valsartan together with ACEIs or β-blockers appeared to experience less beneficial outcome compared with those not on these drugs. At present the CHARM study using candasartan is being conducted and will contribute to our understanding of this group of drugs in analysing whether combination therapy with AECIs is better than ACEIs alone, and also if patients with diastolic dysfunction will benefit from angiotensin II antagonist treatment.

Treatment goals

The goals of treatment of heart failure are to improve or maintain quality of life by improving symptoms, to avoid treatment-related side-effects, reduce major morbid events, and delay death.[13] The aims of management are therefore to improve symptoms using diuretics, digoxin, and ACEIs. Angiotensin II antagonists may be used if patients are ACEI-intolerant or where these drugs are contraindicated. In patients with valvular heart disease careful screening to detect surgically remediable causes should be undertaken. Our management is also aimed at improving survival using ACEIs, β-blockers, nitrates with hydralazine and spironolactone.[14] New therapies for heart failure are being tested. These include vasopeptidase inhibitors and cytokine inhibitors, which are not yet available for routine clinical use. However, the most important way to avoid heart failure is to treat the contributing causes and diseases.

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Issues in Medicine

Monitoring of research — is it practical or only a dream?

Peter Cleaton-Jones

Recently Dada and Dhai[1] made a plea for a national ethics body that would monitor research and investigate allegations of misconduct in South Africa. Such a body is being introduced by the National Department of Health (DOH) in the form of a National Health Research Ethics Council for South Africa[2] with one of the terms of reference being 'to establish mechanisms for ethical inspectorate/monitoring and surveillance of ethical health research . . .'.

Similar pleas have been made by others, for example in good clinical practice guidelines[3,4] and in some ethics guidelines.[5] Other guidelines do not deal with the concept,[6] while the South African Medical Research Council *Guidelines on Ethics for Medical Research* are cautious, stating that 'it is impractical (even if desirable) for an ethics committee to monitor in detail the conduct of ongoing investigations, but committees should not lose contact with those they have approved. Some form of follow-up is desirable, if only an annual questionnaire to applicants. They should establish whether the project has been completed, abandoned (the reason should be given) or is still in progress in the original or another form . . . '.[7]

What is current reality? Clinical trials sponsored by pharmaceutical companies certainly are closely monitored as part of good clinical practice. Reporting of this monitoring varies from institution to institution; at the University of the Witwatersrand a 6-monthly progress report must be submitted to the research ethics committee. The reason this can be done is that the pharmaceutical companies provide the finances and/or staff to do the job and have realised that it is in their interests that trustworthy, quality research is done.

But clinical trials sponsored by the pharmaceutical industry form only part of the research involving humans carried out in our country, hospitals, and universities. At present these institutions have neither the staff nor the funds to invest in the

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staff necessary to monitor ongoing research — finances and human resources are limited and priorities are elsewhere.

So what should a research ethics committee do? At Wits we react at once to any report of ethics deviation, exemplified by a recent high-profile case.[8] Some[1] seem to feel that institutions should vet research presentations and manuscripts before presentation or submission. This would be an overwhelming task — for example at Wits there are some 500 ethics applications each year and each project may produce several outputs. Original data would need to be evaluated.

A further complication concerns the proposed council — will this have a jurisdiction to monitor research not concerned with the clinical management of patients? For example, if a physiologist studies the bowling action of a top cricketer, will this fall under the jurisdiction of the DOH? Certainly if the National Ethics Council is to accredit all research ethics committees it would — thereby increasing the potential workload.

The monitoring concept may be praiseworthy, but where are the necessary expertise and staff? As one who has served on ethics committees for 27 years I can testify to the difficulty of finding individuals dedicated enough to perform just the task of evaluating applications for ethics clearance, which is over and above their normal duties. Monitoring of research requires even more effort and time.

Is self-policing the answer? Will a yearly statement by each researcher that his or her research is still being carried out according to the approved protocol, or that it has been abandoned or perhaps not yet begun, be sufficient? Responsibility in such cases would rest on the researcher. But what will an institution do if the researcher lies, or does not provide the necessary assurance? What is one to do if a researcher has left the institution?

An on-line literature search for guidance on the mechanism of research monitoring has been disappointing. In Britain the Committee for Publication Ethics (COPE) monitors published material by responding to complaints,[9] and there is one report[10] on the experience of a local Scottish medical research ethics committee that recommended on-site review by a lay person and an expert of a random selection of 10% of approved projects. They estimated that in their case six person-hours were required per review plus approximately £120 (approximately R1 600) indirect cost — the time of the reviewers was not costed.

The Scandinavians have national committees that investigate scientific misconduct but have recognised the value of prevention — Scandinavian health scientists are required to attend training in the broad aspects of research ethics.[11] This is partly dealt with in the South African GCP[4] guidelines that lay down minimum standards for clinical trial investigators.

A realistic look at what monitoring can be done in South Africa is needed, perhaps by the existing research ethics committees, the Medical Research Council, the DOH and any other interested parties.

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