



Figure 6.1: Trends in publication outputs in medicine, 1996–2005



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CONSENSUS REPORT ON

REVITALISING CLINICAL RESEARCH IN SOUTH AFRICA

A STUDY ON CLINICAL RESEARCH AND RELATED TRAINING IN SOUTH AFRICA

Report

- Consensus Study provides review of overall state of clinical research in SA
- Joint work of a 13-member Study Panel appointed by Council of Academy of Science of South Africa (ASSAf)

Brief / Aims

- Diagnosis: Identify the barriers that are inhibiting clinical research in South Africa
- Treatment: Make recommendations for the revitalisation of clinical research that can be implemented by the Department of Science and Technology, Department of Health, Department of Higher Education and Training, and Department of Trade and Industry

Chapter 11

We list what we consider to be the barriers to the clinical research enterprise in South Africa:

- Inadequate public engagement with clinical research
- Lack of research planning, regulation and coordination
- Inadequate capacity for clinical research (human resources & infrastructure)
- Lack of adequate and appropriate funding
- Absence of monitoring and evaluation

Recommendations

- A New System for Regulation, Planning, and Coordination of Clinical Research
 - ✓ National Health Research Committee
 - ✓ new Medicines Regulatory Authority (to replace MCC)
 - ✓ National Health Research Ethics Committee
- Build Human Resources for Clinical Research:
 - ✓ National Clinical Scholars Programme to produce 500 PhDs over the next 10 years
 - ✓ 30 dedicated National Research Chairs for Clinical Science
- Create and Fund Clinical Research Centres in each Academic Health Complex
 - ✓ Ensure that Joint Agreements provide for a Research Platform (in addition to the Teaching and Service Platforms)

Recommendations

- A New National Funding Scheme for Clinical and Health Research
 - ✓ Raise the national budget spend on R&D to 2% of GDP, with 20% reserved for health research
 - ✓ National DoH is signatory to the Mexico & Bamako declarations which require expenditure of 2% of health budget on research
 - ✓ Private healthcare industry to invest 2% of budget on R&D
- Monitoring and Evaluation of performance
 - ✓ Individuals
 - ✓ Research institutions
 - ✓ Research councils
 - ✓ Government departments
 - ✓ Private industry



***What Has Happened Following the
Report?***

National Health Research Summit of July 2011 Set Priorities for Health Research in South Africa

1. National Department of Health needs to set the example by investing 2% of health budget in health research: current level is R447 m pa (0.37%) – need to achieve R2bn pa over three to five years.
2. Human Resources for Health Research: A National Health Scholars Programme – 1000 PhDs over 10 years (double the number of health researchers).
3. Infrastructure: A Clinical Research Centre in each Academic Health Complex / Medical School
4. Project Grants: National Priorities Research Fund
5. From MCC to SAHPRA: a progressive and competitive regulatory regime
6. Translation: How to GRIPP? Is NICE the way?
7. Planning, Monitor & Evaluation: Performance of the Health Research System

South African Health Products Regulatory Authority (SAHPRA): a successor to the Medicines Control Council (MCC)

1. Establish a new regulatory authority called SAHPRA: a 'juristic person' independent of the national Department of Health and compliant with the Public Finance Management Act
2. Include medical devices and in vitro diagnostics in the sphere of responsibility of its Authority
3. "It is...envisaged that the entity will be operating, at the latest, by the end of this year", Minister of Health to the National Assembly on 20 May 2011
4. Number of practical details not adequately captured in the law:
 - a) Governance and management structures
 - b) Transitional arrangements
5. Detailed Project Plan and Implementation Plan have been prepared and Project Team appointed

Revitalising the MRC: Current State of the Organisation and Proposal for the Way Forward (30 July 2012)

1. The three key principles:
 - a) The centrality of scientific excellent
 - b) MRC as a custodian of medical research in South Africa
 - c) Prioritise intramural research to maximise impact on health
2. Restructuring the MRC to become a modern research agency
 - a) Intramural research (43% to 40%)
 - b) Extramural research (19% to 40%)
 - c) A innovation entity (Strategic Health Innovation Initiative)
3. Efficiency and effectiveness of the MRC administration (39% to 20%)
4. Creation of a Research Quality Assurance department
5. Revising the supply chain management procedures
6. Information services
7. Special financial considerations

The National Health Scholars Programme (Nov 2012)

1. PhDs in all fields of medical science:
 - Four year fully-funded studentships
2. Leading edge:
 - Select the best and brightest to work with the best researchers
locally or abroad
3. Large scale:
 - 1000 leaders, in all fields of health sciences

PROPOSED CLINICAL RESEARCH CENTRE AT GROOTE SCHUUR HOSPITALS



What About Global Clinical Trials South Africa?

1. Excellent initiative that should be part of the programme to revitalise clinical research
2. This symposium must not end up as a 'talk shop'
3. Recommendations of this meeting should be **published**, and submitted to other organisations that are concerned with the revitalisation of investigator-initiated clinical trial research
 - a) Health Committee of the Academy of Science of South Africa
 - b) The Medical Research Committee
 - c) The NHRC and National Health Research Ethics Committee



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Thank You