

usage, and linked to a model of primary health care.

Yet more than 25 years later, over 14 million Indians suffer from TB, and over 500,000 die of it every year. A 1992 government study found that less than 30 per cent of diagnosed TB patients complete their drug course. Inadequate budgets, chronic drug shortages, an undue emphasis on x-ray diagnosis, poor quality of sputum microscopy, emphasis on case detection rather than cure, poor organisational set-up and support, and a multiplicity of treatment regimes, not conforming to the WHO's standards - all of this contributed to the programme's failure.

This did not seem to concern the government - till the HIV pandemic woke the West up to the fact of HIV-related TB, and the possibility of multi-drug resistant

The Revised National TB Programme focusses on a very different perspective from the earlier programme. The Directly Observed Treatment programme, which worked to control TB among poor people in urban USA, is going to be implemented "in the deserts of Rajasthan...(and) the forests of Gadchiroli", in an effort to bring the disease "under control". The programme will be supported by international grants and 'soft loans' from the World Bank.

It was following stiff criticism of this new approach that the Voluntary Health Association of India commissioned the Nucleus for Health Policies and Programmes to prepare a rejoinder to the draft RNTCP. Assisted by an authoritative advisory committee, Debabar Banerji prepared a position paper on the proposed revised programme focussing on DOT.

The paper was circulated to a number of organisations dealing with the subject - including the World Bank, which actually responded by coming to India for a meeting with the group.

"*Serious implications...*" presents a succinct overview of the TB control programme in India - its epidemiological basis and link to a

people-based health service, problems with its implementation, and international initiatives. A short description by the government of the current and revised strategy is followed by the authors' critique, and their alternative plan for action.

The bibliography is followed by a series of annexures that delineate the process that followed the critique. In March 1996, key institutions and scholars were contacted for their comments; the text of those who responded is reproduced, along with comments from the authors; the minutes of a meeting with the World Bank/WHO is described, along with the Bank's correspondence on those minutes.

Finally, there is the Indian government's official memorandum on a national coordinating committee to plan, implement and evaluate the revised programme.

This package provides a useful picture of the issues involved in the TB control programme.

Short notes

The Marathi publishing house Granthali released two books by doctors last month.

In *Manoos navache jagane* (A living called human being), plastic surgeon Ravin Thatte details the personal influences of the philosopher Dyaneshwar. Dr Thatte said he wrote the book in response to the several questions about life and death which surrounded me" while working as a doctor.

In *Aushadh ani aapan* (Medicines and us), Sharadini Dahanukar maps the history of modern medicines, their making and side-effects.

Corporate charity and public health

The January 1998 issue of *Medical Issues*, the bulletin of the Medical Action Forum, discusses the implications of corporate houses being asked to adopt primary health centres: Can they do it, and what will the

government do if the company closes down after a year? Why should health care be considered charity? Who pays ultimately for that care? And can such moves make a difference without altering the basic causes of poor health?

The author notes that a corporate house which is accused of polluting its environment has offered to look after the local district hospital.

'Health care as corporate charity'. *Medical Issues*. 2 (1). 1998. 11.

Human rights and HIV/AIDS

The mission of public health cannot succeed if it results in human rights violations. People working in the field must be aware of the possibility of such violations. For example, do the rights of the individual to receive treatment overrule those of another to privacy?

Public-health workers and affected communities need a fuller knowledge of human rights principles and a framework for their application.

This is provided in *Human rights and public health in the HIV pandemic*. The authors cover the origins of human rights law, moving from the UN charter to the International Covenant on Economic, Social and Cultural Rights in 1976, then describing the relationship of public health and human rights, the principles of autonomy, cooperation, consent, confidentiality, privacy and discrimination in the public-health response to the HIV epidemic.

They also propose a seven-step framework for reviewing and evaluating the human rights questions raised by any proposed public-health policy or programme. Some of the steps described are: defining the medical and epidemiological facts at issue, examining the strength and efficacy of the public health benefit, ensuring that it targets the desired population and has minimal impact on others, and evaluating it for its impact on human rights.

One of the issues raised is: is it the

least restrictive option that can achieve the desired objective? The process is applied to some current public health issues.

Gostin Lawrence O, Lazzarini Zita: *Human rights and public health in the AIDS pandemic.* 1997. Oxford University Press. Delhi.

Health and human rights

The HIV/AIDS pandemic was one of the motivating forces behind the efforts to link people's health status with human rights issues. The first part of this special section, carried over two volumes, carries a historical perspective to the pandemic, and touches on some of the social determinants of infection in various groups: women, homosexuals, injecting drug users, the deaf community, and the poor in general.

Gruskin S, Mann J, Tarantola D, co-editors: *HIV/AIDS and human rights. Health and Human Rights. Part I: the roots of vulnerability.* 2 (4).

Reproductive health matters

The international women's health movement is the theme of this issue of *Reproductive Health Matters*.

Among the topics covered: a history of the movement, reports from various countries, features including one on female infanticide in Tamil Nadu, policy issues, commentaries (research questions on HIV transmission, eugenic sterilisation), and a round-up of news in research, law and policy, and service delivery.

A short bibliography of publications on the international women's health movement includes the FIGO (International Federation of Obstetricians and Gynaecologists) recommendations for the study of ethical aspects of human reproduction, available through FIGO at 27 Sussex Place, London NW1 4RG, UK, e-mail secret@figo.win-uk.net.

Reproductive Health Matters. The International Women's Health Movement. Number 10, November 1997.

Informed consent

■ Last year, the *BMJ* published a cluster of articles asking whether it should decline to publish studies where patients had not given fully informed consent. It prompted a flood of correspondence, with authors split down the middle on the issue between those who argued for informed consent except in very limited circumstances and those holding that there were occasional exceptions.

In March, a further set of responses includes the issue of consent for publication of material that emerges from the doctor-patient relationship.

Len Doyal argues for informed consent in all trials, Jeff Tobias holds the opposite point of view. They continue their earlier debate on the basis of later comment.

Philosopher Mary Warnock, who chaired Britain's Committee of Inquiry into Human Fertilisation, argues for "the principle of non-exploitation" rather than on informed consent alone.

Speaking as a representative of patients whose voices are not heard in a medical journal, Heather Goodare calls for rejecting all studies that do not include informed consent. Lisa Power asks that the broader issue of patients be considered in planning research. Richard Lindley argues that researchers should educate the public about trials. David and Solly Benatar from South Africa attack both Len Doyal's position and that adopted by the ethics committee in Natal that approved a trial that did not have informed consent. Josephine Venn-Treloar describes how she felt abused by undergoing an investigation without consent.

The editorial discusses the issues raised by the various points of view, in the context of various challenges to the *BMJ's* practices. The *BMJ* plans a conference in London for to decide on a future policy. References are made to guidelines of the International Committee of Medical Journal Editors, and the UK's General Medical Council. The editorial argues that the GMC's proposed guidelines are brief and clear,

but they may oversimplify, be hard to implement, and undermine scientific publishing.

Some of the issues discussed are: publishing material that emerges from the doctor-patient relationship (proposed guidelines are to require informed consent, not just anonymise material); the consequences of material printed in medical journals being reproduced on the internet, or the lay media; publication of family trees in which some don't even know they have a particular genetic trait, which might give some information they don't want; whether respecting consent affects scientific credibility, or public interest; and information on confidential inquiries into patient deaths. The proposed guidelines ask authors and editors to balance the importance and the interest of the piece against the possibility of harm to patients.

Informed consent: edging forwards (and backwards) *BMJ.* 1998; 316:949-951

Routine episiotomy

■ As more women in developing countries deliver their babies in hospitals, they can be routinely subjected to episiotomies, even when unnecessary.

This editorial notes that health staff may be acting in good faith, but the evidence shows routine episiotomy has no demonstrable benefit for the infant or mother but causes the woman unnecessary pain and adverse psychological effects and may cause death.

Episiotomies have become less common in the West over the last two decades. The authors comment on a straw poll of 10 midwives from Zambia, Malawi, Nigeria, Ghana, Kenya, and Nepal attending courses in Liverpool which indicated that health professionals performed episiotomies routinely on primagravidas to prevent third degree perineal tears. Some midwives reported that some were performed to allow midwifery and medical students the opportunity to

practise the procedure.

A search of Medline and contact with the Royal College of Midwives revealed very little quantitative data but found a study in Botswana, where one in three mothers having a normal delivery had an episiotomy, and another study in Burkina Faso where in primary care facilities, 43 per cent of primigravidas received episiotomies - in a health system that frequently ran out of sutures and antibiotics. When health care resources are short supply, episiotomy is more likely to result in complications. This increases the harm done by the procedure, in people who are least able to cope with the increased pain and suffering and least able to afford the prolonged hospitalisation.

The World Health Organisation has taken a clear stand against routine episiotomy. This is an important ethical issue for doctors and patients alike. In the West the procedure is usually discussed with women at antenatal clinics. The authors write that in their experience in developing countries this does not happen. When the procedure is routine it therefore becomes a premeditated surgical procedure carried out without consent from the woman.

They call for a comparison of episiotomy rates between facilities and countries, to guide more informed discussion about the level of unnecessary interventions.

Maduma-Butshe A, Dyall Adele, Garner Paul: Routine episiotomy in developing countries: Time to change a harmful practice. *BMJ*. 1998; 316: 1179-1180

Risks of reproductive technology

■ One of the complications of assisted reproductive technology is the sharp rise in the incidence of multiple pregnancies and births, because of the practice of transferring two or more embryos in the womb for development. As a result, there is also an increase in obstetrical complications in such pregnancies, and neonatal problems such as low birth weight and increased

rates of congenital malformations, neonatal mortality and a higher rate of neurological disorders among the surviving infants.

In the United Kingdom, the 1997 HFEA report stated that the transfer of three embryos - the maximum allowed by law - resulted in 67 per cent singleton, 27 per cent twin, 6 per cent triplet, and 0.1 per cent quadruplet pregnancies.

New concern arose with the introduction of intracytoplasmic sperm injection (ICSI), a more invasive procedure in which one sperm cell is injected through the oocyte membrane, and the fertilizing spermatozoon may carry an increased risk of major congenital defects. The author reports that her clinic has consistently counseled couples about its unknown aspects. A follow-up of babies born by ICSI indicates a slight but significant increase in the rate of spontaneous sex-chromosome anomalies, compared with that in the general neonatal population, though the rate of major congenital malformations is similar to the general population.

While such observations need to be extended by further study, patients should be informed before treatment of the slightly higher risks, and also be reassured that the incidence of major birth defects in children conceived by ICSI is apparently not elevated.

Steirteghem, Andre Van: Outcome of Assisted Reproductive Technology. *The New England Journal of Medicine*. 1998; 338 (3)

Informed consent in India

■ It is commonly believed that patients in India are unable to understand the complexities of their health conditions, and obtaining informed consent is therefore an unnecessary ritual. A study of 100 consecutive patients undergoing elective major abdominal surgery, interviewed them five days after the surgery, and asked them what they had been told of the surgery beforehand.

Seventy per cent recalled the relevant

information, with equal recall among men and women, though the older, less-educated or poor did worse. Most important, 98 per cent of the patients appreciated being given the information, as it reduced their anxiety about the operation.

The conclusion is that Indian patients are able to understand and should be given the details of their operation. Particular care should be taken for the old, poor and illiterate; further, informed consent should be a continuous process rather than a single event, and the information should also be given to a younger, more educated relative.

Sanwal, AK, Kumar M, Nundy S. Informed consent in Indian patients. *Journal of the Royal Society of Medicine*. 1998; 89: 196-198

The hazards of immunisation

■ This correspondence in support of a previous report notes that Indian children who have received only three doses of the oral polio vaccine (OPV) may be inadequately immunised against polio. This leaves them susceptible to intramuscular injection-provoked paralytic polio. The situation is particularly problematic when the immunisation programme includes the intramuscular administration of the diphtheria-pertussis-tetanus (DPT) vaccine.

While parents who bring their children to the immunisation programme do not know of this risk, WHO experts and government health officials knew of it when they introduced the three-dose (instead of a five-dose) OPV regimen with the Expanded Programme of Immunisation. When a 'fully immunised' child develops polio, it is called a 'vaccine failure'. During the 1980s, an estimated one million children developed 'vaccine failure polio' in India as result of the three-dose regime.

"Introducing the widescale use of DPT in a country hyperendemic for poliovirus circulation without taking

reasonable measures ... to protect individual children against polio, or reduce the intensity of poliovirus circulation, was unwise, unscientific, cruel and tragic..."

The writer argues that disease surveillance - and a clear definition to monitor the circulation of polioviruses - should have been set up to monitor the incidence of clinical paralytic illness and the campaign's effectiveness before the WHO-directed polio eradication strategy was started. "Even if transmission ceases we have no reliable way to convince ourselves and others with evidence... So the pulse polio campaign will have to continue indefinitely, till a monitoring system is developed, or else polio will reappear with a vengeance." Meanwhile, indigenous polio vaccine manufacturing units are closed down and the campaign relies on imported vaccine.

This comment points to a major lapse on the part of the government of India, and the World Health Organisation. DPT and poliomyelitis in developing countries.

Jacob John T. *Current Science*. 74 (3): 185-187. See also: Wyatt HV. Adverse drug reactions: DPT and poliomyelitis in developing countries. *Current Science*. 73 (5): 402-403. And: Wyatt HV. Reducing and replacing injections. *Africa health*. September 1997. 14-15.

Where does genetic testing lead us?

■ On what genetically-linked conditions should a society invest resources? Those associated with a beneficial medical intervention should be given top priority. In addition, any discussion on the role of genetic testing must acknowledge other factors such as the scope for discrimination and the importance of patient autonomy and confidentiality. There is also the need for testing programmes to include individual counselling as well as general education on the issues, risks and benefits, allowing patients to make informed decisions free from coercion. Finally, further discussion is needed on

the responsible use of genetic information for making reproductive decisions, where the interests of future generations are at stake.

Allan, D. Ethical boundaries in genetic testing. *Canadian Medical Association*. 1996; 154 (2) 241-244.

Advertising adversities for medical journals

■ Does the Indian edition of the *BMJ* maintain the mother journal's standards for accepting advertisements? No, according to a comparative study of ads from the two publications. While the UK edition had flaws as well, an international panel found that **all** the Indian ads were misleading or made unsubstantiated claims. Some of the comments: "unsubstantiated claims", "claims not in accord with the high incidence of side-effects", "no information on active constituents, side-effects or contraindications", "distorts the side-effect profile", "no evidence for therapeutic effect given" "meaningless claims". At least one company promoted a treatment that would not be permitted in the UK. The fact that 'selections from the *BMJ* appear at the bottom of every page suggests that the *BMJ* endorses the products.

In response to this report, the editors of the Indian *BMJ* reply that in 1994, advertisers had been sent copies of the editorial policies of both editions as well as the WHO's monograph *Ethical criteria for medicinal drug promotion*, and a checklist for future ads. They describe the screening process, and its effects, and report on the comments of editors of other Indian medical journals.

Among the points made by various contributors: the evaluation process is expensive, a truly rigorous review difficult given the financial dependence on advertising revenue, advertisers can be persuaded to bring their claims within scientific propriety, and, finally, that these ads aren't taken all that seriously in the first place, and the scope for misuse extends far beyond journals, to newsletters, promotional

literature, and sponsoring a range of educational activity. "The role of editors and the drug companies are perhaps less critical than that of the reader. Doctors and medical students need to be educated to increase their ability to recognise misleading promotional activities, especially those disguised as research or medical education."

Gitanjali B, Shashindran CH, Tripathi KD, Sethuraman KR. Are drug advertisements in Indian edition of *BMJ* unethical? *BMJ*. 1997; 315: 459-60. And **Commentary: advertising adversities.** Christo GC, Balasubramaniam R.

Whose life is it anyway?

■ That now-trite question has new meaning when it is discussed by a constitutional scholar and a man who was left blind, unable to use his hands, and in severe pain following an accident - and survived all his efforts to be allowed to die. How far may physicians and other care givers go in persuading patients to live? When and in what ways may patients' requests to die be challenged? When must care givers acknowledge that the patient's choice, even for death, must be honoured? A comment on the discussion follows.

Cowart D, Burt R. Confronting death: who choose, who controls? *Hastings Center Report*. 1998, 28 (1): 14-24. When comes 'the end of the day?' Arnold DG, Menzel PT. A comment on the dialogue between Dan Cowart and Robert Burt. *Hastings Center Report*. 1998, 28(2): 25-27.

Getting better all the time

■ Not only do we worry about efforts to improve our lot in life, we actually encourage them. Yet advances in biotechnologies aimed at this same laudable goal have given some pause for concern. Does it make any sense to worry about, say, a new psychopharmacological agent that promises to improve concentration This essay attempts to explain why it does.

Parens E. Is better always good? The enhancement project. *Hastings Center Report*. 1998, 28(2). Special Supplement.