Letter from Berlin

WHO SHOULD PAY FOR ANTI-OBESITY DRUGS?

The recent introduction in Germany of prescription remedies (*Orlistat* and *Sibuttramin*) for weight reduction has led to a lively discussion in the media about who should pay for these drugs. This is of obvious interest in a health system that is entirely based on a mandatory health insurance scheme, where every one pays a certain amount to the system and expects to get maximum medical care for all medical problems.

According to current estimates, almost half of the entire German adult population are either overweight or frankly obese by World Health Organization standards. As every overweight individual is aware, long term weight reduction by will power alone remains notoriously unsuccessful. The situation is aptly described by the term 'yo-yo effect', which may well be a cardiovascular risk factor in its own right.

Clearly, an inexpensive, potent, safe and well tolerated pharmacological treatment that will ensure long term stability of body weight either by promoting loss, or perhaps by even just preventing further weight gain, is something every obese person in the world is waiting (and probably praying) for. Now that the first drugs that may fulfil some, but certainly not all, of these criteria are hitting the market, the question regarding who is to pay for this treatment is of obvious importance in an insurance-based health system. At current costs, we are talking about nearly DM 200 (about Rs 5000) a month for a treatment that may have to be carried on for life.

At this point, we must stop to consider what is so special about obesity, when compared to other cardiovascular risk factors such as hypertension, hypercholesterolaemia or diabetes. The cost for treating these 'traditional' risk factors is reimbursed by the health insurance system and, as far as I am aware, there has never been any wide criticism of this state of affairs. If we compare obesity to hypertension, there are several similarities. Both are major risk factors for cardiovascular diseases, are promoted by an 'unhealthy' lifestyle, are amenable to non-pharmacological intervention (at least in the short term) and are generally life-long conditions that require long term management. Of course, we know that dietary salt restriction lowers blood pressure in most hypertensives, but in real life, it is so much simpler to prescribe a cheap and effective thiazide than spend hours on dietary counselling and patient education, which have yet to be proven beneficial in morbidity and mortality trials. As for obesity, there is not a single study demonstrating that long term weight management (over years and decades) by modification of lifestyle is feasible or effective in a relevant proportion of affected individuals. I am not talking about the lucky few who have the will power to make new year resolutions and actually stick to them, and live happily ever after.

But despite these obvious similarities, I believe that the situation with obesity is not fully comparable to that of hypertension. While epidemiological data do suggest that obesity is a major risk factor for cardiovascular disease and other disorders, there is yet no randomized controlled intervention study proving that weight reduction actually decreases morbidity or mortality. Similarly, although there are data indicating that the new anti-obesity drugs (in combination with mild caloric restriction) may significantly reduce weight and improve surrogate measures such as glucose and lipid control, there is no proof that this will indeed result in a reduction in 'hard' end-points. Until then, in the present era of evidence-based medicine, there is certainly a strong argument against expanding insurance coverage to include the costs of anti-obesity drugs. This does not mean that such drugs should not be used for the treatment of obesity. It only means that the cost for such a treatment should not be borne by the health insurance system until such evidence becomes available. Clearly, it is up to the drug companies to prove that their compounds are not only safe and effective, but also contribute significantly to reducing obesity-related morbidity and mortality.

ARYA M. SHARMA

Letter from Mumbai

AN UNUSUAL FORUM FOR A DISCUSSION ON MEDICAL ETHICS

Mumbai is fortunate in having some excellent bookshops for the discerning reader. One of these, Crossword, near the Mahalaxmi temple, has two added attractions. Its coffee shop dispenses some of the finest brew in town. Believing that bookstores should also arouse social and cultural consciousness, Crossword organizes discussions and debates on topics relevant to the books it sells. One such discussion, on 9 March 1999, centred around the book *Stillborn—A medical thriller* by Rohini Nilekani (Penguin Books, New Delhi, 1998, Rs 200).

Ms Nilekani has turned from reporting for a periodical to the 'lonely business' of writing a book whilst managing a home and bringing up two children. Research over several months into current trends for controlling fertility and studies with tribals on B.R. Hills (near Bangalore) provided grist for her mill. She has benefited from the expertise of individuals such as Drs Firuza Parikh, Bhavana Doshi and H. Sudarshan. In the process of writing a thriller, she has touched upon a range of problems in medical ethics.

Her tale revolves around 'a mysterious hunk called Anshul Hiremath' who, on returning from America, has set up a research laboratory with the aim of being the first to produce a successful

anti-fertility vaccine for women. The story unfolds as her heroine, Poorva Pandit, a journalist, pursues clues doggedly. Problems encountered during the research and the means used to bypass them provided the basis for discussion that evening.

Nilekani discusses several ethical issues in her book.

Indian pharmaceutical manufacturing practices

'Taking advantage of the confused patent laws in India, which are designed to protect local industry and not necessarily local customers, our companies duplicate new products born of foreign research by altering the process of manufacture. The drug is then sold cheaper here than in the country of origin, but at a hefty profit for the local manufacturer who need pay no patent fees or incur R&D investment expenses.'

Population policies

'Population policies or family planning methods cannot be imposed from above. The social and psychological costs, especially for women, can never be factored into a government programme. Nor, it seemed, into a research project.'

Secrecy in research

Dr Gayatri, a senior gynaecologist, points out: 'Usually these researchers are very secretive till they are sure of their product.'

Suppression of crucial information

Anshul was honest about the pitfalls in research when talking to Poorva: 'There is no way anybody can guarantee anything. No medical research would be possible with such a caveat. The element of chance will always remain. But you have to take this chance consciously and take all precautions. Keep yourself informed so that you can intervene quickly at the first sign of trouble.' This attitude did not help him avoid a classic pitfall for researchers. When he encountered complications that could jeopardize his research, he suppressed information on them. He compounded his error by trivializing them: 'I deserve the chance to make corrections if things go wrong. We have not created any life-threatening situations for anybody. We had a few conceptions in the early stages. That is natural . . .' When the complications were finally discovered, Poorva Pandit found that the 'You can't make an omelette without breaking a few eggs' school disregarded them.

Volunteers in Indian research projects

'How does one get people to volunteer as guinea pigs for the development of something like that (contraceptive) vaccine?' Poorva Pandit asks her father, a public relations officer (PRO) for a drug company. The answer rings true: '. . . That's the least of the problems in a country like ours. If the incentives are good, if the investigators can convince volunteers that the risks are non-existent or low, you can find the people . . . You can play around a lot with those things. Technically, ethically, even legally, no trial can be conducted without the written, informed consent of the participants. But then our people have so little information! They may not understand all the implications. The doctor is God here.'

Tribal women, enrolled in the study, tell Poorva Pandit: 'It is our men who have turned the minds of the women. The investigators, they pay money if we sign our names. They give clothes, they give rations. Our people have become lazy. They want easy money. So they tell the women, go take the injections. Why should they bother what happens inside our bodies?'

Informed consent

'I told him (retired Drug Controller) about the tribal women I had met and I asked him about the requirement of informed consent. Yes, those rules, at least on paper, are very strict. In all these trials, volunteers must sign a form saying: "I am willing to take this treatment. The risks have been explained to me." But let me tell you there are many ways around it. Especially when the people are illiterate. The person who takes this informed consent is the key. If he or she is sincere, fine. Otherwise I have known of cases where instead of consent for anaesthesia, people are asked, "Are you a vegetarian? If so, sign here." After fifty years of independence, not even fifty per cent of our people are functionally literate enough to tell the difference anyway. So what consent? What information?'

Poorva Pandit continues her narrative: 'I fished around a little, tried to find out if the women (participating in the trial on the contraceptive vaccine) had given informed consent. Whether they knew exactly that as in all experiments, there were unknown risk factors. From what I could gather nobody seemed aware that there was a genuine risk. The men were happy because of the compensations. The women were getting free contraception.'

'India, predictably, has stringent laws on informed consent—in the books. Ethical review committees have been set up. We are good at that sort of thing.'

'I pieced together the story as Madhamma (a tribal woman) continued to speak . . . She had taken the contraceptive vaccine twice. The "doctors" had promised rations and clothes for the little ones. They had delivered . . . Everything had been all right for a while after that . . . Then she had quit going to the research centre. Her man had . . . gone to work in another tribal area . . . She had followed . . . (She) developed all the symptoms of pregnancy . . .'

Corruption of the tribals

'. . . Indian and international companies . . . set their sights on (medically useful indigenous plants). Suddenly the hills had become a veritable hot spot of tourists from the scientific community, fishing around for opportunities, mining for information from the tribals, offering huge sums of money to anyone willing to share his inherited knowledge . . . Soon some multinational will file a patent for a very commonly used remedy . . . while the people here won't know what hit them.'

Drug Controller of India and similar agencies

The question posed by Poorva Pandit: 'What if there are problems during the trials? Who takes the responsibility?', elicits the following response from the PRO. 'The researchers should. The company should. But often in these trials, follow-ups are neglected. So the volunteers may not even make any connection between the problem that has developed and the clinical experiment. And then, you know how it is. Our enforcement agencies can easily turn a blind eye when they want to.'

Nilekani describes such complications as failure of the contraceptive vaccine, babies conceived despite the vaccine, being born with severe deformities, women almost dying from complications of pregnancies that should never have occurred.

'Nobody wants poor tribals to proliferate. So the government is quite content to look the other way. The Drug Control Authority of India has many officers who are pliable on these things. Like every public institution in Bharat desh hamara.'

A retired drug controller tells Poorva: 'The Drug Controller's (DC) office just does not have the resources to keep to the letter of requirements in such cases. They are short on funds, short on

staff. They have to rely on random checks. Things can and do slip through.'

Poorva Pandit: 'People say the DC's office can also be quite accommodating. Could I bribe my way through to the end of a product cycle?'

Retired DC: 'I won't deny that there must be several corrupt drug inspectors. They may hasten approval or confirm the quality of some batch of drugs . . .'

When pushed by Chandrakant Hiremath, Anshul's father and a highly placed bureaucrat in the Prime Minister's Office, the Drug Controller's office pushed clearances for Phase 2 of Anshul's trial even though it was known that some problems had cropped up.

'Sure the Drug Inspectors came on a regular basis . . . They were treated royally by Anshul. They quite agreed that the question of unwanted pregnancies was due to an unrelated problem.'

On harvesting kidneys from poor or unsuspecting people

'A young man named Hamid. Construction worker. He had gone into a small-town hospital near Bangalore for an emergency operation and had returned home minus . . . his appendix and one kidney. His father, a fifty five-year-old drunken lout had been compensated with five thousand rupees.

'Knee-jerk government responses. Doctor witch-hunts. . . . throw[ing] the baby out with the bath water . . . Now even legitimate patients are deprived of their donor kidneys because of all this damn legislative hotch potch. As usual the very rich and the very corrupt will still find a way around. That's like bringing back the bath water and leaving out the baby!'

These and other aspects of unethical practice came up for discussion that lasted well over an hour.

A member of the audience asked whether the Medical Council of India and the state medical councils were charged with the responsibility of ensuring ethics in medical practices. When the inefficiencies of these statutory agencies were exposed, he asked whether a wronged research volunteer or patient could seek justice at the courts of law or the Consumers' Courts. Once again, it emerged that these were not serving the purposes for which they were intended. The courts of law had thousands of pending cases over decades. The Consumers' Courts were bogged down by lack of support from their funding agencies—the governments—and were thus lapsing into inefficiency and delays similar to those in civil and criminal courts. Only half in jest, the person posing the questions then asked: 'Is this why doctors are now being targeted by gunmen? Perhaps this may be the only way to ensure ethical practice—bump off those not following the straight and narrow path!'

In many minds, the doctor was viewed as an unprincipled materialist out to make a fast buck at the expense of the patient. Several members of the audience complained of the manner in which drugs were prescribed without any explanation regarding their mechanisms of action or possible complications. This was especially true when the patient was poor and illiterate. A lady in the audience pointed out that it was unrealistic to depend on the authorities or the medical profession for every solution. They have shown that they are unwilling or incapable of improving matters. It is high time that every patient demands and obtains information of what is being done to her/his body and makes decisions after weighing pros and cons. If and when the doctor is found to misbehave, the patient must seek assistance from legal help cells and ensure that her/his plaint is heard and justice done to her/him.

Stillborn will have performed a distinct service if it stimulates general interest in the ethical aspects of medical practice and research and, as a consequence, stimulates society to offer a cohesive front against wrongdoers.

SUNIL K. PANDYA

Letter from Chennai

AN IRON FIST IN AN IRON GLOVE

The Madras Medical Service was one of the first organized systems for the delivery of medical care in the country. The leaders were British members of the Indian Medical Service, who were usually deputed from the Armed Forces. They were assisted by some of the locals, who came to be known as Civil Assistant Surgeons and Civil Surgeons, to distinguish them from their military counterparts. There were only two ranks in the service. Since there has to be a pyramidal structure to any service, one cannot have the same number of Civil Surgeons as Assistants, so a large number of doctors began and ended their professional lives as Civil Assistant Surgeons, with no promotion at any stage. This situation prevails till today, though a minor sop was introduced in the form of a category of Senior Civil Assistant Surgeon and one of Additional Civil Surgeon. The knowledge that however hard one works, the chance of promotion is very small, can hardly be conducive to enthusiastic service.

The Tamil Nadu Government Doctors' Association (TNGDA) and the Tamil Nadu Association of Civil Surgeons (TNACS) demanded that every government doctor should receive a promotion every sixth year of his service to the twenty-fourth year. Talks were held between the Government of Tamil Nadu and these Associations, and the sticking point came when the government said it would agree to promote 50% of the more than 10 000 government doctors, while the Associations held out for 67%. Further, the Health Minister said he could not agree to time-bound promotions, as so many senior positions may not be available. Promotion could only be to sanctioned posts, though he was ready to increase the number of such posts.

On the face of it, the Associations' demands are absurd, and do not exist in any service in the world. While a whole life spent with no prospect of promotion would kill anyone's ardour, automatic promotions would remove any incentive to work hard and outshine others. As it is, promotions in the Tamil Nadu Medical Service are based on seniority. This is a recipe for mediocrity.