

Clinical trials in South Africa: Need for capacity building and training

To the Editor: The *Lancet* recently highlighted the importance of prioritising clinical research in South Africa.¹ However, public hospitals do not encourage young medical professionals into clinical research. A plan to revitalise clinical research in South Africa is urgently needed.²

The focus of research and development (R&D) in South Africa is clinical trials.³ The South African Clinical Research Association (SACRA) estimates that in 2008 approximately R2.2 billion was generated through conducting internationally sponsored RCTs.⁴ This figure was limited by local regulatory approval times and insufficient suitable research sites. The Medicines Control Council (MCC) has recently made significant strides in reducing approval times. The deficiency in suitable trial sites must be addressed specifically by increasing capacity.

International sponsors have favoured South Africa for research as the population is genetically and socio-economically diverse, relatively drug-naïve and in need of safe and effective therapies for a broad range of diseases.⁵ Moreover, South Africa has a sound regulatory framework and efficient telecommunications, stipulates mandatory good clinical practice (GCP) training with 3 yearly updates, and is widely English-speaking.

The future of clinical trials depends on many factors, including recruitment efficiency and quality data. Despite recent growth in the industry, clinical research is not recognised as a speciality with formalised training (other than GCP), and proven expertise and competence is not assessed.⁶ Training programmes and certification processes must be standardised, with a core curriculum and reliable accreditation. Such training would improve investor and patient confidence and promote the generation of quality data. An increase in the number of trial sites would also increase patient recruitment potential and contribute towards capacity building. Such training is neither easily defined nor easily accessible. Internationally, a Masters in Public Health is regarded as the traditional degree for clinicians interested in research. International associations offering investigator certification programmes include the American Clinical Research Professionals (ACRP), the Society of Clinical Research Associates (SoCRA) and the Drug Information Association (DIA);^{7,8} however, a minimal number of researchers obtain such certification.

Recently, several foreign universities have been offering master's degrees in clinical research, and the Royal Colleges of Physicians' Faculty of Pharmaceutical Medicine offers a Diploma in Pharmaceutical Medicine. In South Africa, numerous GCP courses are offered⁹ and specific clinical trial-related courses are slowly emerging. The Health Science Academy offers a course entitled Introduction to Clinical Research and another in Project Management for Clinical Trials. The Wits Health Consortium recently launched a quality control course for research sites; future courses include Starting Up a Research Site. Stellenbosch University offers a post-graduate Diploma in Pharmaceutical Medicine.

Clinical research is finally starting to receive the recognition it deserves. For the industry to be regarded with academic credibility, we must generate original research in peer-reviewed journals. Editors have previously not been amenable to publishing work of this nature, but there is gradual progress in this area. Additionally, we need to focus on capacity-building conferences where we can share information with colleagues in the industry.

For clinical trials to grow, standardised training and accredited certification processes must be implemented, which would foster sponsor investment, promote patient confidence and, above all, ensure rigorous data quality and integrity – the cornerstone of the research industry.

**L J Burgess
N U Sulzer**

TREAD Research/Cardiology Unit
Department of Internal Medicine
Tygerberg Hospital and
Stellenbosch University, W Cape
lesley@treadresearch.com

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Surviving in the public sector

To the Editor: I have read the latest Med-e-Mails from SAMA with increasing distress. The apparent failure of our new Minister of Health to solve the problem of enabling doctors to negotiate just salary increases, because of labour legislation, is sad indeed. The obvious anger that this has evoked among members of the profession is very serious. It is awful to hear threats of resorting to strike action once more in this essential service. We can expect that the brain drain will again accelerate. Medical and nursing staff who decide to stay in the service for love of our people will be increasingly open to burn-out and discouragement.

My experience of 48 years in the public health structures of this nation suggests that those who stay will not find help in coping from the Department of Health. Those sensitive to their neighbours' pain then often find the situation intolerable – they have to opt out for their own well-being. My own experience of that, as a gynaecologist in a rural KZN town, came in 2001. Dealing with as many as 120 child rapes per annum over a period of 10 years upset me so much that I had to pass this important and difficult work on to more junior staff with less experience. Now, with more time to consider the problem, I realise that medical staff in public hospitals must take care

to structure their own support, which can be done in several ways.

Those of us who are members of faith communities will usually be able to find a mentoring individual or group to provide a secure place where we can off-load and find objective insights to help deal with our own pain.

In the 60s and 70s, in a deep rural mission hospital, our weekly journal club was run in such a way that we could give one another mutual support. That sometimes included insisting that someone take time off. We were a small group of 5 doctors looking after 550 inpatients. But there is no reason why like-minded doctors should not form small support groups even in the largest hospital. That is better than always taking flight from a difficult situation without helping one another to make it more bearable.

Any person who becomes aware that they are suffering from significant burn-out (illogical rage reactions, sleep disturbances, depression, etc.) should seriously consider seeking the help of a psychologist. That decision has significant financial implications, but if one chooses the right colleague, it will be well worth the expense.

These and other similar solutions should be sought in good time by all who feel strong enough and who desire to stay and work for our people. It is often too late to begin when one is actually in crisis. In that situation, the only sensible way to cope may be to leave!

J V Larsen

Private Bag X010
Howick
3290
jonvl@netactive.co.za

Meckel's diverticulitis revisited

To the Editor: Meckel's diverticulum, a true congenital diverticulum, is a small bulge in the intestine present from birth. It is a vestigial remnant of the original yolk sac or vitello-intestinal duct¹ and was originally described by Johann F Meckel in 1809.^{2,3}

I present a case of Meckel's diverticulitis in a 4-year-old boy who presented with overt iron deficiency anaemia. Ferritin levels were low and the peripheral blood showed a hypochromic, microcytic anaemia consistent with an iron-deficient picture. The haemoglobin concentration was 10 g/dl. He had a bright red melaena stool and right iliac abdominal pain. A barium meal showed Meckel's diverticulitis. The Meckel's diverticulum and adjacent ileum were successfully removed surgically.

Meckel's diverticulum is found in 2% of the population, more frequently in males; it is usually 2 foot from the ileocaecal valve and 2 inches in length (the rule of the 2s). The

diverticulum usually contains oxyntic cells from gastric mucosa that cause an ulcer giving rise to intestinal bleeding. The diverticulum may contain pancreatic tissue and may obstruct or strangulate in a type of volvulus.

This patient presented with iron deficiency anaemia, but Meckel's diverticulitis can often simulate acute appendicitis. It is generally not necessary to remove Meckel's diverticula found incidentally during surgery for other reasons.⁴

Hilary Denis Solomons

PO Box 64203
Highlands North
Johannesburg
2037
hillysol@netactive.co.za

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Mercury exposure in a low-income community in South Africa

To the Editor: I read the recent article on mercury exposure with a great interest.¹ Oosthuizen *et al.* concluded that 'As primary health facilities will be the first point of entry for individuals experiencing symptoms of mercury poisoning, South African primary health care workers need to take cognisance of mercury exposure as a possible cause of neurological symptoms in patients.'¹

I would like to contribute some thoughts on the subject. Firstly, not only recognition of the problem but also close surveillance is required. Indeed, the problem can be expected, based on the nature of the factory. If it holds risk of mercury exposure, monitoring the environment as well as workers and the nearby population is recommended. These issues continue to be problems in actual practice in developing, poor countries in Africa and Asia. Secondly, there are many other toxic substances that can cause neurological symptoms. The complete differential diagnosis of other possible causes of intoxication and further medical disorders is still important for the primary health care worker confronted by such cases.

Viroj Wiwanitkit

Wiwanitkit House
Bangkhay
Bangkok
Thailand 10160
wviroj@yahoo.com

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