## True love means better information

Love your heart : notes from a cardiologist to anyone with a heart. Vivek K Mehan. Productivity Services International., Mumbai, 1999. Price: Rs 70. pp. viii +85.

Attempts at health education are always welcome, in that they enable people to be better consumers, to approach the system with less trepidation, and to make the best use of health services. This book is appreciated for its effort to respond to the many doubts and fears of people going for diagnostic and therapeutic procedures for heart disease. It describes the cardiovascular system and disease in simple language; it tells the reader what to expect before and after various tests and procedures, and finally, it describes the components of a healthy lifestyle.
Having said this, why do I feel unsatisfied? Because despite the writer's best intentions, he has produced what is effectively a brochure for cardiac surgery. For example, it is true that an aging population and changing lifestyles may correspond to an increasing rate of age-related conditions including

Conference: Ethical Issues in Clinical Trials

A conference on Ethical Issues in Clinical Trials will occur on February 25th and 26th, 2000 at the University of Alabama at Birmingham. Topics include: informed consent, informed consent in special populations; placebo controls; decisions to terminate or repeat trials; multinational clinical trials. For conference registration material, please send name and address to: Harold Kincaid, Center for Ethics and Values in the Sciences, 900 13th St. So., Birmingham,
AL USA 35294 or email: kincaid@uab.edu
heart disease. However, to support his statement that coronary artery disease has reached "epidemic proportions in our scities", he cites the "evergrowing numbers of ... angiographies, angioplasties and bypass surgeries being performed daily". Both common sense and a general awareness of the promotion of high technology in the private sector tell us that the excessive numbers of procedures can indicate overuse of the procedures rather than an "epidemic" of heart disease.

Perhaps as a consequence of this unquestioning perspective, the book fails to raise questions that I would have as a potential patient. Such as: what should you ask the doctor if you are told that you need bypass surgery? Unfortunately not one statement in the book suggests that these procedures are overused. The information in this book may reduce people's anxieties before undergoing procedures, but it cannot make up for an uncommunicative or pushy doctor promoting unnecessary surgery of little benefit and possibly some harm.

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FROM OTHER JOURNALS

## "When we were young..."

This letter-writer comments on the common practice of viewing the past through rose-coloured glasses. "We... were just as insensitive and inhuman as our current counterparts." Just as the senior physicians of today view the younger generation with distress, "my professors thought we were mesmerised by gadgetry. They questioned our humaneness and ethics when we scoffed at their practice of housecalls. My guess is that their predecessors looked at them in the same way." At the heart of this is the eventual incorporation by all practitioners of the healer's art. "with all the negativism, introspection, economic buffets, gain and losses of respect, triumphs and failures, progress and retreats, this process continues ad infinitum - keeping alive the flame of medicine's art and humanity."

Matz R: The good old days. The Lancet 1999; 353: 596.

## Unwarranted faith in medical screening

Medical screening for a variety of conditions is justified on the strength of the assumption that the earlier disease is detected, the better it is for the patient. On examination, however, the assumption turns out to be severely flawed, and inadequate anyway, since it is not only the patient with whom we should be concerned, but healthy people as well. Instead of making assumptions about the ill, we should prove a test's overall benefit to the individual taking it before we recommend it. Some of the examples that the author discusses in the course of this essay are routine mammograms for women in their 40s, digital rectal exams and PSA screening for prostrate cancer and cholesterol screening.

Malm HM: Medical screening and the value of early detection: when unwarranted faith leads to unethical recommendations. The Hasting Center Report. 1999; 29(1): 26-37.

## DALY discriminates

- The authors argue that the World Bank-launched Disability Adjusted Life Year discriminates against the disabled. The approach behind the DALY, a combined measure of morbidity and mortality, presupposes that the disabled have less valuable lives than do people without disabilities, and that they are less entitled to scarce health resources for life-extending interventions. The authors note that such assumptions are in contrast with basic principles of the WHO.

Arnesan T, Nord E: The value of DALY life: problems with ethics and validity of disability-adjusted life years. $B M J$ 1999; 319: 1423-1425 Education and Debate

## Sham surgery

- Is it ethical to perform "placebo brain surgery" on patients with a neurological disease to test an experimental treatment? Two papers in this issue of the New England Journal of Medicine argue the cases for and against.
Dr Thomas Freeman reports on a trial evaluating the value of foetal nerve cell implants to regenerate brain cells in patients with Parkinson's disease. "Thirty-six adults with advanced Parkinson's disease whose symptoms could not be satisfactorily controlled with medical therapy consented to be randomly assigned to one of two experimental methods, or to placebo surgery." In the third group, the surgeon bores a hole into the patient's skddull, but does not receive the brain cells; however, s/he does get the same follow-up treatment, including the anti-rejection drug cyclosporin. The doctor argues that placebo surgery is essential to prevent the proliferation of untested medical life-saving techniques.
The study is strongly opposed by ethicist Dr Ruth Macklin, who notes that 'sham surgery' poses significant physical risks, and violates the tenet of minimising the harm to volunteers in medical research.

Freeman TB et al: Use of placebo surgery in controlled trials of a cellular-based
therapy for Parkinson's Disease. The New England Journal of Medicine; 341 (13): 988 Macklin Ruth: The ethical problems with sham surgery in clinical research. The New England Journal of Medicine 1999; 341 (13)

## Medical professionalism

In this discussion of the concept of medical professionalism, the authors note that physicians today are not equipped to respond to the threat to their professionalism from "perverse financial incentives, fierce market competition, and the erosion of patients' trust". Medical professionalism is being forgotten in the battle between the open competition and government regulation. "Physicians, feeling trapped between these camps, are turning to unionisation and other tactics." They propose that reference to three guiding principles - devotion to service, profession of values, and negotiation within society - would permit physicians and their organisations to raise dissent in an ethical manner.

Wynia MK et al. Medical professionalism in society. The New England Journal of Medicine 1999; 341 (21)

## Ethics of restraints

A newspaper investigation which concluded at least 142 patients in the US had died while in restraints or seclusion in the past decade accelerated work on new standards for patients' rights. These standards apply to all patients in governmentsubsidised Medicaid and Medicare health programmes. The author describes the new guidelines, notes the improvements, and points out their limitations. The central problem, he argues, is that "the rules do not make it clear enough that competent patients have a right to refuse any medical treatment and the use of restraints can never be justified as a means of forcing treatment on a competent patient who is refusing treatment." He illustrates his point through the case of a competent adult asthma patient who voluntarily entered a hospital for treatment, was restrained against her
will and without the permission of her family, and forcibly intubated.

Annas GJ: The last resort: the use of physical restraints in medical emergencies. The New England Journal of Medicine 1999;314(18)

## Better research

In response to the clearly ineffective role played by journals in influencing therapy, the authors note: "in only one of the 122 reports of randomised controlled trials of selective serotonin reuptake inhibitors were adequate details given about the method of randomisation, and these reporting deficiencies are present in some of the world's most prestigious medical journals." This essay discusses the value of publicising a study's protocol and of electronic publishing and archiving of medical research, and describes the history of such efforts, with special reference to the role of the Cochrane database of systemic reviews.

Chalmers I, Altman DG: How can medical journals help prevent poor medical research? Some opportunities presented by electronic publishing. The Lancet 1999; 353: 490-93.

## Persistent vegetative state

- How does one respond to the ethical and legal problems raised by a diagnosis of persistent or permanent vegetative state (PVS)? Strict adherence to the doctrine of the sanctity of life would require carers to continue to maintain the individual, perhaps for many years. However, few would regard this as an appropriate outcome when the person clearly has no capacity to interact with the environment and has no likelihood of recovery. However, the ethical and legal commitment to the sanctity of life has led courts to employ a variety of approaches to this situation in order to find a way in which the person with PVS can be allowed to die. It is argued that each of the approaches is disingenous and ultimately unhelpful. What the law is doing is endorsing nonvoluntary euthansasia, but dressing it up as something else. This is unhelpful for all concerned and the time has come for a review of all end-of-life decisions so that doctors, patients and relatives
can make honest decisions without fear of legal reprisal.

McLean SA: Legal and ethical aspects of the vegetative state. Journal of Clinical Pathology 1999; 52: 490-93

## Too many C-sections

- While rising Caesarean section rates have been the subject of much attention and debate worldwide, there is not much information available on this rate and its potential adverse impact in India. This survey based on a standard Expanded Programme on Immunisation 30-cluster design, was carried out in an urban, educated, middle/upper class population in Chennai. Mothers of 210 children aged 12-36 months were interviewed and data collected on immunisation and breast-feeding practices as well as mode of delivery. This generated population-based data on the C -section rate and its influence on breast-feeding. It was found that 45 per cent of the babies had been delivered by C section; these babies started late on breastfeeds, were given prelacteal feeds more often and colustrum less often. The authors note that a rate of $40-50$ per cent is extremely difficult to justify, and that C-sections adversely affect breast feeding practices. They call for more data and audits on C - section rates in India, and a wider debate on its potential adverse impact on the health of mothers and newborns.

Pai $M$ et al: A high rate of Caesarean sections in an affluent section of Chennai: is it cause for concern? The National Medical Journal of India 1999; 12 (4): 156-158.

## Need better informed consent for implant surgery

- A report by the US Institute of Medicine (IoM) concludes that silicone gel-filled breast implants do not cause chronic disease, but warns that they often cause local and perioperative problems that have to be corrected surgically. About 70 per cent of the 1.8 million women in the US with such implants by 1997 had them for cosmetic reasons. In the last decade, many brought law suits arguing that the implants leak silicone and cause
systemic immunological damage. The committee's chairman says, "It is clear that silicone breast implants can cause serious problems. It is essential that women understand these risks before they decide to undergo this surgery." The report calls for a new procedure for obtaining informed consent in which plastic surgeons must tell women about the incidence of postoperative and long-term complications. Other researchers have concurred, and called for an international research collaboration following women with implants. One researcher added, "There is a discrepancy between the mostly uncontrolled case reports and the largescale studies. So perhaps there ought to be a small door left open, to see if there is something we have missed."

Mitchell P: No syndrome linked to breast implants, says IoM. The Lancet 1999 353: 2215.

## We need such statistics

In June 1999, the UK National Health System published the first comparative statistics on death rates after surgery. The statistics are meant to identify hospitals which are out of line with the average. While there were many complaints on what the statistics did not account for, as well as about errors and other data quality issues, the publication of such figures is considered a milestone in the UK.
It is only five years since England began publishing comparative administrative indicators - hospital waiting times, ambulance response times and operation cancellation rates. The June report had six clinical indicators involving mortality, discharges and readmission, as well as 41 revised performance indicators including hospital waiting times, cancer survival rates and tooth decay in children.
Just two decades ago medical audit was regarded as such an invasion of clinical independence that the royal commission into health refused to even look at it. This changed with the Bristol inquiry following the media outcry of which the health secretary called for a "system which collects and monitors information on clinical
performance, provides an early warning if things are going wrong, and then helps put things right." Ironically the current statistics are too broad to have picked up the unacceptably high death rate among children after heart surgery in Bristol, but the aim is to make them more precise over time.

Dean Malcolm: Medical audit reaches the UK national health system. The Lancet.1999; 353: 2219

## Sleep-deprived doctors

This letter comments on a study of surgeons' proficiency and speed using a virtual reality laparoscopic surgery system which found that surgeons who had been deprived of sleep made about 20 per cent more errors and took about 14 per cent longer than when rested. The writer notes that these and other similar findings have failed to curtail this common, and correctable, current medical practice in the US. "Given the current evidence, unless a randomised, prospective, double blind, controlled trial shows that sleep deprivation of surgeons does not diminish the quality of surgical (or medical) care, patients should not have to suffer from the iatrogenic disease of having a sleep-deprived physician."

Altschuler EL: Prospective, randomised trial of sleep deprived versus rested surgeons. The Lancet 1999; 353: 501.

Taffinder NJ et al: Effect of sleep deprivation on surgeons' dexterity on laparoscopy simulator. The Lancet 1998; 352:1191.

## Sociology of health care

This review on sociology and modern health care summarises some of the major areas of health sociology, and shows how many of these areas have been incorporated into clinical practice in the past decade. "While avoiding evangelism, we show that the medical profession needs a keener and more self-conscious understanding of where it fits into the broader organisation of society."

Chard J et al: Looking beyond the next patient: sociology and modern health care. The Lancet 1999; 353: 486-89

