Global and local forces shaping the research agenda and the governance of research ethics

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Powerful global forces shape and skew the science research agenda, generally. We describe these and the local forces that fashion research priorities in science, technology and health in South Africa. We conclude with some comments on the governance of research ethics globally and locally.

Global forces shaping the research agenda

The 'knowledge society' emerged at the end of the 20th century and is becoming the new catchphrase in political, scientific and economic circles.[1] Scientific research, the most important source of new knowledge, has been influenced by almost every aspect of social life. Some of these forces, briefly reviewed in Box 1, illustrate that the pursuit of knowledge is not value-free. In general terms it is true to say that the questions that are asked and researched by scientists are those that attract resources, or that are driven by those with resources who seek answers that are of interest or value to themselves.

Local forces shaping the research agenda

Not too surprisingly, the influence of the market on South African science is evident in the fact that science is strongest in those disciplines that have been influenced by the country's national wealth. These include fields such as ecology, geology and geosciences, plant and animal sciences, and astronomy.[16] Local forces shaping the research agenda include the amount of expenditure on research and development, bottom-up (or aggregation) forces, top-down (or steering) forces and the skewed expenditure on health care (Box 2).

African countries are under pressure from overseas sponsors and their researchers to accommodate increasing numbers of clinical trials using research subjects from local populations. Subjects with every conceivable disease are readily available in large numbers, local scientists lack resources, research is generally less expensive than in northern countries, and it is popularly thought that ethics review of research protocols is less thorough than in the developed world.

It has been estimated that approximately US$150 million is spent on clinical research in South Africa annually, and the amount of funded research in other African countries, particularly magnet countries such as Kenya and Nigeria, is growing rapidly.

The increasing volume of research in developing regions of the world, coupled to inadequate resources for training in research ethics, makes them vulnerable to exploitative research. Research ethics committees (RECs) in Africa face two serious problems: (1) insufficient resources; and (2) a lack of expertise in research ethics. Public health-care structures in the region are notoriously under-funded. As a result, research and research ethics have a relatively low priority, compared with the provision of care and training of health-care personnel.

Science and technology priorities

There has been growth in steering of research in order to shift priorities back towards local needs in South Africa. The priorities that have been determined centrally for science and technology are research on energy, natural resources, building human capacity, biodiversity and such aspects of life in Africa as governance, efficiency, economic productivity and political instability.[22]

Within health care, steering to control research is exemplified by the Essential National Health Research programme and the recent South African Medical Research Council strategy to maximize health research investment by addressing the burden of diseases and the degree of inequity in health in our country.[28] The aim is to promote health and development on the basis of equity and social justice by prioritizing research on water and sanitation, AIDS, violence, women's health, health systems, development research, intersectoral research, and capacity-building in research.

Balancing aggregation and steering

The debate about whether research should be spearheaded by scientific curiosity, or be mission orientated to solve specific problems, has been long and heated. Comroe and Dripps showed many years ago that 41% of advances in the treatment of cardiopulmonary disease between 1940 and 1970 had resulted from research that was not directed at solving a clinical problem.[29] Deliberate steering of research has not been prominent in South Africa, but the tide has turned. An appropriate balance must be achieved. If powerful global forces dominate the research agenda in South Africa, then many local and relevant needs will not be researched. On the other hand, if local steering dominates, over-emphasis on relevant research may eclipse the 'blue sky' (curiosity-driven) research of creative scientists, and displace them to more attractive research environments, thus contributing further to the brain drain.[30]

A recent evaluation by a philosopher regarding who should govern scientific research provides an interesting historical perspective on the balance between scientific autonomy and external governance.[31] Kitcher's conceptual analysis identifies three functional subsystems as a collective or social endeavour that involves both scientists and those with the ability to contribute through democratic processes: (1) an inquiry subsystem to identify which scientific questions should be pursued; (2) a certification subsystem to identify what new knowledge is genuine; and (3) a transmission subsystem to make such new knowledge widely available. He thus suggests a scientific forum approach that would be more democratic, without relying merely on majority decisions.

Governance of research ethics

International

High profile international interest in the ethics of human research was initiated by the revelation of atrocious experiments carried out by the Nazis, and the resulting Nuremberg Code in 1949. Prominence given in the 1960s to ongoing unethical research on humans in prestigious medical schools in the U.S. and the U.K., and the public outcry in 1972 on exposure of the 40-year-long U.S. Public Health Service study of the natural history of

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untreated syphilis in a cohort of black men in America, boosted interest in regulating human research.[32]

National and international guidelines have since facilitated universal approaches to regulation of human research. These include the World Medical Association's Declaration of Helsinki, the Council for the Organisations of Medical Sciences (CIOMS), and the Nuffield Council on Bioethics. The U.S. National Academies of Science have promoted the education of scientists in ethics and social responsibility.[33] Unethical research continues, despite all this interest.[34]

The ethics of research on humans is also applicable to research in the social sciences. There have been recent strong objections by social scientists about the application of the biomedical model of protection of research subjects to social science research.[35] The HIV/AIDS pandemic has greatly increased sensitivity to the range of psychological and physical harms that may follow unethical medical and social science research. These concerns have been buttressed by the growth of research as an international collaborative endeavour with the potential to exploit vulnerable subjects and researchers in poor countries.[36]

Sensitivity to the need to reduce such exploitation led the U.S. National Institutes of Health to fund 18 centres around the world (with an annual budget of $4 million) through its Fogarty International Center, to promote capacity-building education in research ethics in developing countries.[37]

National

Many countries have formulated their own local guidelines for research on humans. Guidelines on the ethics of medical research were first formulated by the South African Medical Research Council in 1979. These were subsequently updated in 1987, 1993 and 2002.[38]

All medical schools in South Africa have had research ethics committees for many years. Most REC members have been senior clinicians and scientists, but few have had any significant training in research ethics. Recently there has been a trend towards a wider spread of committee members—inclusive of junior members of faculty, women, nurses, other health professionals and lay members—many of whom have had training in research ethics.

In the early 2000s, the South African minister of health appointed an Interim National Health Research Ethics Committee (INHREC). During the four years of its existence, this committee produced a set of national guidelines for medical research, and developed plans for the registration, and ultimately accreditation, of all RECs in the country.[39]

Following passage of the 2004 Health Act, the National Research Ethics Council, legislated for in the act, has now been formed. The council's tasks will include issuing regulations for every REC in the country to become accredited, establishment of a clinical trial register, and a requirement that all REC members must have some training in research ethics.[40] It is anticipated that increasing pressure will force other African countries, where substantial research is done, with sponsorship from developed countries to enact similar regulations. This is likely to lead to a growing demand for high-quality research ethics training.

South Africa is currently the site of two Fogarty-funded programmes: the International Research Ethics Network for Southern Africa (IRENSA) based in Cape Town, and the South African Research Ethics Initiative (SARETI) that allies the universities of Pretoria and KwaZulu-Natal. Each of these programmes has a different focus. In an era in which interna-

Box 1 — Global forces shaping the research agenda

Market forces: the most powerful and dominant shapers of the research agenda.
- Link between power and money has a long history, and the progress and 'development' of nations are generally measured in economic terms.
- A sevenfold increase of the global economy in the past 50 years is associated with widening disparities in wealth and health between the top quintile of the world's population and the bottom quintile.[2,3]
- The U.K. Department of Health recently launched a strategy to promote national economic growth by harnessing biomedical research to meet the needs of industry and enhance research productivity through market competition.[4]

Scientific curiosity
- Scientific curiosity became a powerful force after World War II, when the U.S. government was convinced that providing resources for scientists to pursue their ideas would foster economic prosperity.
- Advances in science and technology have allowed exploration of very large structures (the universe) and very small structures (viruses, genetic structures, and nano-particles). Growth has been stimulated by military and space research, and by human and plant genetic biotechnology.
- Because advances in these areas contribute to national power and prestige, they attract vast sums of money. Indeed, biotechnological advances are seen by some as the solution to health problems in the developing world.[5,6]
- A burst of major philanthropy for health from the Bill and Melinda Gates Foundation,[7] the Global Fund[8] and others in recent years has steered research towards diseases requiring intensive research on a large scale.

Military research and the political economy of war
- In the 1980s, 64% of $487 billion research and development expenditure in the U.S. was devoted to military research, 7% to space research, and only 22% to various forms of civilian research.
- In same decade the then European Council spent 26% of $320 billion on the military and 5% on space, with 59% on civilian research.[9] In 2002, following the events of 9/11, the United States increased expenditure on bio-terrorism research tenfold.[10]
- Research expenditure increased by 8%, while funding for the National Institutes of Health barely kept pace with inflation, increasing by just 2.6%, whereas support for the National Science Foundation declined by 2.5%.[11,12]

Selective valuation of lives
- The global research agenda is influenced by consideration of the lives of the wealthy and powerful.
- Of approximately $70 billion spent each year on medical research in the late 1990s, 90% was spent on research on those diseases that cause 10% of the global burden of disease.[13]
- Of 1393 new drugs marketed between 1975 and 1999, only 16 were for tropical diseases or tuberculosis.[14]
- This research agenda is largely shaped by the pharmaceutical market (amounting to about $406 billion globally in 2002), with 60% of profits being made in the U.S.A. (with 5% of the world's population).
- In the early 2000s, 87% of $2.2 trillion annual health expenditure in the world was spent on 16% of the world's population, who bear 7% of the global burden of disease, expressed in disability-adjusted life years (DALYs).[15]

tional collaborative research is expanding rapidly and cross-cultural understanding is required,[41] both programmes are making highly valued contributions to capacity-building in international research ethics in southern Africa.[42,43]

The overall goal of the IRENSA diploma programme is to develop and nourish sustainable, multidisciplinary expertise in international research ethics in southern Africa. More specifically, it prepares mid-career health and allied professionals to assume positions of leadership in research ethics in their home institutions. This programme is unique on the African continent in focusing exclusively on training mid-career professionals in three intensive two-week modules, spread throughout one year, with assignments carried out at their home institutions. Between 2003 and 2008, IRENSA had trained 71 mid-career professionals (41 men, 30 women, 28 white, 43 black) drawn from 20 institutions in South Africa and from 11 institutions in 8 other African countries.

The overall goal of SARETI is to build capacity for ethical review of health research and strengthen Africa's institutional training capacity. To achieve these goals, it offers a multidisciplinary, modular master's degree programme, an advanced, non-degree programme resulting in a certificate, and a training programme for 40 ERC members.[44] To date, SARETI has sponsored 16 master's students from nine African countries, and 17 non-degree fellows from seven African countries, in addition to several self-funded students.

One of the spin-offs of these educational programmes has been to stimulate the formation of a network of chairs of South African Human Health Research Ethics Committees. This has significantly improved liaison across the country. A newsletter from the Bioethics Unit at the University of Stellenbosch on research ethics activities in the country further facilitates such networking.[45] It is important to recognize, as Volmink and Dare have pointed out, that:

> Research with, rather than in or about Africa, is the goal. This will demand joint working to set agendas for research and mutual respect for countries' priorities, values and choices. Partnerships should be transparent, clearly showing what each side brings and what each stands to gain. Furthermore, there must be clear mechanisms to ensure that some funds for research are directed to strengthening the capacity to conduct research, manage research, and develop skills in scientific writing.[46]

Box 2 — Local forces shaping the research agenda in South Africa

Expenditure on research

- A key economic indicator of a country's commitment to research is the percentage of GDP spent on research and development (R&D).[17]
- For South Africa, this was 0.76% in 2004, having been about 1.0% in the early 1990s.[18]
- The Department of Science and Technology has committed themselves to increasing the R&D to GDP ratio to 1.0% by 2010;[19] the latest figure of 0.91%, up from 0.87% in 2006, suggests that this target will soon be achieved.
- Since the GDP for South Africa in 2007 was US$567.6 billion,[20] each 0.1% increase in the R&D/GDP ratio adds a further R2–4 billion to the national research system.*

Sources of research funding in South Africa 2005[21]

- Business: R6.21 billion.
- Government, including science councils: R5.40 billion.
- Foreign sources: R1.92 billion.
- Other: R0.62 billion (higher education sector, not-for-profit organizations and individual donations).
- Total R&D expenditure of R14.15 billion represents an increase of almost 18% on the R12.01 billion spent in 2004.
- National Treasury, in partnership with the Department of Science and Technology, has introduced a new tax incentive scheme for investment in R&D (2 November 2006). Contributions from business will probably increase in the years ahead.

Aggregation

- Aggregation (bottom-up) drive for research comes from institutional agendas, interests of researchers and their ability to attract resources from national and international sources.
- The business sector is the largest performer of R&D (R8.24 billion in 2005 out of the total of R14.15 billion).
- Government follows at R2.95 billion, higher education at R2.73 billion, and non-profit organizations at R0.23 billion.[21]
- In the medical and health sciences, which comprise 14.8% of total R&D expenditure, researchers' interests have converged in the era of HIV/AIDS and multi-drug-resistant diseases such as malaria and tuberculosis.

Steering

- Steering, or the top-down drive for research, is shaped by national priorities and relevance.[22]
- There is a lack of the coherence required to optimize benefits of R & D expenditure.[22]
- For health research, the agenda for low- and middle-income countries, including South Africa, is largely determined by external forces and focuses on a few conditions, such as HIV/AIDS, tuberculosis and malaria.[23]
- External funding concentrates on specific projects and seldom leaves behind a sustainable research platform or provision for translating research findings into effective action.

Health expenditure (2003/4)

- Private sector annual expenditure on health care (R62 billion) provided care for the 18% of the population who have private insurance (R5500 per person per year). About two-thirds of the country's medical practitioners work full-time in the private sector.
- In the public sector, comprising 82% of the population, expenditure of R37 billion (R950 per person per year) covers health care and all health-care training institutions.[24]
- Progressive weakening of public sector health-care services over the past decade, and a tendency for pharmaceutical research to be shifted towards the private sector, have led medical researchers to seek private research funds.
- Private funding is increasingly required to support the research endeavour in medical schools because of inadequate public expenditure on medical research (25% of research protocols approved by the Research Ethics Committee at the University of Cape Town were for contract research[25]). Global market forces now shape the medical research agenda more than local needs.
- Problems arise when close links develop between academia and pharmaceutical companies, and other sponsors threaten the professional ethical values of independent scientists.[26] The rise of economic power within transnational corporations that are not accountable for how they use their power, is of additional concern.[27]

*The exchange rate for the SA rand and the US $ has fluctuated between R6 and R8 to the dollar in the past few years.

Strong, well-motivated and well-governed research ethics committees can make a significant contribution to achieving these goals.

The recent stand taken by the chairpersons of RECs in South Africa not to permit studies that fail to provide insurance cover for research-related projects is one example of how improved knowledge and coordination in South African RECs is making such a contribution.[47]

In addition to health science faculties,

all academic facilities and all disciplines within such institutions that undertake research on human subjects should set up research ethics committees. While procedural requirements need to be met to ensure appropriate accountability, excessive focus on bureaucratic aspects of research ethics governance should be avoided.[48]

Conclusions

Research agendas globally and locally are significantly shaped by economic and political forces focused on acquiring and maintaining economic and other power, and by the interests of scientists in pursuing interesting intellectual questions.

More focus is now being placed by government on steering the research agenda towards relevant local problems in South Africa (and in other countries). This is appropriate, but there is danger of inhibiting useful scientific curiosity and progress, if steering becomes too dominant. In addition, if market forces are allowed to have a greater influence, as in the U.K.,[4] this may enhance economic growth but not necessarily be good for either research or health.

Research ethics, previously inadequately governed, is now increasingly becoming dominated by justifiable procedural processes, but these should not overshadow vitally important substantive knowledge of the ethics of research and the process of moral reasoning. More emphasis is required on professionalism,[49] including education on substantive issues in research ethics, on the social responsibility of being a scientist,[33] and on capacity building in professional ethics.

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