Intersex in the Age of Ethics argue that an ethical clinical response to intersexuality (i.e., the intermingling, in varying degrees, of male and female sex characteristics) will be possible only when this question can be answered on the basis of well-documented, long-term case studies of the lives of intersexual persons. To date, this information has not been collected and clinical practice is based on ill-founded assumptions."

Reviews of the changing medical response are interspersed with first-person accounts by intersexual people and their families. The editor argues that the relations among anatomy, sexual identity, and sexual practices can vary extremely, and until this subject is better understood, medical intervention for intersex characteristics should be delayed till the person can make an informed choice about the options.

Marshall Yvonne: Review: Intersex in the age of ethics. Edited by Alice Domurat Dreger. *The New England Journal of Medicine* 2000 May 11; 342.

What do patients really want?

■This qualitative study of 35 patients aimed to investigate what patients had in mind when they saw a doctor, whether their agendas were addressed in the consultation, and the consequences of not addressing patients' needs. The study found that patients' agendas are complex, and rarely fully voiced during the consultation. Patients described symptoms and asked for information on the diagnosis, but rarely shared other important issues such as anxieties about what the diagnosis entailed, and side effects. As a result there were several major misunderstandings such as unwanted prescriptions, non-use of prescriptions, non-adherence to treatment, and poor health outcomes. The authors point out that when patients do not voice their needs, they cannot be addressed by doctors. "Steps should be taken in both daily clinical practice and research to encourage the voicing of patients' agendas."

Charles C et al: Patients' unvoiced agendas in general practice consultations: qualitative study *BMJ* 2000;320:1246-1250

Violence and doctors

■ This issue of *Lancet* carries a collection of essays on some of the less familiar intersections between medicine and violence. They also highlight why many medical practitioners resent being expected to act as society's moral leaders.

Many doctors feel irritated at being called upon to be activists in the cause of violence prevention. This writer points out that such advocacy can work at different levels. Doctors can use their credibility to support arguments they believe in. Second, medical research can measure health problems caused by violence. Third, doctors can do their job well. Though a woman is at increased risk of violence if her partner abuses alcohol, a US study found that 94 per cent of primary-care physicians failed to include substance abuse among the five diagnoses they offered when presented with early symptoms of alcohol abuse in an adult patient. Doctors don't need to wave banners or make speeches, in order to prevent violence. Just doing their job will make a difference.

Violence and the doctor's role *Lancet* 2000; 355: 1737

CALENDAR

September 21-24, 2000, London, UK: International Association of Bioethics. Fifth World Congress of Bioethics: Ethics, Law and Public Policy. Contact: Congress Office, In any Event UK, 1 Riverside, St Anne's Road, Bristol, BS4 4ED, UK. Email: enquiries@inanyevent-uk.com, or Anne.Lavender@bristol.ac.uk. Website: http://www.uclan.ac.uk/facs/ethics/fifthcon.htm.

November 5-9, 2000, Beer Sheva, Israel: Eighth International Congress on Ethics in Medicine: Ethics Across Cultures, Eras and Borders. Contact: Congress Secretariat, Peltours-Te'um Cogress Organisers, POB 52047, Jerusalem 91520, Israel. Email: teumcong@netmedia.net.il. Website: www.teumcong.co.il.