MORE ABOUT....ETHICS

ETHICS OF RESEARCH IN PRIVATE MEDICAL PRACTICE

LYN HORN, *MB BCh, DTM&H, DCH(SA), M Phil Applied Ethics, Dip IRE*
Division Research Development and Support, Faculty of Health Sciences, Stellenbosch University

The clinical trials industry in South Africa has increased exponentially in recent years. In 2003, 6 of the top 10 multinational pharmaceutical companies spent a total of R512 million on research.[1] Although many academic institutions are involved in industry-sponsored clinical trials, an increasingly large number of clinical trial sites also exist in the private sector. In this short article I will highlight some of the ethical issues that I think are pertinent to clinician investigators involved in industry-sponsored clinical trials within the private sector.

Training in good clinical practice (GCP) and research ethics

Clinicians in the private sector often lead a busy, pressured and sometimes fairly isolated existence and may find it particularly difficult to find time to attend training in GCP and research ethics. The Medicines Control Council (MCC) requires that all investigators registered for a clinical trial do a basic GCP course, usually a minimum of a full day, and attend a refresher GCP course every 3 years. The introduction of the National Health Act in 2004 in many ways heralded a new era in terms of the regulation and ethical monitoring of research in South Africa. An entire chapter of this Act is devoted to the regulation of research. In addition, the Department of Health is in the process of drafting and promulgating more detailed regulations related to health research.

Investigators can no longer rely almost exclusively on their clinical trial monitors to attend to the ethical and regulatory aspects of clinical trials, but will increasingly be obligated to do so themselves. Ethical guidelines for health research, published by the Department of Health in April last year, spell out the responsibility of principal investigators in detail: 'Principal investigators bear full responsibility for the scientific and ethical aspects of their study, and are the means of communicating with the ethics committee while obtaining approval. Once a study is in progress, all reports of adverse events and management issues dealt with by the sponsoring company should be transmitted to the ethics committee, ideally through the principal investigator, who should be fully informed of these issues.'[2]

Participant selection: the 'therapeutic misconception'[3]

Research participants within the private sector may be recruited via an advertisement but may also be patients of the clinician investigator and already have a well-established relationship, built on trust and an understanding that the doctor always acts in the best interest of his patient.

A 'therapeutic misconception' arises when study participants confuse the goals of therapy and research, and fail to distinguish between the two. The aim of therapy is to provide the best available treatment to the individual patient. The main goal of research is to acquire 'generalisable knowledge' that may improve the treatment of future patients. The immediate interests of the individual patient take second place. When the researcher has been, or still is the patient's primary clinician, this 'misconception' is even more likely to be prevalent. Clinicians must

Table I. **Differences between research and clinical practice**[4]

Clinical care	Research
Primary goal is to provide the best individual patient care, i.e. act in the patient's best interests	Primary goal to acquire generalisable knowledge in order to improve care of future patients
Treatment alternatives recommended based on what is believed to be best for the individual patient	Treatments allocated by randomisation, not by clinical judgement
Patient care involves medicine or interventions whose side-effects and risks are usually well documented or understood	Risks may be relatively unknown or not as yet clearly understood
Medication dosages can be increased or decreased according to clinical response	Medication dosages are fixed with no flexibilit to alter dosages according to individual patient response

recognise this and explain these differences clearly to potential research participants. Table I outlines the distinctive differences between a therapeutic relationship outside the research context as opposed to a relationship within a research context.

It is important to note that the clinician/investigator can also easily become caught up in the therapeutic misconception and cease to retain a clear conception of the difference between research and therapy and of the implications those differences hold for the individual participant.

Financial conflict of interest

Doctors working in the private sector may justifiably feel that they are at the whim of both health care funders and patients, who have a 'pay-the-doctor-last' attitude. Participating as an investigator in a clinical trial has the attraction of being paid generously and promptly by the sponsor. The danger exists that the attraction of financial remuneration may become the main motivator in enrolling patients onto a trial, possibly to the detriment of the individual patient. It is worth noting that one of the main topics under discussion at the IRENSA (International Research Ethics Network South Africa) workshop, presented in September 2005 by the Centre for Bioethics at the University of Cape Town, was entitled 'Excessive investigator remuneration in industry-sponsored research'.

Billing practices

Patients in the private sector who participate in industry-sponsored clinical trials need to have a clear understanding of exactly what expenses will be covered by the sponsor and what expenses they will have to meet themselves. It is of great importance that private clinicians act with integrity and transparency in this regard. Research ethics committees in South Africa have received complaints that private practitioners continue to bill trial participants for consultations even though they are being remunerated for the consultation by the sponsor. This practice is obviously ethically and legally unacceptable.

Conclusion

The development and practice of evidence-based medicine is reliant on research. Participating as an investigator in clinical trials is often a rewarding experience. However, clinicians both in public and private practice must accept responsibility for ensuring that the fundamental research principle of respect for persons is upheld at all times.

References available on request.

UNDERSTANDING ASPECTS OF THE TERMINATION OF PREGNANCY LEGISLATION

CHELSEA MORRONI, *MPH, MPhil*
Senior researcher, *Women's Health Research Unit, School of Public Health and Family Medicine, University of Cape Town*

GEOFFREY BUGA, *MB ChB, MMed, PhD*
Professor, *Department of Obstetrics and Gynaecology, Faculty of Health Sciences, Walter Sisulu University, Mthatha*

LANDON MYER, *PhD*
Senior lecturer, *Infectious Disease Epidemiology Unit, School of Public Health and Family Medicine, University of Cape Town*

Experience worldwide shows that restrictive termination of pregnancy (TOP) laws lead women to have unsafe abortions, in turn contributing to approximately one-third of maternal deaths. However, legalised TOP remains a controversial issue in South African society. Before liberalisation of the law in 1996, about 1 000 legal abortions were granted annually in South Africa, mostly to middle-class white women.[1] At the same time, an estimated 200 000 unsafe abortions were performed annually, the vast majority among poor black women, resulting in 45 000 hospital admissions and 425 deaths from septic abortions each year.[1]

The 1996 Choice on Termination of Pregnancy (CTOP) Act[2] affords women and girls the right to choose whether or not to have a safe TOP. As a direct result of this legislation, abortion-related morbidity and mortality have plummeted across the country.[3] The Act is underpinned by the constitutional right of South African women and men to make decisions concerning reproduction as well as to have control over their own bodies.[4] In addition to respect for individual autonomy, the CTOP Act is rooted in the principle of making basic health services accessible to all South Africans, regardless of socioeconomic status.

The Act states that a pregnancy may be terminated at a woman's request during the first 12 weeks of gestation. Beyond 12 weeks and up to 20 weeks, a TOP may be performed for any of the following reasons:

- if, after consultation with a pregnant woman, a medical practitioner is of the opinion that continued pregnancy would pose a risk to the woman's physical or mental health
- there exists a substantial risk that the fetus would suffer from severe physical or mental abnormality
- the pregnancy resulted from rape or incest, or
- the continued pregnancy would significantly affect the social or economic circumstances of the woman.

From 20 weeks' gestation onwards terminations are available under limited circumstances, including those in which the continued pregnancy would endanger the woman's life, pose a risk of injury, or result in severe malformation of the fetus. The Act further provides that, regardless of the pregnant woman's age, only her consent is required for a termination, that non-mandatory and non-directive counselling be given,

and that women must have access to information concerning their rights in relation to the Act.

For some health care providers a conflict between professional responsibilities and personal beliefs leads to dilemmas in considering patients requiring TOP. Several situations that primary care providers frequently face demonstrate the boundaries between professional ethics and personal opinions.

Minor consent for TOP

Many women seeking TOP are minors, and there are often important reasons why a minor may choose not to consult her parents. Requiring parental consent could endanger young women's lives by hindering access to safe, timely medical care. The constitutional right of women to bodily and psychological integrity, including the right to make decisions concerning reproduction, is not age restricted. As a result, in this situation practitioners should advise the minor to consult her parents, guardians or family members before the abortion, but cannot withhold care on this basis.

Requests for repeat abortions

Some providers may feel that requests for repeated abortions are problematic. However, a woman's right to procreative autonomy is not affected by whether she has had an abortion before. Therefore, the professional ethical obligation of health care providers is not diminished by the number of times a woman has had an abortion.

Right of health care workers to freedom of conscience

The conscientious objection of providers who do not wish to perform abortions is supported by the constitutional rights of all South Africans to freedom of thought, belief and opinion.[4] However, this support is limited by the professional obligation of health care workers to inform a woman requesting a TOP of her rights in terms of the Act. Necessary details that practitioners must provide include the circumstances in which abortion is legal, that no consent is required other than that of the woman, and the location of facilities where TOP is performed.

The requirement that providers who refuse to perform abortions must give patients accurate TOP-related information is problematic for some practitioners, who may feel that providing such information to patients suggests that they support the procedure. However, the professional obligations outlined in the Act are intended to ensure that a woman's reproductive autonomy and her right to health services are not influenced by the personal beliefs of health care workers. In this instance, individual rights to reproductive autonomy are not qualified by providers' freedom of thought, belief and opinion. In addition, in terms of the constitutional right of all South Africans to emergency health care,[4] a conscientious objector is ethically and legally obliged to care for patients with complications arising from an abortion, whether induced or spontaneous.

The CTOP Act upholds the principle of reproductive autonomy and has greatly reduced morbidity and mortality. Whatever their personal opinions, health care providers need to be aware of their rights and responsibilities regarding TOP services, and how these contribute to the improved health of all women in South Africa.

References available on request.

SINGLE SUTURE

EASY BREATHING IN THE BIG APPLE

New York has shown that public smoking bans work. After a year of smoke-free bars, restaurants, bingo halls and bowling alleys, the city's hospitality workers feel much better. In July 2003, New York outlawed smoking in public places. To see whether the new law would have the predicted beneficial effects Matthew Farelly and his team from the Research Triagle Institute in New York recruited 24 non-smokers who worked in smoky environments. They measured the levels of cotinine, a by-product of nicotine metabolism, in the workers' saliva. The test was repeated 3 months, 6 months and 1 year after the ban started. The workers were asked about their exposure to smoke at work and elsewhere and about symptoms such as itchy eyes, runny noses, wheezes and coughs. During the year the number of hours the workers were exposed to smoke dropped from 12 to 0.2 and cotinine levels decreased by 80%. The number of workers who suffered from itchy eyes and irritated noses and throats was cut by half. Interestingly, the workers also reported less exposure to smoke outside their working environment, suggesting that public smoking bans may be reducing smoking more generally.

New Scientist 2005; 20 August: 7.