



Lipidology: contributions and threats

The ever-reducing support for South Africa's academic health centres long preceded our democratic change and has continued unabated. National and provincial heads of health focusing narrowly on service requirements, repeatedly lament their lack of control of academic heads of departments, registrars and others involved in the education process. Unlike the current Eskom power delivery debacles, which are on or off, often with disastrous effects with the latter, the insidious erosion of capacity of our teaching institutions is not immediately apparent. David Marais in his editorial¹ outlines the effects of this situation on a unique service and research facility. He emphasises the importance of multidisciplinary teams that integrate clinical practice, clinical research, specialised laboratory diagnostic procedures and laboratory research.

The unique experience of the Cape Town team with over 1 000 patients with familial hypercholesterolaemia (FH) is documented comprehensively by Jean Firth and David Marais.² FH is a common, serious disease affecting all ethnic groups in South Africa. It can be diagnosed by clinical features and routine laboratory tests at primary care level. Effective treatment prevents early and debilitating cardiovascular disease. FH is an autosomal dominantly inherited disorder. The heterozygous phenotype is characterised by a personal family history of premature ischaemic heart disease, tendon xanthomata and elevated plasma low-density lipoprotein (LDL) levels. The homozygous phenotype displays tendon and cutaneous xanthomata and higher plasma LDL levels, and often presents in childhood with physical signs and complications of the disease. A diet low in cholesterol and saturated fat should be started during childhood. Treatment with statins has contributed to improvement in survival in these patients.

The experience of the team with severe hypertriglyceridaemia as a result of familial chylomicronaemia is reported by Pouwels and colleagues.³ Severe hypertriglyceridaemia is often encountered in clinical practice, where it is usually secondary to diabetes, alcohol excess, renal disease or medication. Familial chylomicronaemia is an autosomal recessive disorder and is a rare cause of severe hypertriglyceridaemia. Successful therapy depends on expert dietetic advice and the patient's adherence to fat restriction. The lipid-lowering agents are not effective in familial lipoprotein lipase deficiency.

Paying clinical trial participants

Doctors take clinical trials for granted. Learned journal articles and pharmaceutical representatives extol the virtues of products shown to be effective in such trials. But we rarely think about the participants and what being in a trial means to them in terms of financial and other sacrifices. In order to protect participants, good practice now demands that ethical

clearance for such research is obtained from recognised authorities before it is commenced. Lyn Horn discusses the contentious issue of the payment of clinical trial participants in her editorial.⁴ Payment for expenses incurred is generally accepted. Payment for time, inconvenience and recognition of a contribution is far more contentious. Another category, an inducement to participate, is widely regarded as being unacceptable. She concludes that a one-size-fits-all approach is injudicious and that the final decision should be made by the research ethics committee after consideration of all factors.

The patients' perspective of remuneration for participation in a clinical trial was investigated by Lesley Burgess, Nicky Sulzer and Shaunagh Emanuel.⁵ Reasons for participating in clinical trials included contributing to scientific understanding, learning about their condition, achieving a sense of belonging and having access to services that they would otherwise be unable to afford. Participants believed that they should be compensated for travel expenses and time spent. The authors conclude that the blanket compensation of R150 per study visit as mandated by the Medicines Control Council is unrealistic and that policy should be revised.

The role of the pharmaceutical industry in clinical trials is explored by Michael Kahn and Michael Gastrow.⁶ They conclude that the focus of pharmaceutical research and development is in the area of clinical trials and not discovery. In South Africa there are good prospects for increased clinical trials activity. Policies (such as those addressed above) should therefore be directed towards this end.

Nevirapine-associated hepatitis

Despite scientific evidence to the contrary, political pronouncements alleging the severe toxicity of antiretroviral treatments have done much to sow confusion among the public and hamper appropriate treatment programmes. Further evidence backing the medical/scientific approach is reported by Black and Rees,⁷ who investigated nevirapine-associated hepatitis in an antenatal clinic (hepatitis is a side-effect of nevirapine therapy of concern to physicians). Their study found that nevirapine-containing ART has a favourable safety profile, with a low incidence of serious hepatic events.

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5. Burgess L, Sulzer N, Emanuel S. Clinical trial remuneration: the patients' perspective. *S Afr Med J* 2008; 98: 95-97.
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