Science, Technology and Innovation for **Public Health in Africa**



AFRICAN UNION



NEPAD A Programme of the African Unio

Editors: Fetson Kalua, Abolade Awotedu, Leonard Kamwanja & John Saka

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Editors: Fetson Kalua, Abolade Awotedu, Leonard Kamwanja and John Saka

Research Assistants: Lukovi Seke, Margaret Rampa and Nthabiseng Legodi

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About NEPAD Science and Technology Programme

The New Partnership for Africa's Development (NEPAD) is a socio-economic development programme of the African Union (AU) whose express objective is to stimulate Africa's development by bridging existing gaps in Infrastructure (Energy, Water and Sanitation, Transport and ICT); Agriculture and Food Security; Human Resource Development, especially Health/Education, Youth and Training, Social Affairs; Science, Technology and Innovation; Trade, Industry/Market Access and Private Sector Development; Environment/Climate Change and Tourism; Governance/Public Administration, Peace and Security; Capacity Development, and Gender Development. The implementation of these programmes is based on the AU/NEPAD principles of African leadership and the ownership of the continent's development agenda and process, as well as a commitment to good political, economic and corporate governance.

African leaders have explicitly recognized that socio-economic transformation of the continent cannot be achieved without increased investments in science, technology, and innovation. To that end, the leaders have initiated a number of concrete actions geared towards promoting the continent's scientific and technological development. The actions include the creation of the African Ministerial Council on Science and Technology (AMCOST) and its subsidiary bodies -- the NEPAD Office of Science and Technology, and the AU Commission for Human Development, Science and Technology. These institutions have collectively developed a comprehensive strategy and action plan -- Africa's Science and Technology Consolidated Plan of Action -- adopted at the second African Ministerial Conference on Science and Technology in Dakar, Senegal, in September 2005.

The main goals of Africa's Science and Technology Consolidated Plan of Action (CPA) are to strengthen Africa's capacities to develop, harness and apply science, technology, and innovation to achieve millennium development goals (MDGs), as well as mobilizing the continent's expertise and institutions to contribute to the global pool of science and technological innovations. Key to these goals is the promotion of transnational Research and Development (R&D) programmes.

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List of Contributors

Professor Aggrey Ambali, Acting Advisor, NEPAD Office of Science and Technology, P.O. Box 395, CSIR Campus, Building 10F, Meiring Naude Road, Pretoria 0001, South Africa. Tel: +27 12 841 3688 • e-mail: aggrey@nepadst.org

Professor Abolade A. Awotedu, Head, Department of Internal Medicine, Walter Sisulu University, P/Bag X1, Mthatha, 5100, South Africa. Tel +27 47 502 2590 e-mail: aawotedu@wsu.ac.za

Mr Bob Bell, (Ph.D Student), School of Information, University of California, Berkeley, 102 South Hall, Berkeley, CA 94720-4600. Tel / Fax: (510) 969 5399 Cell: (510) 677 9684 e-mail: bbell@ischool.berkeley.edu

Professor Warigia Bowman, The Department of Public Policy Leadership, The University of Mississippi, 107 Odom Hall University, MS 38677. Tel: 662 915 1904 e-mail: mwbowman@olemiss.edu

Professor Joanna Chataway, Professor of Biotechnology, Development Policy and Practice Unit, Department of Development Policy and Practice Faculty of Technology The Open University Walton Hall Milton Keynes, MK7 6AA. Tel: + 44 1908 655 119 / +44 1908 655 708 • Fax: + 44 1908 654 825 / +44 1908 654 325 e-mail: j.c.chataway@open.ac.uk / dpp@open.ac.uk

Kalpana Chaturvedi, Former Research Assistant in Development Policy and Practice Unit, The Open University, Walton Hall,Milton Keynes, MK7 6AA. Tel: +44 1908 655 708 • Fax: +44 1908 654 325 • e-mail: dpp@open.ac.uk

Dr Rebecca Hanlin, Lecturer in Development Policy and Practice Researcher, ESRC Innogen Centre, The Open University Walton Hall Milton Keynes, MK7 6AA. Tel: +44 (0)1908 858572 / +44 1908 655 708 • Fax: +44 1908 654 325; +44 1908 654 325 e-mail: R.E.Hanlin@open.ac.uk

Dr Corinna Hawkes, Research Fellow at the International Food Policy Research Institute (IFPRI). e-mail: C.Hawkes@cgiar.org

Professor Hassan Kaya, Coordinator, IKS Centre of Excellence, North-West University, Private Bag X2046, Mmabatho 2735, South Africa. Tel: +27 18 389 2294 Cell: +27 82 857 9425 • e-mail: kayah.kaya@nwu.ac.za **Dr Fetson Kalua**, Senior Lecturer, Department of English Studies, University of South Africa, P.O. Box 392, Pretoria, 0003. Tel: +27 12 429 3826 • Cell: +27 74 852 8828 e-mail: kaluafa@unisa.ac.za

Professor Leonard Kamwanja, Pro-Vice-Chancellor, University of Malawi, Box 278, Zomba, Malawi. Tel: +256 1 526 622 / +256 1 525 247 • Cell: +256 9 916 838 • e-mail: provc@unima.mw

Professor John Mugabe, Institute for Technological Innovation, University of Pretoria. e-mail: john.mugabe@up.ac.za

Dr Julius Mugwagwa, Research Fellow, Development Policy and Practice/ERSC Innogen Centre Maths, Computing and Technology Faculty First Floor, Chambers Building, The Open University Walton Hall, Milton Keynes, MK7 6AA, United Kingdom. Tel: +44 (0) 1908 332 069 • Fax: +44 1908 654 325 e-mail: j.t.mugwagwa@open.ac.uk / dpp@open.ac.uk

Dr Clifford Mutero, PostNet Suite 812, Private Bag X4, Menlo Park, 0102, Pretoria, South Africa. Cell: +27 72 4432 707 • e-mail: c.mutero@mweb.co.za

Margaret Nyambura Ndung'u, African Centre for technology Studies and African Technology Policy Network (ATPS). Tel: +254 20 2714 092 / 168 / 498 • Fax: +254 20 2714 028 e-mail: info@atpsnet.org

Dr Marie T. Ruel, Division Director at the International Food Policy Research Institute (IFPRI). e-mail: M.Ruel@cgiar.org

Professor John D.K. Saka, Dean of Science, director of the Southern African Biochemistry and Informatics for Natural Products (SABINA) network. Chancellor College, University of Malawi, Box 280, Zomba, Malawi. Tel: +265 1 524 222 / +265 1 527 133 Cell: +265 9 939 472 • Fax: +265 1 524 046 • e-mail: jsaka@chanco.unima.mw

Dr James Smith, Acting Director & Senior Lecturer in African Studies Organisation, African Studies, School of Social and Political Science, University of Edinburgh, 406 Chrystal Macmillan Building, 15a George Square, Edinburgh, UK EH8 9LD. Tel: +44 131 650 4321 • e-mail: James.Smith@ed.ac.uk

Dr Frank Teng-Zeng, Research Consultant and Associate, Institute of Economic Research and Innovation (IERI), Tshwane University of Technology,159 Skinner Street, Pretoria 0001, South Africa. Tel: +27 12 382 3073 • Cell: +27 82 36 59 363 e-mail: frank.tengzeng@gmail.com / frank@ieri.org.za. **Godber W. Tumushabe**, Executive Director of Advocates Coalition for Development and Environment (ACODE). e-mail: g.tumushabe@acode-u.org / godbert@stanford.edu

Professor David Wield, Professor of Innovation and Development Development Policy and Practice, Faculty of Maths, Computing and Technology, The Open University, Walton Hall Milton Keynes, MK7 6AA. Tel: +44 (0) 1908 652475 / +44 1908 655 708 Fax: +44 (0) 1908 654825 / +44 1908 654 325 • e-mail: d.v.wield@open.ac.uk / dpp@open.ac.uk



A. Ambali, J. Mugabe & C. Mutero

Introduction

African countries face formidable challenges in public health, particularly with the rapid spread of HIV/AIDS and the persistence of malaria and related killer diseases such as tuberculosis which wreck havoc with people's lives. Other challenges the African countries are experiencing include the deterioration of health infrastructures and low and declining investments in health research. For many of these countries, this state of affairs has resulted in a considerable drop in life expectancy in the last two decades. This is particularly so in the sub-Saharan Africa where the burden of disease is pervasive and most pronounced.

Broadly, the challenges confronting Africa are located in scientific and technological developments as well as related emerging institutional arrangements. As a UNDP report puts it, "Technology-supported advances in health, nutrition, crop yields and employment are usually not just one-time gains. They typically have a multiplier effect...raising incomes and building capacity for future innovation—all feeding back into human development."¹ This message is echoed by the United Nations Millennium Project in its report entitled *Innovation: Applying Knowledge in Development*.

However, Africa now has opportunities to address these challenges. More than ever before, the continent is better placed to combat malaria, tuberculosis, HIV/AIDS and other diseases, as well as eradicating extreme hunger, stemming environmental degradation, improving water quality and sanitation, and advancing other aspects of human development.

The Healthcare Challenge

Africa has the lowest human development and highest poverty indicators in the world. Many African countries have the highest illiteracy rates and the lowest primary education enrolment. Health is another area of major concern. In sub-Saharan Africa, the rapid spread of HIV/AIDS has proven cataclysmic, with life expectancy now at 46.1 years, compared to the North African average of 71.5. According to UNAIDS², in 2006, an estimated 63% of all persons infected with HIV lived in SSA (~24.7 million people), with an estimated 2.8 million of these having become infected in 2006 alone. An estimated 2.1 million AIDS deaths were recorded in Africa, representing 72% of global AIDS deaths. Southern Africa, however, that has the highest prevalence of HIV and AIDS so that in 2006, the region accounted for 32% of the people living with HIV globally, and 34% of global AIDS deaths. While Chapter 6 provides detailed coverage of Africa's health challenges, Chapter 1 examines health innovation

systems and strategies for integrating global programmes with national and regional health innovation systems.

Technological Trends and Innovation Systems in Public Health delivery in Africa

There is need for a common and shared understanding of what can be done in order to tap science, technology and innovation tools to address Africa's current huge burden of disease. First, African countries and institutions have to show the qualities of leadership necessary for generating and utilizing technology and innovations in health in order to address diseases that are peculiar to this continent. It is evident that many of these diseases are not being addressed by the global scientific community for reasons which need no enumerating here. This can only be Africa's responsibility.

Secondly, Africa needs to position itself strategically with regard to shaping and driving a new research and innovation agenda necessary for disease treatment and diagnosis. Today, the continent does not have access to relevant health innovation tools that are widely available around the world. Worse still, Africa is not a key player in the public health research and innovation enterprises. Inequality in science, technology and health innovation capacity in Africa is evident in the extent of the disease burden in many countries. Consequently, the current global funding arrangements for public health, including for global pandemics and neglected diseases, must go beyond merely treating the symptoms through the provision of treatment but should also focus on building requisite health research and development infrastructure on the continent.

Thirdly, new continental initiatives must focus on shifting the apparent successes in health innovations to product development and product delivery. It is evident that while promising innovations have been developed in Africa and/or for Africa's specific diseases, not many investments are taking place in product development and product delivery. It is therefore important to address this shortcoming in the context of the Africa health strategies for NEPAD and the AU.

Finally, Africa must take advantage of the wide pool of scientific knowledge and technology tools available globally. This means that, on the one hand, individual countries and continental institutions must invest in technology prospecting in order to exploit existing and relevant health technologies and products. On the other hand, Africa must invest in setting up or transforming research institutions that are not only knowledge-based but also oriented towards product development. There is an immediate need to strengthen African institutions, especially universities and schools of medicine, by increasing funding and revising the curricula. Thus the issue of how science, technology and innovation can alleviate Africa's burden of disease is discussed fully in Chapter 2 of this volume.

Indigenous Knowledge and Innovation and Public Health

In most African countries, traditional medicine is used by nearly 70-80 percent of local populations to deal with their basic health care needs. There is scientific evidence that over 120 pharmaceutical products are derived from plants, and 74% were first utilised by indigenous cultures. Most of African countries have recognised the role of role of indigenous knowledge and innovation, however, existing policies and legislative mechanisms are ineffectual in that they do not fully protect and promote the use of indigenous knowledge and innovation. Chapter 3 discusses the role, opportunities and potential of indigenous knowledge to improve public health in Africa.

Agriculture and Health

Agriculture and health are linked in many ways. First, agriculture is essential for good health: it produces the world's food, fibre and materials for shelter; in many countries it is also an important source of livelihood among the poor. At the same time, agriculture can be linked with poor health, including malnutrition, malaria, food-borne illnesses, human immunodeficiency virus/acquired immunodeficiency syndrome, livestock-related diseases, chronic diseases and occupational ill-health. Health also affects agriculture: people's health status influences the demand for agricultural outputs, and in agricultural communities, poor health reduces work performance, reducing income and productivity and perpetuating a downward spiral into ill-health. Chapter 4 looks at the links between agriculture and health.

E-Health

E-Health refers to health services rendered through the use of technology. With many countries having adopted policies on Information and Communication Technologies for improved health, the major challenges concern infrastructural development and sustainability of E-Health projects. Again, issues of ICT policies including the legal, regulatory and policy frameworks with regard to E-Health become important. Chapter 5 discusses the evolution of E-Health and specific projects and related facilities in selected countries.

Intellectual Property Rights to Improve Public Health

There is currently substantial debate on the potential and actual relationship between the current global intellectual property rights architecture and health in Africa. In many ways, Africa, compared to the rest of the world, suffers substantial inequalities of various forms. These inequalities include the following: allocative and distributive inequality in health innovation R &D investments; limited research and development focusing on what is often referred to as orphan diseases; the apparent bias of global efforts towards transnational diseases compared to global diseases; and the lack of access to essential medicine for many rural populations and poor people in Africa.

The fundamental question is whether the current global IPR architecture explains the range of health inequalities that Africa is facing today, and whether changing that architecture can address such inequalities. There are also questions of whether IPRs affect procurement, access and diffusion of critical health innovations, including medicines and diagnostic technology. In addition to these problems, the global debate on IPRs has been shifting away from the traditional international policy platforms (within the relevant UN agencies) to the World Trade Organization (WTO) -- an unfamiliar territory for many African countries. Even the basic debate on access to medicine is no longer entirely pursued as a moral issue but rather as a political and trade one located within the context of the Agreement on Trade Related Aspects of Intellectual Property (TRIPS).

There is need to generate more empirical evidence to form a basis for appropriate policy -- legal and institutional -- to ensure that IPRs contribute to narrowing the health equity gap between Africa and the rest of the world. Areas that require more empirical studies include those relating to IPRs and technology transfer, IPR and access to medicine, IPR and foreign direct investments, as well as the range of flexibilities built into the TRIPS Agreement. While some work has been attempted, available evidence is only anecdotal and largely inconclusive for it to be useful for policy. Chapter 6 deals with the link between IPR and public health.

Funding for Health R&D and Health Innovation in Africa

Addressing the problems of public health in Africa will also depend on the structure and scope of funding for health research and development, health innovation and health product development programmes. Although investment in health research is increasing in most countries, available evidence, suggests that African countries have not met targets set by the Africa Union Health Ministers of 15% of national budgets being devoted to the health sector, 2% of which would be set aside for research and development.

As indicated in Chapter 7 of this monograph, an analysis of existing health R&D funding sources and commitments also shows that the bulk of the funding comes from external sources. For the three major pandemics (HIV/AIDS, Malaria and TB), the bulk of the funding comes from the Global Fund.

While the national health research systems are weak, it is often viewed solely as a source of new knowledge. This situation is unlikely to change, unless there is an immediate transition from project by project initiatives to national and regional systems of innovations for health whereby the use of research to generate new services and intervention is clearly articulated in policy development and priority-setting. Nevertheless, the major barriers in the continuum from upstream basic research to downstream end-user applications and practice still exist and include: lack of enough funding for sustainability of research, policy gaps, action gaps

and insufficient community and stakeholder empowerment in health research. Giving specific examples, Chapter 7 examines the situation and patterns of funding for health R&D in Africa.

Notes

¹ UNDP (2001). Human Development Report 2001, Making New Technologies Work for Human Development, p. 2. United Nations Development Programme, New York.

² UNAIDS - Joint United Nations Programme on HIV/AIDS.

CHAPTER 1

Building the Case for Systems of Health Innovation in Africa

J. Chataway, K. Chaturvedi, R. Hanlin, J. Mugwagwa, J. Smith & D.Wield

Abstract _

Science, technology and innovation are vital to poverty alleviation and improved health. Improving immediate access to health care and existing health technologies is essential but simply importing technologies and products is not enough to create sustainable health care systems. Countries also need to build the capacities and institutions to develop their own innovations which are tailored to local needs. For innovation to meet local needs, countries need urgently to develop dynamic and integrated health innovation systems. This would enhance understanding between those in the world of healthcare and those who work in health innovation and production of pharmaceuticals, as well as promoting networking between researchers and producers with local users and consumers.

Secondly, improved innovation capacity that responds to the needs of users does not occur in isolation – it is not the product of one-off scientific inventions, heavy investment in science or one-off policies. Rather it is dependent on networks through government institutions, private companies and a wide variety of end-user groupings at national, international and sectoral levels. Finally, knowledge is not accumulated and built up in one set of institutions and transferred to another set – it results instead from the interplay between different organisations and institutions.

There is now an unparalleled opportunity both to address the issues of neglected diseases and to develop such integrated health innovation systems. Huge investments are currently being made in global health programmes which seek to improve health services and health innovation systems. The challenge for African policymakers, as we discuss in this chapter, is to adopt strategies for integrating global programmes with local and regional health innovation systems.

Introduction

Science, technology and innovation (STI) are crucial to economic and social development. Simply importing new technologies is not a solution for building the expertise and capacity needed to put science and technology to productive use and make it work in the interests of developing country populations. The premise of this paper is that improving immediate access to health care and health technologies is essential but not sufficient for sustainable health improvement and poverty alleviation. The use, adaptation and creation of health technologies and innovation are fundamental to Africa's ability to deliver better health care to its people. One essential challenge for policymakers is to harness technologies and innovation to the needs of Africa's diverse populations. Health innovation systems perspectives can help in meeting that challenge.

Innovation systems thinking tells us that success in innovation is not a product of one-off scientific inventions, heavy investment in science or particular organisations and policies. Rather, sustained success in promoting and delivering productive innovation depends on linkages and networks running through government institutions, private companies and a wide variety of end-user groupings at national, regional and sectoral levels. Since innovation does not occur in isolation, the pattern of particular innovation systems will depend on political, economic and cultural factors. This has major implications for national policy makers and points to the importance of creating 'innovation friendly' national institutional environments.

The emphasis of innovation systems thinking is on the continuous incremental build up of innovation capacities across different actors and institutions rather than on one-off inventions. It points in the direction of a focus on building up 'absorptive capacity'¹ and learning rather than the acquisition of discrete technologies or highly specialised scientific and technical skills. The key point is that economic and social development requires improved institutional capacity in innovation so that consumer and user needs are articulated to producers and researchers who can respond. This means that there is no need for each African country to undertake all the health related production and research; rather Africa should increase its commitment to health provision by getting countries to focus not only on access to medicine but also to increase their role in research and development (R&D), production and learning in relation to user needs. This means that capacity building, training and policy formulation must be rooted in outward looking institutions and must focus on dynamic linkages and interactions that result in innovation.

There is currently an unparalleled effort by global health partnerships, the United Nations, public private partnerships and bilateral agencies to address the issues of neglected diseases and endemic health problems in Africa. The challenge is to grasp the opportunity and build functioning health systems and health innovation systems that will enable African populations to benefit from quality health products and services on a more sustainable basis.

Thus innovation systems stress the interaction between knowledge and linkages amongst

researchers and organisations. This chapter covers a more in-depth overview of the relationship between these different aspects of innovation systems. We use a wider definition than was originally conceived and one which acknowledges multiple levels of action that create connections, reinforcing and strengthening what can be termed the wider 'ecosystem'. We then discuss what such a definition means for the way a health innovation system is perceived. This builds on previous definitions of a health innovation system (Mugabe 2005; Mahoney and Morel 2006). More specifically, the definition acknowledges the need to deal with policy disconnects between social policies and industrial and innovation policies together with the way that systems develop – evolve – according their goals and needs. Thus there is no single health innovation system formula. Instead, as we discuss in Section 3, there are different dimensions around which a system is developed. To these six we add a seventh: the importance of 'system-making' initiatives or the organisational and learning capacity within and between different actors. The emphasis here is placed on the involvement of local stakeholders in order to build on and strengthen existing capacities.

In order to highlight how important these seven dimensions are, we provide examples from a number of different developing countries and cross-country networks. Each example provides a descriptive account of how different countries and networks have built up one or more of the seven determinants in ways that create different but always relevant forms of a health innovation system. We conclude the chapter with a number of policy recommendations. The result is an integrated policy making which links health with innovation system activities and ensures that relevant capacity building takes place. Second, we recommend increased recognition of innovation's cross-border activities and therefore the need to work with global health programmes.

1. Definition of Innovation Systems

An essential feature of thinking about innovation systems is the focus on the interaction between public and private sectors and the complex interactions and feedback mechanisms that exist between different elements of the value chain and users. Alternative strands of the analysis highlight various characteristics and different system 'boundaries'. One summary of systems perspectives is as follows:

> "The systems of interacting private and public firms (either large or small), universities and government agencies, aiming at the production of science and technology within national borders. Interaction among those units may be technical, commercial, legal, social and financial, in as much as the goal of the interaction is the development, protection, financing or regulation of new science and technology." (Niosi et al. 1993, p.212)

A large section of the literature on innovation studies deals with nationally bounded innovation systems (Lundvall 1992; Nelson 1993). These studies describe how national institutions

(both structures such as hospitals, government ministries, finance institutions and also rules and regulations) influence the ways in which innovation does and does not occur. Whilst national perspectives are key to policy thinking, there is clearly a problem in drawing analytical boundaries around national systems only. The boundaries which identify exact systems are clearly imprecise. Metcalfe and Ramlogan (2005) write:

> "With increasing evidence in the literature that innovation processes are distributed across national boundaries an analytical focus on a national system seems something of a conundrum. The national perspective underlying national innovation systems has been predominantly adopted on the basis that many institutions, culture, language, common norms, technology policy, and education influencing innovation had a national character... But proponents of the approach admit that these systems are open and heterogenous and that there can be other levels (local, sectoral) at which they can be analysed..." (Metcalfe and Ramlogan 2005).

Whilst it is vital to understand social and economic institutions in terms of national boundaries, scientific and technical knowledge works within a range of other geographical and non-geographical boundaries. Some authors emphasise the importance of systems properties, and in particular learning characteristics (Lundvall 1992; Edquist 1997) that go beyond national boundaries. So, for example, a major concern is how knowledge is transferred from domestic and international universities or companies to local organisations and institutions. Again, whilst not denying the centrality of national systems, other authors focus on sectors as the primary lens through which to examine systems (Malerba 2004; Mugabe 2005). The focus here is on how different sectors such as pharmaceuticals or engineering evolve and what sorts of institutions, organisations and linkages characterise different sectors. Yet another approach considers how innovation takes place within clusters and industries or technologies (Carlsson 1995; Kiggundu 2004; Oyelaran-Oyeyinka and Rasiah 2005).

Cutting across these different notions of non-geographically bounded systems, Metcalfe et al. (2004) talk about 'micro-innovation systems'. This concept indicates that innovation systems at the national level co-evolve with many 'micro-innovation systems' or innovation based initiatives, projects and enterprises. An example of the relevance of the concept to this chapter are global health partnerships such as the International AIDS Vaccine Initiative (IAVI) which can be thought of as micro innovation systems connecting across national and regional boundaries and assisting in some cases with the building of capabilities in relatively weak national environments. In this chapter conceptual tools are adopted from a variety of systems perspectives to look at the development of health innovation systems within national and regional contexts.

At the centre of innovation systems analysis is a concern with knowledge accumulation and how knowledge and research pertain to economic and social development which has enormous implications for policy. For example, what sort of education would a country want for its citizens, one may ask. Some people might feel that theoretical physics is essential for a healthy intellectual environment and yet Nobel Prize winners in this field are of limited use in improving hospitals. A theoretical physicist will probably not understand how to engineer a laser machine for use in hospitals even though they may understand the principles on which such a machine should operate. Research biochemists can build an understanding of how certain chemicals change biological states, but they cannot alone design new drugs. In any innovation process a mix of skills and perspectives are required. Yet, in Africa, experiments in mixing more vocational or problem-based learning with more theoretical and academic perspectives are few and far between. Mytelka and Oyelaran Oyeyinka (2003) identify higher education institutions as one of the barriers to innovation in the African context, saying that Africa is unable to adapt to the inherited colonial pure scientific model of tertiary education to serve current innovation needs. Many national and regional initiatives have proved unsuccessful in creating flexible institutions that can respond to pressing social and economic problems.

These more conceptual issues translate into immediate and pressing realities. Health systems and health innovation policymakers need to grapple with issues of whether new initiatives should be regional, national or local. Should they be grounded in a traditional understanding of 'academic excellence' or should they be rooted in practical activities and applications of knowledge? These issues are at the heart of the challenge involved in creating 'systems' and networks that will facilitate innovation in health and other sectors. Identifying a conceptual apparatus to help construct useful institutions is key. If we cannot be precise about geography (national, regional or local) and about which 'systems' or 'models' that we can deploy, how do we use systems concepts to help in the process of creating useful institutions and networks in health innovation? It is therefore needed to distinguish between 'innovation ecologies' representing the sets of individuals, organisations and knowledge repositories in any national context and the "'system making' connections that ensure the flow of information..." (Metcalfe and Ramlogan 2005).

Table 1: (National) Health Innovation Systems						
	MACRO LEVEL SYSTEM	SECTORAL LEVEL SYSTEM	MICRO LEVEL SYSTEM			
Defined as:	National Innovation System	Sectoral / Cluster / Technological Innovation System	Micro Innovation System			
ACTORS / ACTANTS	World Trade Organisation (WTO) Trade Related Intellectual Property Rights (TRIPs) framework	Institutions, rules and norms of National Health Systems	Individual firms and organisations working in health research, care, financing and delivery	TEM MAKING		
	National government policy on innovation	Health and health innovation policies	Initiatives around the production of e.g. ARVs	SYSTEM CONNE(

2. Health Innovation Systems

'Health innovation system' is an overarching term that includes relevant aspects of the macro environment of institutions, pertinent rules and procedures within a national system of innovation, the activities of health institutions within a national health system and the micro level innovation activities of individual companies and organisations involved in the health care value chain including production, delivery, financing and research.

The report of the Millennium Project Task Force on Science and Technology Indicators highlights the importance of technology and innovation to health:

"A broad number of health interventions require the development of new treatments and vaccines through improved science (e.g. anti-malarials, HIV treatments and prevention, drug-resistant tuberculosis, vitamin and other micronutrient deficiencies in children and mothers, etc). In addition, the production of generic medicines holds the promise of improving the poor's access to essential medicines. A particularly important contribution of science and technology in this area lies in improved monitoring systems for pharmaceutical quality." (2005:36)

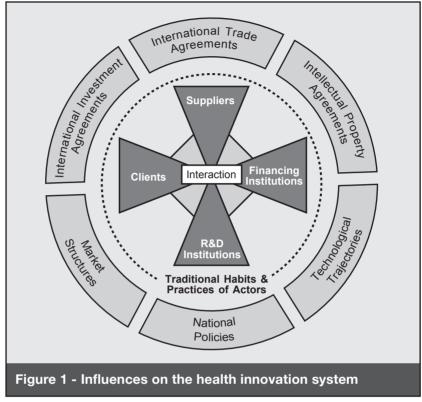
The report also considers that the challenge of improved technology and innovation lies in the capacity of policymakers to tackle issues systemically, building innovation systems that facilitate, promote and respond to developments. A special *Nature Biotechnology* supplement in 2004 made a powerful case for building up health innovation systems in developing countries as part of the effort to develop innovation appropriate to the needs of the world's poor (Thorsteinsdottir et al. 2004). Developing innovation and manufacturing capacity in Brazil, India, Cuba, South Africa, South Korea and China, for instance, has led to significantly increased research and product development for diseases afflicting countries in Latin America, Asia and Africa.

In thinking about health innovation systems, an analytical and policy focus is required that is informed by the more general 'systems' framework set out in the previous section. The way that national innovation systems impact on health care and innovation needs consideration. A wide range of institutions that impact on health will have varying relevance in different national contexts: educational and policy infrastructure, intellectual property frameworks, financial facilities, social welfare and insurance provision, broad economic policy etc. We need to consider sectoral institutions such as hospitals and drug distribution networks because without the basic health systems, the effectiveness of any other interventions including global health partnerships will be limited. The whole value chain associated with health provision is thus extremely complex, including science labs, many highly industrialised, to health services, over the counter and private providers of all kinds, including top hospitals where much incremental innovation takes place.

Figure 1 outlines the different elements of a health innovation system that influence the rate and direction of change and which are influenced by the numerous 'micro systems' in development at any one time. The linkages between users and producers of health care should be considered. For example, policy changes relating to financial restructuring or intellectual property (IP) rights management might have profound impacts on people's access to medicines and also on domestic capacities. One important aspect of systemic perspectives is the attention paid to mismatches and gaps and the potentially contradictory effects of policies. For example what is good for domestic industrial policy (such as the promotion of domestic pharmaceutical industry) does not always match with health policy which emphasises access to medicines via generics available from elsewhere in the world (Kaplan and Laing 2005).

This highlights the fact that in policy terms there is a worrying, endemic gap between social policies on the one hand and industrial and innovation policies on the other. Dealing with such disconnects² is vital. Development and the eradication of mass poverty and disease requires a massive increase in productive capabilities and production in developing countries. Some countries, notably in Asia, are achieving this. Yet 'pro-poor' aid policies, especially for the least developed countries, focus strongly on social sector distributional mechanisms and operate almost entirely without reference to policy thinking on promoting innovation and productivity. Conversely, researchers on innovation and industrial policies tend to know little about the potential for social protection to support innovation and productivity improvement. Thus, there tends to be a profound lack of understanding between those who research and make policy in the world of health care and provision of health services and goods and those whose interest is in health innovation and production of pharmaceuticals. Several authors have begun to tackle this divide (Gore 2007; Mackintosh et al. 2007; Mkandawire 2007).

If health innovation systems that directly serve the needs of local populations are to be created this gap needs bridging. Industrial and innovation policies designed to increase productive capacity need aligning with social and health policy designed to address distribution. Social policy can in turn enhance innovative capacities. Mkandawire (2007) and Gore (2007) from UNCTAD urge policymakers to adopt policy frameworks which view social policy and distributive mechanisms as development opportunities.



Source: Mytelka (2007)

Mackintosh and Tibandebage (2007) considered care markets and providers in Tanzania and concluded that informalisation and market liberalisation had created incentives for perverse provider behaviour; associated with heavy reliance on private providers this was inhibiting innovation and efficient and effective provision of health care. The market incentives encouraged rather than discouraged poor quality provision and illegal activities. The authors point out that while there are now high demands for investment in health systems and innovation systems, policy in the Tanzanian and other contexts undermine system capabilities.

> "Active support for health system integration and organisational sustainability and probity is essential for poverty-focused care and innovation, and will require major investment and deliberate structural change after many years of deregulation and fee-based finance. Policy should aim to constrain perverse market dynamics and move towards system integration" (Mackintosh and Tibandebage 2007:23)

Thus, thinking about health innovation systems requires some revision of the traditional demarcations between production and provision in creative ways. This view is endorsed

by both NEPAD's health and science and technology (S&T) strategies. Mugabe (2005) says:

"The notion of a health innovation systems, is... more than just the sum of the R&D institutions, health care organisations and medical scientists and practitioners, but includes also the policy regime that determines how well there are mutual interactions among various actors. It is a system with changing actors, connections and interactions."

The main features of health innovation systems in Africa is now briefly discussed.

3. Health Innovation Systems in Africa

The NEPAD health strategy paints a daunting picture of the situation in Africa.

"The HIV/AIDS epidemic poses an unprecedented challenge for Africa, reversing the gains made in life expectancy over the past half a century. Life expectancy in the most severely affected countries has been reduced by almost a third, from 60 years to 43 years. About 2.4 million people died from AIDS in 2002 and around 3.5 million infections occurred... 1 million deaths [are] caused by malaria each year and 600,000 deaths caused by tuberculosis. Malaria has slowed economic growth by 1.3% per annum at a \$12 billion economic cost. Countries have a tuberculosis burden exceeding the 300 per 100,000 population benchmark for severe disease, with 1.6 million new active cases occurring annually. Sleeping sickness is resurging, affecting between 300,000 and 500,000 people annually." (NEPAD 2003)

These challenges, to different degrees, impact on all African countries, which have extremely diverse health systems and innovation capacities differ greatly. However, health systems in many contexts are impoverished and fragmented because there are very low capacities to undertake scientific and technological development relevant to local diseases and local needs.

3.1 Dimensions of Health Innovation Systems

Six major areas influence innovation systems in different countries: R&D; manufacturing; domestic markets; international markets; IP and regulation. It is critical to build capacities in each of these areas in systematic ways that help to link healthcare delivery issues and concerns with innovation policies and issues so that both might meet local needs for new approaches and initiatives. This section provides a schematic overview of the existing state of affairs in each of these six areas and then points towards some of the new approaches that are being developed and how systemic approaches can be built when attention is given to these six determinants.

3.1.1 R&D

Determining scientific capacity and levels of research and development is not straightforward. A 2001 Rand report provided an assessment of scientific capacity and indicators of levels of R&D in developing countries based not only on the usual patent and citation data. Rather the report attempted a more sophisticated and accurate measurement based on a comprehensive index of capabilities. These included: the per capita gross national product (GNP) as proxy for general infrastructure; the number of scientists and engineers per million people to capture the human resources available for S&T activities; the number of S&T journal articles and patents produced by citizens of that nation to characterise scientific outputs; the percentage of GNP spent on R&D to measure the society's level of input into S&T; the number of universities and research institutions in the nation per million people to characterise the infrastructure for S&T; a measure of the number of the nation's students studying in the United States adjusted for those who chose not to return home at the conclusion of their studies to characterise the country's contact with external knowledge sources; and the number of patents filed through the U.S. Patent and Trademark Office and the European Patent Office (Wagner et al. 2001).

Countries were categorised into four groups. There are no African countries listed in the 22 countries that made up the 'Scientifically advanced countries' group. Only four countries in Africa are grouped as having built, or as being in the process of building, their scientific capability; South Africa was placed in the 'Scientifically proficient group' while Egypt, Benin and Mauritius where seen as 'Scientifically developing countries' (Wagner et al. 2001).

Mugabe (2005) notes that only a few developing countries possess the necessary capability to engage in scientific research and in the development of medicines or manufacture of pharmaceuticals: "in Africa it is South Africa, Egypt and Kenya that possess capability to conduct drugs research" (Mugabe 2005:7). Nevertheless as Mugabe points out and as other sections in this chapter will show, there are R&D initiatives taking root in Africa and there is a base to build upon.

3.1.2 Manufacturing

Industrial competitiveness in much of Africa is poor. Manufacturing value added per capita is not only lower than most developing country regions of the world, but contrary to global trends, it is not growing. Table 2 shows this.

Mugabe (2005) notes that in Africa, only South Africa and Egypt have local companies engaged in some pharmaceutical manufacturing activities. Algeria had reported capability to produce pharmaceutical products such as oral liquids, tablets, capsules and ointments. This potential has not yet translated into capacity because of the absence of a strong industrial production base.

In an overall assessment of constraints on health innovation capabilities in Africa, Mugabe notes the following as important factors: lack of any policy focus on health R&D; low levels of investment in R&D in health with most developing countries spending less that 0.5% of their GDP on health R&D and weak links between public health R&D institutions and private industry (Mugabe 2003:9).

Table 2: Manufacturing values				
	<i>Manufacturing value added per capita</i> (in US\$ adjusted to 1995 values)			
	1990	2002		
Industrialised economies	5,161	5,839		
Transition economies	863	596		
Developing economies	221	356		
East and South-East Asia	247	576		
South Asia	48	75		
Latin America and the Caribbean	670	674		
Middle East and North Africa	273	365		
Sub-Saharan Africa	99	89		
Excluding South Africa	33	33		

Source: Pietrobelli (2006)

3.1.3 Domestic Markets

Markets in Africa are dominated by both public and private institutions, involving both state dominated provision of goods and services and increasingly also involving the private sector operating on the basis of commercial rules. The large scale of private funding and provision of healthcare in Africa also involves an important role for non-governmental providers (Bloom 2004; Bennett et al. 2005). Markets also include actors like Non-governmental Organisations (NGOs), donors and multilaterals.

On a global scale the Africa market is very small. In pharmaceuticals the global market is worth over \$406 billion, 77% of which is in the US, Europe and Japan. Only 1% of total spending occurs in Africa, which accounts for 25% of the disease burden in the world (Scheffler and Pathania 2005). There is little large-scale regional production of pharmaceuticals in Africa due to a lack of capacity and expertise to produce not only the drugs needed but also vaccines and diagnostics. These figures lead to the coining of the phrase 10/90 gap to illustrate how only 10% of all health research and development is spent on issues affecting 90% of the world's population. What spending there is in Africa on health related R&D is increasingly funded by public sector institutions and through new organisational forms called 'public-private partnerships' (Moran 2005). This is because the private sector pharmaceutical companies find it too costly and risky to invest in development of drugs for diseases affecting those in the developing world, so-called 'neglected diseases', where demand is high but ability to purchase drugs is low (Trouiller et al. 2002).

A wide diversity of policies exists to encourage positive private sector engagement in African health. Policies include: promotion of private corporate investment in African health systems, as in the 2006 International Finance Corporation initiative; support and regulation initiatives to change small providers' behaviour, such as the Tanzanian Food and Drugs Authority initiative to train staff, accredit and locally monitor a network of rural drug shops; and numerous small scale insurance initiatives. Mackintosh and Tibandebage (2007) however note that although all of these schemes depend on good market information, the "field research-based and analytical literature on the operation of the private health sector in developing countries remains thin". They go on to talk about two negative features of the way liberalised markets operate drawing also on a broader cross-country study of health care commercialisation (Mackintosh and Koivusalo 2005). There has been an increase, firstly, in the money spent on out of pocket payments for health care and secondly, related to this healthcare has increasingly undergone 'informalisation' where to varying degrees there is a "lack of enforcement" of regulations and quality (ibid.).

What Mackintosh and Tibandebage highlight is the need to think through the implications of sets of policy that cover access to medicines with those that promote production of medicines. Clearly, you need innovation in delivery systems at low income levels, as well as technological innovation. If access policies are serving people poorly, it is impossible to get new technological developments and innovations to those people. Where scientific and technological innovations could contribute enormously to testing and quality supervision, 'informalisation' of systems may hinder efforts to put technology to use. There is a need to consider factors influencing both supply and demand within healthcare.

3.1.4 International Markets

International markets in generic drugs are of vital importance to Africa. For example with the bulk of HIV/AIDS infection in African countries, the production of cheap anti-retroviral (ARVs) drugs is vital. The production of generic or non-patented drugs for controlling HIV/AIDS by Indian companies has reduced the cost of these antiretroviral drugs by 97% (Henry and Lexchin 2002) making them more affordable for HIV positive populations in African countries. The cheapest regimen, a fixed dose combination of stavudine, lamivudine, and nevirapine, decreased in price from US\$350 annually in 2001 to \$168 in 2004, and was selling at between \$132 and \$148 in 2005/6. The price of combinations of zidovudine-lamivudine and efavirenz decreased more slowly and is currently around \$400. Second-line drugs remain even more expensive, with an average price of \$900 in least developed countries and \$1600 in middle-income countries in 2005 (Schwartländer et al. 2006).

The production of generic ARVs made in Africa is small – limited to Kenya and South Africa with Tanzania starting in 2006. The wider branded drug market is also small. A number of countries (particularly, South Africa, Kenya and Nigeria) have local production capacity and some international pharmaceutical companies have licensing agreements with African companies to produce their products in Africa. However, local drug markets are dominated by imported drugs from India.

Although African pharmaceutical companies are expanding and partnering with larger international firms, there are still numerous access issues. The factors impacting international and Northern based pharmaceutical companies' activity in producing essential medicines for African countries also affects companies in Africa e.g. price, quality assurance and IP rights. As such pharmaceutical companies in Africa may follow in the footsteps of their Northern hemisphere and Indian colleagues and increase production of drugs where they can make a profit and which respond to the changing epidemiological transition away from 'diseases of poverty' to more lucrative products targeting heart disease and obesity or as South Africa is doing and move into 'health tourism'. Particularly of note is the fact that IP agreements inhibit sales. As the ongoing disputes over IP and HIV/AIDS drugs show, there is a struggle over Africa's access to IP protected drugs definitions of what constitutes national emergencies and when compulsory licensing might be called for and so on.

3.1.5 Regulatory Capacity in Africa

Regulation is fundamental to the provision of good quality pharmaceuticals and healthcare. Failure to regulate and monitor presents obstacles both in contexts where new treatments and drugs are being developed and in ensuring consumers' rights. Building capacity in regulatory and monitoring mechanisms is fundamentally important as African countries attempt to supply appropriate treatments to its people. Most countries in Africa have a drug regulatory authority as Table 3 shows.

The World Health Organisation (WHO) is concerned that while all countries in Africa have national drug regulatory agencies, the majority of them have limited capacity (SAIIA 2005). For example, Dr Jean-Marie Prapsida of the WHO Regional Office for Africa noted that even the South African Medicines Control Council, touted as the reference point for other African agencies, still has limited capacity, especially for monitoring and evaluating clinical trials. Limited capacity has resulted in countries being unable to enforce proper drug regulations, putting at risk the health of millions from improper drug use, all this happening in the backdrop of mounting complexities from killer diseases such as malaria, tuberculosis and HIV/AIDS. Additionally, some multinational corporations conducting clinical trials in Africa have bemoaned the weak drug regulatory capacity in Africa, with Boehringer Ingelheim, for example, failing to register its single-dose nevirapine in the USA after some clinical trials in Uganda. Some irregularities with data recording and improper reporting were highlighted, and the company had to withdraw its registration application (SAIIA 2005).

The WHO notes that part of the solution to these challenges lies in strengthening medical control councils and regulatory bodies to enable them to offer adequate support and to monitor trials effectively. In 2003, the WHO started a programme to assess the weaknesses of drug regulatory agencies in Africa in order to come up with the best measures for assisting them. The WHO also offers on-going capacity building through universities, especially aimed at human resource-capacity building, but they have no direct authority, as according to Tim Farley of the WHO, they 'do not want to undermine the work that goes on at national level'. The WHO also provides the latest available information to countries to assist them in their decision-making processes. In their programme on Strengthening Drug Regulatory Authorities (DRAs)³, the WHO provides the following: assessment of National Regulatory Systems; Practical manuals; Training Courses, Model websites for DRAs; Model system for computeraided drug registration; Certification scheme for the quality of drugs moving on the international market and; the biennial WHO international conference for drug regulatory authorities. For example, Kenya (www.pharmacyboardkenya.org), Tanzania (www.tfda.or.tz), Uganda (www.health.go.ug/national drug) and Ethiopia (www.daca.gov.et) have benefited immensely from the activity on developing model websites for drug regulatory agencies. The available capacity in each country also determines to what extent they can tap into and benefit from these initiatives.

Table 3: African Drug Regulatory Authorities				
Country	DRA			
Angola	National Medicines Directorate			
Benin	Direction Des Pharmacies			
Botswana	Drug Advisory Board / Drug Regulatory Unit			
Burkina Faso	Directorate of Pharmacy and Medicine			
Cameroon	Pharmacy & Medicines Department, Pharmacy & Drug Directorate			
Central African Republic	Inspecteur des Services Pharmaceutiques			
Congo	Direction des Service Sanitaires			
Cote d'Ivoire	Directorate of Pharmacy and Medicine			
Djibouti	Ministry of Health			
Egypt	Drug Policy & Planning Centre			
Equatorial Guinea	Aprovisionamiento de Medicamentos			
Eritrea	Medicines Control & Regulatory Services			
Ethiopia	Drug Administration & Control Authority			
Gambia	Medicines Board			
Ghana	Food and Drugs Board; Pharmacy Council of Ghana			
Guinea	Direction Nationale de la Pharmacie et du la Laboratoire			

Country	DRA
Kenya	Pharmacy Board Kenya
Lesotho	Medicines Control Authority
Liberia	Pharmacy Board of Liberia
Libya	Drug Regulatory Authority
Madagascar	Agence du Medicament
Malawi	Pharmacy, Medicines & Poisons Board
Mali	Direction Pharmacie et Medicament
Mauritius	Pharmacy & Drug Regulation Dept, Ministry of Health
Morocco	National Laboratory for Drug Control
Mozambique	Pharmaceutical Dept, Ministry of Health
Namibia	Drug Control Unit, Ministry of Health
Niger	Direction Générale de la Pharmacie
Nigeria	National Agency for Food & Drug Administration and Control
Papua New Guinea	Medical Supplies Branch, Ministry of Health
Rwanda	Pharmacy Services, Ministry of Health
Senegal	Direction de la Pharmacie et des Laboratoires
Sierra Leone	Pharmacy Board of Sierra Leone
Somalia	Ministry of Health
South Africa	Medicines Control Council
Sudan	General Directorate of Pharmacy
Swaziland	Pharmacy Services, Ministry of Health
Tanzania	Pharmacy Board Tanzania Food & Drug Administration
Тодо	Direction Generale de la Sante Publique
Tunisia	Directorate of Pharmacy & Medicine
Uganda	National Drug Authority
Zimbabwe	Medicines Control Authority

Source: Table generated from data in proceedings of the WHO International Conference for Drug Regulatory Authorities (1996, 1999, 2002 and 2004)

Thus, the WHO provides extensive advice on how regulatory authorities should be constructed, making it clear that it is national Ministries of Health who are charged with formulating and implementing regulatory provision.

However, the requirements for drug regulation as set by the WHO are not being met by many African countries. The problem relates to inadequate human, financial and infrastructural resources. This scenario makes it difficult for the drug regulatory authorities to cope with

demand especially in light of increasing pressures of technological developments which mean that new products are being placed on the market at an increasing rate. The challenge to ensure quality, safety and efficacy is not one that most African regulatory authorities are meeting effectively. Recent studies have highlighted the importance of regulation in health innovation and have differentiated between regulatory approaches that constrain on the one hand and enable innovation on the other (Tait et al. 2005; Chataway et al. 2006).

3.2 From Separate Determinants to Building Integrated African 'Health Innovation Systems'

Systems of innovation frameworks revolve around the importance of collaborative networking between actors/actants at different levels of innovative activity and learning capabilities. Linked to this are the 'system making' connection components or the purposeful activity around the six determinants outlined above that create linkages between the actors within the health innovation system. We now examine a case example of Niprisan (NICOSAN[™]) to highlight the interplay of these six determinants with the different actors within a health innovation system. It also demonstrates that productive 'system-making' initiatives are possible even in difficult circumstances and that the challenge is to maximise the potential of these successes.

3.2.1 Niprisan for Sickle Cell Anemia

Sickle Cell Disease (SCD) is an inherited blood disorder caused by an abnormality in the hemoglobin molecule. The disease changes the shape of red blood cells carrying oxygen through the body resulting in pain and anemia. Those with the disease suffer a higher than average frequency of illness and premature death, especially in infancy.

Nigeria probably has the highest sickle cell disease population in the world (four to six million, roughly three to five percent of the population). More than 100,000 Nigerian children are born each year with the ailment. As a result, since the early 1990s, SCD topped the list of priority research projects of Nigeria's National Institute for Pharmaceutical Research and Development (NIPRD). In 1993 NIPRD established collaboration (contractual agreement) with a traditional health practitioner and commissioned a clinical study (1993-2001) using plant abstracts. From the findings of the study, 'Niprisan' was developed by NIPRD.

Niprisan is a drug cocktail, with phyto-pharmaceutical composition of four traditional plants extracted in a proprietary process. It has been patented in 46 countries and is jointly owned by NIPRD and the traditional health practitioner. The funds for patenting and conducting R&D of the drug were provided by the UNDP. In July 2002, Niprisan was licensed to XECHEM Inc., an Indian pharmaceutical company based in the USA, by the Nigerian Federal Ministry of Health. Xechem Nig. Ltd (a subsidiary of Xechem Inc.) commenced local production of Niprisan in 2003. Further pharmacelogical studies have resulted in standardization of Niprisan into capsule dosage form. In this new form, the drug has been approved, under

the name NICOSAN[™]/Hemoxin, by Nigerian drug regulators, the National Agency for Food and Drug Administration and Control and launched in Nigeria for sale on July 6th, 2006. Nicosan/Hemoxin has received orphan drug status from the US Food and Drug Administration (2003) and by its European equivalent (2005).

Despite recent setbacks⁴, the journey of Niprisan, from plant extract to medicine in capsule dosage form, and from a traditional health practitioner in Nigeria to global markets demonstrates success in developing a range of systems-building capabilities. This example of a micro level innovation system has addressed a number of the six determinants: ensuring R&D and manufacturing capabilities are in place; developing markets for the product and; dealing with IP issues. Nigerian institutions have effectively used the intellectual property system to leverage financial and social benefits from the country's natural resources. National R&D expertise customized to address a specific domestic problem has also lead to some global success. Technology transfer links have been made with national public research institutions in the process of the production of Niprisan in Nigeria by Xechem creating a potential income stream in the form of royalties and other revenue flowing from the agreement with Xechem as well as building local R&D infrastructure.

Systems-making connections have been made between NIPRD, traditional health practitioners, local community members (during trial activities), UNDP which provided a sizeable grant, hospitals and clinicians, patent agents who facilitated the patenting of the product in multiple markets, and a private firm.

While it offers potential as a case to learn from and build on, it has been argued (Oyelaran-Oyeyinka and Sampath 2007) that many public research institutions like NIPRD still suffer from poor funding and subsequent lack of facilities for biotechnology-based research as well as weak institutional mechanisms. For example, until recently, the Nigerian government showed little interest in funding R&D providing only 10% of NIPRD's research funds. Many public research institutions suffer from weak institutional and regulatory infrastructure to conduct meaningful partnerships with, for example, holders of traditional medicinal knowledge or to test for efficacy and safety of traditional preparations. Similarly, at times, there is still weak private sector interest in drug development and few spin-off companies created from public research institutions.

3.3 The Missing Determinant: Organizational Capacity?

The Niprisan case study highlights a need to look beyond the market. It illustrates the need to focus on building and maintaining organizational and learning capacity within and between the different actors. International partnerships afford opportunities for this but maximum impact requires that national and regional institutions are built and improved. Several large international networks (in which African countries participate) place emphasis on building capacity within health innovation systems, albeit in different ways. For example, networks such as IAVI, Medicines for Malaria Venture (MMV), Drugs for Neglected Diseases initiative

(DNDi) and the South African AIDS Vaccine Initiative (SAAVI) are involved in the production and clinical testing of new drugs and vaccines for diseases affecting African countries. The R&D capacity in many African countries is, at present, insufficient to perform such studies. Thus one pressing challenge for both government and private sectors is to construct funding and institutional mechanisms that effectively facilitate enhancing capacity. Activities that focus on creating local capacities would involve building physical capacity, training staff, developing lab-infrastructure, improving microbiological and immuno-diagnostics, promoting good clinical practice and ethics infrastructure, and will involve north-south as well as southsouth capacity building activities.

For example, SAAVI is a national level public private partnership (PPP) that was set up in 2000 to develop an effective and affordable HIV vaccine for Southern Africa and the surrounding region. The partnership is made up of the South African government, public sector research organisations, private sector companies and financiers. SAAVI has worked on more than just developing a vaccine. With an emphasis on collaboration and strengthening knowledge capacities, SAAVI has built scientific research capacities in skills, knowledge and products in the laboratories, academia and in clinical trials. It has also built stronger health systems mainly through its trial sites operations by creating advanced infrastructure, facilities and trained staff. A combination of capacity building and collaboration between different sectors has produced important knowledge flows between disparate and discrete sectors. These flows occur within and across S&T, policy, community and health actors.

Another interesting project from a systemic capacity building viewpoint is the Tanzanian Essential Health Interventions Project (TEHIP). The project essentially aims to link S&T and other forms of capacity building into broader health systems through the creation of computer based data collection and analysis of burden of disease statistics to aid policy making at the district level. TEHIP demonstrates the importance of integrating research and capacity building and of working in an interdisciplinary fashion that brings together varied skills (social, scientific, economic) together with management knowledge.

A recent initiative that promotes south-south linkages for capacity building is the African Poverty Related Infection Oriented Research Initiative (APRIORI). APRIORI aims at establishing a state-of-the art clinical research centre in Tanzania by involving African Centres of Excellence in Mali and Ethiopia with assistance from a number of Northern based institutions. Strengthening south-south collaboration, the programme aims to build capacities and establishments for malaria, tuberculosis and HIV/AIDS. Streamlining of activities on these three diseases to obtain internal cohesion, collaboration and cross-fertilisation, the programme aims to utilize existing knowledge and innovative research (new tools and strategies). The strong links between centres of excellence from Africa (through south-south initiatives) and Europe (through north-south initiatives) which merges into research and capacity building besides facilitating knowledge flows is very innovative.

The Global Health Research Initiative - HIV/AIDS Prevention Trials Capacity Building grant recently instituted also aims to build capacity in African institutions to conduct HIV/AIDS prevention trials by supporting the development of both new and existing partnerships between African and Canadian research teams. The focus of the grants is to build and enhance individual and institutional competencies required to conduct high quality research, and to build site capacity to conduct planned and anticipated trials in Africa, in particular related to research on, and development of, prophylactic vaccines, microbicides and other preventive interventions. The programme has the specific objective to promote and support partnerships between interdisciplinary teams of Canadian and African researchers. Grants under this initiative are intended to be complementary to other global investments (e.g. Gates Foundation, National Institutes of Health and European Union initiatives) and therefore will not fund prevention trials themselves, but rather capacity building related to conducting such trials.

As these cases illustrate, there is no just one model for building capacities but rather a diversity of approaches that can be pursued. These approaches point to the importance of local stakeholder involvement. International efforts are important but they cannot substitute for local efforts and, in this context, local capacity building is a serious concern. The key issues that need to be addressed to develop successful and meaningful capacity-building programs include: understanding the local context and facilitating local operations; strategising a mix of short-, medium-, and long-term interventions; and thinking and encouraging the development of systems of innovation. Local strengths must be built on, and efforts must be tightly related to, local problems and infrastructure. But building on existing capabilities in local contexts involves a range of time scales and time-bound planning (short-medium-long term) that progresses and builds the local innovation capacities (skills, capabilities, and institutional infrastructure) in a systematic way.

It is evident from the literature that Africa has made progress in S&T. Many countries have shown positive action by creating ministries for S&T, and these ministries have produced policies for implementation. However, in many cases such policies are not integrated with other sectoral policies, and therefore, involve separate strategies that have no link to national (health) development. Also many of these actions are still designed or greatly influenced by international financial institutions and donor countries and they are not always appropriate in the local context. Lack of functioning institutions is one of the main factors restraining Africa's technological development.

4. Learning from Others

A number of developing countries, notably Brazil, China, Cuba, India and South Africa, have advanced in health innovation, following different paths to create selective capacities and capabilities in the pharmaceutical and health sectors. They have created a number of 'system making' connections linking the institutions and individuals working within the

macro, sectoral and micro levels of innovative activity. By so doing they have addressed the seven determinants as needed to overcome specific obstacles to innovation. The initiatives taken by these countries show some homogeneity such as building of education and health systems, investing and creating large reservoirs of specialised scientific skills within health sectors, long term planning of R&D activities; and creating research networks within the country. They are not meant to be uncritically followed. Indeed, their relatively high resource levels for developing countries make that impossible. Our case studies and analysis of some of the system making connections and capacities below provides better understanding of the successes and failures of these countries and from which valuable insights can be learnt.

4.1 Brazil

Brazil has invested in health related biotechnology since the early 1970s and has emphasized the importance of health research since 1900 with the establishment of a federal institute, the Oswaldo Cruz Foundation (known as Fiocruz). In the 1970s the government's National Research Council launched two biotech programmes which were followed in the 1980s by the National Biotechnology Programme that integrated all those working on biotechnology in a programme dedicated to capacity building. The result is a strong public sector dominated biotechnology and health research base, predominantly based out of the main universities of San Paulo, Rio de Janeiro and the Federal University of Minas Gerais. The dominant independent public research institutes are Fiocruz and the Institute Butantan based in San Paulo (Ferrer et al. 2002).

Private sector investment in health research and particularly biotechnology has risen rapidly since the 1990s. During the 1990s the number of biotechnology firms in Brazil increased more than four-fold from 76 firms in 1993 to over 350 in 2001 (ibid.). However, although Brazil has a large pharmaceutical market as well as a growing private biotechnology sector, interaction between these and the public sector has only recently been encouraged with the passing of an Innovation Law (see Box 1). This reversed a previous law that made illegal public sector researcher employment by industry firms.

Box 1 - The Brazilian Innovation Law

Following consultation the Brazilian Innovation Law was introduced in October 2005. The law reverses a situation that made illegal public sector research staff employment by private sector firms thus incentivising partnerships between public and private research institutes. The law also aims to encourage participation of public sector research institutes within the innovation process more generally, as well as innovation between private companies particularly through intellectual property rights and licensing agreements. For example, the Innovation Law created the opportunity for product development, as with

Acheflan, an anti-inflamatory cream developed by a private sector Brazilian drug company, Ache, through collaboration with a university research base. Acheflan was Ache's first patent-protected bio-medical innovative product. Ache has gone on to develop other partnerships with Brazilian universities.

Sources: Ryan (2006); www.scidev.net; www.wipo.net

One strength of Brazil's strong public sector health research based around universities and other academic institutes is strong human resource capacity. Fiocruz creates not only a large number of highly trained personnel with skills to produce world-class innovation but also accumulates scientific knowledge and absorptive capacity that strengthens and builds the Brazilian innovation system. However, the lack until recently of opportunities for knowledge exchange between the public and private sectors limited the degree to which knowledge exchange took place. Although the introduction in 1994 of National Conferences on STI in Health created national dialogue on the issue, bringing together not only the Ministries of Health, Education and Science and Technology but also involving representatives from research institutes and the general public. These Conferences have been used to set the agenda for research around health related STI in Brazil and the base for which government funds and calls for research proposals are based.

The STI Conferences and the new Innovation Law exemplify the importance of links between different actors within the Brazilian health innovation system, providing a good example of the creation of links between the welfare system and the innovation system (da Motta et al. 2001). Brazil appears to have recognised that the health innovation system is not simply made up of those organizations, institutions, rule and norms influencing the purely scientific innovative process of R&D and product development. It emphasizes the importance of a systemic approach that works to build systems making connections at every, and between, all levels of the innovative process.

Brazil's commitment to health innovation and provision of health services to its population has enabled it to play a policy role internationally. Along with India, South Africa and others, Brazil has argued strongly on behalf of developing countries in the context of WTO discussions. Brazil is a leading member of south-south networks dedicated to producing and distributing better products and treatments for neglected diseases. These include the South to South HIV/AIDS Technological Cooperation Network and the (India, Brazil, South Africa) IBSA dialogue forum which considers issues of trade and intellectual property.

4.2 Cuba

Particularly since the 1985 publication of 'Good Health at Low Cost' by The Rockefeller Foundation, Cuba's health system has been championed for its cost-effective performance. Part of its success is due to the building up and integration of its health research sector into the healthcare system, particularly in the area of biotechnology. In the last two and a half decades, Cuba developed significant national capacity in biotechnological knowledge and infrastructure. In focusing on developing national research capacity with Cuban scientists and professionals, the first priority of biotech research is the domestic market, meaning that the Cuban people themselves directly benefit from the country's medico-scientific expertise. This concern with the well being of the local population goes hand in hand with developing new medical products for export. For example, in the early 1980s, Cuban R&D programmes led to the first and only vaccine for a particular strain of meningitis which was used to stem a local outbreak in the mid 1980s. Further research into meningitis vaccines resulted in Cuba becoming in the 1990s the first country to develop and market a vaccine for meningitis B. It is currently delivered to 30 countries, including China, India, Russia, Pakistan and many Latin American countries (Thorsteinsdottir et al. 2004). More recently, Cuba produced the world's first human vaccine with a synthetic antigen that protects against *Haemophilus influenzae* type B infection, which often leads to pneumonia and meningitis in children under the age of five.

New biotechnologies were expected to facilitate product diversification and import substitution at a time when the collapse of the Soviet Union and the U.S. trade embargo forced it to develop home-grown solutions to local health problems. The development of a national capacity of biotechnology was also seen as a strategy to increase sovereignty and independence from transnational companies of the industrialized countries. This is not to say that Cuba has not collaborated with international companies. One of Cuba's premier research centres, the Carlos Finlay Institute collaborates with GlaxoSmithKline (GSK) to develop and distribute the meningitis B vaccine. Future examples of such efforts could encompass the development and dissemination of vaccines for AIDS, cholera, dengue and other diseases. Researchers at Cuba's Center for Genetic Engineering and Biotechnology (CIGB) and the Finlay Institute are making substantial progress in these and other areas. New partnerships with Latin American and other countries including China and industrialized countries mean that Cuba is at the forefront of developing drugs for international users and markets.

The Finlay Institute (see Box 2) is an example of how Cuba's development model is based on harnessing the nation's wealth in human resources and science to create a knowledgebased economy focused around health. Since the 1959 revolution, the cornerstone of the country's social development has been education and health care. Beginning in the early 1960s, biotechnology and medical research became a top priority of the Cuban government, with over one billion dollars invested in biotech R&D in the 1990s alone. Today, Cuba boasts a ratio of 1.8 scientists per 1000 inhabitants, a level comparable to the European Union (though with a far smaller Gross Domestic Product) (Hurlich 2003). There are 38 biotech centres, grouped together in a science park to the west of Havana, which integrate research, development, production and marketing. Cuban students and specialists are educated and trained in the most technologically advanced countries like USA, France, Japan, Switzerland, Canada, Mexico, England, Germany, and Finland contributing to the impressive knowledge base that exists today in Cuba.

Box 2: The Finlay Institute

The Finlay Institute has become an essential component to Cuba's vaccine research and production efforts. Its most successful and best-known product is the vaccine against meningitis B and its current meningitis B and C combination vaccine. As part of the Cuban National Immunization Program, 10 of 27 vaccines currently in the research phase in Cuba are being developed at the Finlay Institute. Previous successes in coordination with institutes such as CIGB have included development of vaccines against tetanus toxoid, leptospira, and hepatitis B. In 2002, the Finlay Institute developed a new vaccine against typhoid fever, similar to one produced by Belgian and French pharmaceutical companies. The Finlay Institute is currently working with GSK on clinical trials of its meningitis B vaccine in both Europe and Latin America, with hopes of extending trials to the United States. Along with the financial benefits received by the Finlay Institute, there is also the political and symbolic importance of a developing country vaccine being used in the north. The VA-Mengoc-BC vaccine is a good example of the need to step beyond narrow international constraints to work for a higher purpose and the benefit of humanity. Finlay Institute researchers are currently involved in applied microbiology, molecular biology, fermentation processes, vaccine development, and immunology.

4.3 China

Extensive government reforms in the late 1970s and early 1980s - including policies that began to shift the nation from a centralized, planned economy towards a market-based one - identified the science system as central for the country's modernisation and economic development (Zhenzhen et al. 2004). China has created giant industrial districts in distinctive entrepreneurial enclaves. Niche cities (Beijing, Shanghai, GuanZhong) reflect China's ability to form 'lump' economies, where clusters or networks of businesses feed off each other, building technologies and enjoying the benefits of concentrated support centres. The Chinese government has played a central role in promoting capacity building and innovation in the health and biotechnology sector. In 2002 China established its pharmaceutical S&T policy covering the period 2002 to 2010.

Like Cuba, an emphasis has been placed on building up the capacity of China's health biotechnology innovation system. The origins of modern biotechnology research in the country can be traced to the late 1950s policy of the 'great leap forward'. Health biotechnology industrialization was not widespread until after the mid 1980s, but expanded rapidly when some public research institutes were transformed into enterprises for manufacturing medicines. Under the ninth Five Year-Plan in 1997 the health biotechnology research system received increased financing and support to build up institutions and research capacities as an effort

to establish a National System of Innovation (MIHR 2005). At present there are about 500 Chinese public and private sector biotechnology firms. Emphasis is placed on building up human resource development not only through higher education facilities but also through the public research institutes. A central role is given to the Chinese Academy of Science which conducts research, education and training activities. China's strong public education and research programmes are driving innovation in both state owned enterprises and the burgeoning number of private enterprises.

Parallel to this has been the growth of the Chinese pharmaceutical market. This is one of the world's largest markets, second only to Japan in Asia and is expected to become the world's fifth largest by 2010. The growth of the pharmaceutical output has been phenomenal in China in the last decade with an annual average growth rate of about 20% over the past 15 years. The domestic pharmaceutical industry has been a key contributor to the country's staggering economic growth. There are approximately 6,800 Chinese pharmaceutical firms, of which, 5,000 produce medicines and the remainder are involved in packaging and equipment supply. However, due to an emphasis placed on public sector investment in biomedical science and research, the Chinese private pharmaceutical sector has remained highly fragmented and has suffered from substantial shortages of investment capital to undertake high risk product R&D. Public Sector focus has been strongly on research rather than development. Recently, the Ministry of Commerce announced plans to build 100 export-oriented "innovation bases" for the pharmaceutical sector by 2010. By offering financial and technical support and facilitating the entry of Chinese firms into international markets, the strategy aims to bolster Chinese exports of high-tech products while fostering domestic innovation in the pharmaceuticals.

Special attention has been given to traditional knowledge and mechanisms to use this resource as a base for the biotechnology and pharmaceutical sectors. The protection and domestic commercial exploitation of traditional knowledge is an important issue in China. Traditional medicines are used by large portions of the population and have a significant role in public health. One such medicine is Artemisinin - the frontline treatment for malaria (see Box 3). Used for centuries as a traditional medicine to treat malaria a Chinese pharmaceutical firm is collaborating with Novartis to produce modern malaria drugs. However, weak patent policies and regulations as regards to these have led to a loss of materials to foreign research. Increasingly China is acknowledging the importance of robust and inclusive IP policies in this area to ensure protection of its indigenous knowledge and often return of rewards to its communities sometimes in the form of trust funds that have nurtured this area.

Box 3 - Artemisinin

The herb *Artemisia annua* has been used for many centuries in Chinese traditional medicine as a treatment for fever and malaria. In 1971, Chinese chemists isolated from the leafy portions of the plant the substance responsible for its reputed medicinal action. This compound, called qinghaosu (QHS, artemisinin), has been used successfully in several thousand malaria patients in China, including those with both chloroquine-sensitive and chloroquine-resistant strains of *Plasmodium falciparum* malaria. Derivatives of QHS, such as dihydroqinghaosu, artemether, and the water-soluble sodium artesunate, appear to be more potent than QHS itself. Sodium artesunate acts rapidly in restoring to consciousness comatose patients with cerebral malaria. Thus QHS and its derivatives offer a totally new class of antimalarials.

In 1991, Novartis (then Ciba-Geigy) began collaborating with Kunming Pharmaceuticals on Coartem (derivative) production and obtained marketing approval in 1998. Novartis partnered with WHO in 2001 to make Coartem available in malaria-endemic countries on a not-for-profit basis. According to WHO, since the Global Fund for HIV/AIDS Tuberculosis and Malaria (GFATM) began disbursing funds in 2003, the demand for combination therapies based on artemisinin has increased rapidly and led to a drug shortage in late 2004. Since 2001, Novartis has supplied more than 10 million treatments. "The original 2001 agreement forecast demand for Coartem at just over 2 million treatments in 2005... Since then, nonbinding demand forecasts provided by WHO have continuously increased, including a sixfold jump between December 2003 and March 2004, when the 2005 forecast surged from 10 million to 60 million treatments." (Hans Rietveld, global marketing manager for tropical medicine with Novartis)

4.4 India

The Indian pharmaceutical industry produces a wide range of complex pharmaceutical formulations and over 400 active pharmaceutical ingredients. The industry ranked fourth globally in terms of volume and thirteenth in terms of value at an estimated US\$6.0 billion in 2004 (IMS Health 2004). But until the 1970s, India had virtually no domestic pharmaceutical industry producing drugs from basic raw materials, relying heavily on imports. The 'access to medicines for all' perspective that ruled Indian thinking in the 1950s and 1960s (Amsden and Cho 2003) and the need to build self-sufficiency in local antibiotic production provided the starting point for change.

Liberalization in the 1990s further facilitated a shift from an import-substitution economy to an export-oriented one, enabling the emergence of a competitive domestic industry and set the foundation for world-class generic drug production capabilities in India. Private firms

gradually advanced to creative imitation stage (chiral synthesis) during the early 1990s and started to enter and establish themselves in regulated markets (mainly USA and Europe). Signing of the TRIPs agreement and transition to product patent regimes since 1995 has facilitated research in the Indian pharmaceutical firms to enhance their R&D focus and spend on new drug delivery systems and new chemical entities.

In 2006 there were 5.877 pharmaceutical private companies operating in India. The organized sector consisting of 250-300 companies accounts for 70 percent of products in the market with the top ten companies (out of which 9 are Indian) representing 30 percent. Approximately 75 percent of India's demand for medicines is met by local manufacturing (KPMG 2006). Over the years, the co-evolution of policy and innovation in the public and private sector have contributed to India's rapid development of pharmaceutical and biotechnology (Chaturvedi and Chataway 2006) with the development of industry-institute linkages and private investments for biotechnology ventures. Indian institutes and public research labs not only provide the scientists and technicians for the sector's workforce, but also contribute research discoveries of relevance to pharmaceutical and biotechnology firms. Traditionally, the role of universities was in education and training, whereas laboratories, both public and private, focused on research. Today, the lines are blurring, as universities incorporate research activities and national laboratories provide training for students to join industry later on. A good example of such blurring is seen in the Indian Institute of Science (IISc), Bangalore. Its department of biochemistry is working on immunology, reproductive biology and plant development as part of the study of diseases such as malaria, rabies and tuberculosis, as well as carrying out applied research on drug targets and vaccines. The 1990s saw a flourishing of numerous institutes and laboratories dedicated to biotechnology. Some of the most active in health biotechnology include the National Institute of Immunology and the Institute of Microbial Technology and the IISc. All these Institutes have multiple joint projects and collaborations with domestic as well as international drug giants. Market pull and government push for innovation in health research has enhanced PPPs tremendously in the recent past and the cumulative impact of these factors on knowledge creation and knowledge diffusion is unquestionable.

Box 4: Shantha Biotech

Shantha Biotechnics, an Indian biotechnology start-up, began research for an affordable indigenous vaccine in 1993. A western company had earlier denied the technology assuming that India did not have the resources to pay the high technology fee for buying the vaccine nor the ability to absorb the technology. Initiated as an R&D exercise at Osmania University, under the industry-university interaction programme the research was subsequently conducted at the Centre for Cellular and Molecular Biology. Since biotechnology was a relatively unknown segment and there were no venture capitalists around at that time, funding proved difficult. The project finally received funding from the Sultanate of Oman of 50 per cent equity. It also received a longterm loan from Oman International Bank. Later, a loan was organized for technology development and commercialisation. Shantha Biotechnics launched India's first recombinant hepatitis-B vaccine, Shanvac-B, in 1997 followed by Shankinase (recombinant Streptokinase). Apart from supplying the product all over India, Shantha Biotechnics supplies it to various other countries directly and also through UNICEF agencies after Shanvac-B received the WHO-Geneva pre-qualification. The indigenous development of recombinant hepatitis-B vaccine enabled India to join the select club of five countries in the world to have the know-how to produce hepatitis-B vaccine. Shanvac-B was a huge national success since it developed a vaccine for local health needs, bringing down the prices of imported vaccine from Rs780 to Rs50 in 1997 and to Rs25 in 2003.

Scientific achievements in the field of biotechnology have been very encouraging and of direct relevance for the specific challenges of India's needs. For instance, the Hepatitis B vaccine was first developed by a small biotech firm, Shantha Biotechnics, in 1993, (see Box 4) with government aid and since more than 300 biopharmaceutical products have been put on the world market (STI 2006). According to a recent survey there are 96 exclusive biotechnology enterprises operating in India, making the Indian sector the third largest in Asia. The sector is a diverse mix of private domestic small and medium sized enterprises, such as Shantha Biotech and Bharat Biotech; larger firms like Biocon and Dr. Reddy's, Ranbaxy and Wockhardt; and some public enterprises including Haffkine Bio-pharmaceutical and Indian Immunologicals (Kumar et al. 2004). The result of public and private efforts has been the creation of a large pool of highly qualified personnel and world class biotech and pharmaceutical infrastructure.

4.5 South Africa

South Africa has explicitly incorporated systems thinking into its innovation strategy. The strategy was implemented following the adoption of a White Paper on Science and Technology in 1996 and the setting up of the Department of Science and Technology (DST) (see Box 5). The White Paper placed science and technology innovation within the broader macroeconomic context within which South Africa was operating, emphasizing competitiveness; job creation and human resources; quality of life; environmental sustainability; the information society and knowledge embedded products and services. Thus an integrative approach was taken. As mentioned in the section on Brazil, South Africa has been a leading member of policy oriented efforts to create global policy mechanisms to support national innovation efforts in developing countries.

The DST has encouraged working with stakeholders to develop health research priorities through a National Research and Technology Foresight Project and National Science and Technology Forum as well as collaborative research programmes such as the South African

Malaria Initiative and SAAVI (discussed in Section 2) together with numerous efforts to encourage dialogue with and between academic, industry and policymakers.

Significant and creative efforts have been made to link science funding into innovation and to support more systemic approaches and initiatives. Recently the DST has supported the creation of a Biotechnology and Health Working Group which is a non-governmental 'trouble-shooting' group dedicated to taking "a leadership role to advance efforts designed to make South Africa a more significant participant in the global biotechnology and biomedicines industry, to address the country's public health requirements and to stimulate innovation in biotechnology"⁵.

Two DST activities of particular note have been the efforts to promote competitiveness through the introduction of an Innovation Fund and the emphasis placed on incubators and regional innovation centres within the 2001 National Biotechnology Strategy. The Innovation Fund was designed to encourage innovation at the later stages of the product development pipeline. As such to act as a venture capitalist investing in projects which due to the high risk of later stage development costs may not otherwise have been taken forward. There have been questions raised at the idea of using public funds for venture capitalist type activities. A mechanism to encourage innovation in biotechnology has been the development of regional innovation centres and biotech incubator hubs. These centres have not yet received the tenants that they require to be sustainable. Problems in encouraging start-ups are thought to be partly related to a shortage of venture capital funds.

Although South Africa is clearly committed to investing in science and technology, expenditure on R&D is still less than 1%. Private sector investment in health related biotechnology is low. South Africa's regulatory system has also been widely criticized for slow response times and inefficiency. Siyabulela Ntutela outlines a number of challenges:

"... the cost of patenting, the sale of intellectual property rights outside of South Africa, the quality of licensing agreements and the professional management of intellectual property protection in universities" (Ntutela 2006).

Box 5: South Africa's Department of Science and Technology (DST)

Scientific discoveries and the associated development of new technologies are key long-term drivers of economic growth and development. Innovation, technology mastery and the diffusion of knowledge and new products and services into markets are key elements in this growth and result in sustainable improvements in the quality of life of all South Africans. The White Paper on Science and Technology (1996) created the policy framework for the then Department of Arts, Culture, Science and Technology (DACST) to establish key enabling policies and strategies to inform the strategic development of S&T in South Africa.

In 2002 Cabinet approved the National Research and Development Strategy. The National R&D Strategy requires performance and responses in three key areas: 1) enhanced innovation; 2) providing science, engineering and technology human resources and transformation; and, 3) creating an effective government S&T system.

It is in this context that the DST has been established as a separate department to ensure that there is greater coordination, integration as well as better understanding and management of all government funded science and technology institutions and to provide a holistic overview of public expenditure on science and technology.

4.6 Building African Health Innovation Capacities

Clearly these countries are at different stages of development, have public and private sectors of varying degrees of maturity and hence are diverse in their approaches. They are also some of the most advanced developing countries, and we should be wary of simplistic calls for 'imitation' and knowledge transfer. But, African countries can surely learn a great deal from the ways in which China, Brazil and India have built industrial and R&D capacity. Cuba provides fascinating insight into policy approaches aimed at developing S&T and health innovation for domestic health improvement. South Africa is experimenting with systems innovation based policy and more integrated policy development. However, it is important to highlight that most of these countries have been only partially successful in meeting their overall development goals in health and health innovation.

Each country has undertaken activities that have built system-making connections along the determinants identified in Section 2 in attempts to strengthen its health innovation system. What emerges from an analysis of the strengthening of their health innovation systems is that the six determinants of the framework are linked in a dynamic manner. Progress in one requires progress in most, if not all other determinants. It is difficult to progress in R&D capability without first increasing manufacturing capability or without having a domestic or export market to generate resources for investment in production facilities (Mahoney 2005). One of the ways in which developing countries can access new technologies for strengthening health innovation is to enter into joint ventures with technology savvy firms in developed countries as India and China are aggressively pursuing. South-south collaborations could be an important vehicle to facilitate knowledge flows within developing firms will gauge their level of willingness to form joint ventures based on the value of the domestic market in the developing country, the capability of local R&D centres, and the expected level to which IP will be protected.

While the pharmaceutical and health biotech industries in India and China have shown

spectacular growth health provision for the majority in those countries has not improved so dramatically. Thus, in some cases industrial and innovation policies designed to increase productive capacity have not been aligned with social development despite promising policy visions such as "Health For All" and "Access and Affordability of Medicines". There are serious gaps in putting knowledge and policy into practice. The case study of Cuba is perhaps the best example of an attempt where policy coherence has, on one hand, supported research infrastructure and strong health and education system and on the other hand, has promoted strong linkages between the research system and its health delivery system. The major hospitals are partners in the health biotechnology cluster and the cluster has therefore both users and producers of health biotechnology. Thus the delivery system is by default an integral part of the health innovation system, and distribution and health care services are well integrated into health innovation.

The challenge of improved technology and innovation, as we discussed in Section 1, lies in the capacity of policymakers to tackle issues systemically, building health innovation systems that facilitate, promote and respond to the local health care primarily and possibly global market needs through research and development, manufacturing, distribution and services. Reconfiguration of macro frameworks and integration of multiple technology micro initiatives like genomics, stem cell research or new products like microbicides and vaccines or even new knowledge fields like bioinformatics in health innovation is crucial.

The country cases outlined here have provided strong indicators for the policy, process and practice with examples of how system-making connections can build the determinants of an innovation system. It is useful to build local R&D and manufacturing capabilities – not just in terms of infrastructure provision through the national innovation system but also institutional level organizational capacity to innovate. This needs to take place within the context of the wider international arena in which both the national and international (healthcare) markets and economy play out. Regulation and intellectual property need to be strongly developed and made relevant to local knowledge and situations.

However the case studies also demonstrate the disconnect between thinking about innovation and industrial policy on the one hand and social development policy on the other. In India, China and Brazil policies in these two areas are often disarticulated. Huge increases in scientific and manufacturing capacity have not been pursued with reference to changes in social development policies so that R&D could serve the immediate needs of populations. In Africa, of course, this disconnect is also present but has different dynamics with access issues being dealt with completely separately from industrial or innovation policy. It is obvious and relevant also, to note the fact that African countries suffer from huge difficulties of weak resources of all kinds and extremely fragile relevant institutions, which will require massive focus on core problems, with internal clarity and external support. We return to these issues in Section 6. Before that we will consider some initiatives currently trying to match R&D to African needs.

5. Health Innovation Networks

Innovation does not occur within strict geographical boundaries. It is influenced by international markets and regulatory frameworks, as well as cross-national trading and capacity related opportunities and constraints. Successful innovation requires collaborative activity not only at a national level but between countries and increasingly at a regional African level and at a sub-regional (e.g. West African) level as well. The form that such collaborative activity takes is also important. As such regional and sub-regional, together with international initiatives, are taking shape and gaining in strength forming 'health innovation networks' providing the catalyst for successful research, development and access to drugs, vaccines, diagnostics and health services in Africa.

5.1 The Globalisation of Knowledge

In acknowledging the fluidity of interactions related to innovative activity it can be argued (Carlsson, 2006) that there has been an 'internationalisation of systems'. Innovation often takes place within a 'national system of innovation' being influenced by a network of national structures. However regulations and frameworks, and knowledge spillovers are increasingly 'international'. Knowledge is now retransferred across organizations and absorbed from and exported to international corporations and other foreign entities (ibid.). This is not only due to the advances in communications but also changes in the way healthcare and innovation are taking place. Health issues are seen as increasingly complex, ignoring territorial boundaries and requiring solutions that take account of spatial, temporal and cognitive changes (Lee et al. 2002) while firms are often multi-national or trans-national. At a smaller scale, advances in communication and the rise of internet technologies, have enabled less sizable companies and business individuals to access information and markets throughout the world. The relationship between local and global is changing leading not only to 'globalisation' (bringing the global to the local) but also the local influencing the global. The result is multiple, varying forms of knowledge and information flow.

5.2 Learning from Current Health Innovation Networks

Health innovation networks take no specific form but are the result of interactions with external groups by individual entities or industry clusters operating at various levels within national systems of innovation. As such they operate within and across national, sectoral and micro levels of systems of innovation. International partnerships, bilateral south-south initiatives or regional clusters can all constitute networks. Health innovation networks can also have different objectives focusing either on strengthening one determinant of an innovation system specific to their own activity (e.g. capacity for R&D) or multiple determinants of a health innovation system as illustrated by the work of a number of international health partnerships such as MMV. By looking at how a number of health innovation networks operate – how they transfer knowledge, build their organizational structures and network

between members – it is possible to highlight how building initiatives across national, subregional and regional institutions can facilitate and support innovation through establishing solid relationships that are vital for sustainability.

5.2.1 Mode 2 forms of networking

At the heart of these networks is collaborative activity. Innovation requires a strong knowledge base, for example, good research institutes and universities but this on its own is insufficient as there is no pre-determined linear movement of this knowledge upstream to the creation of products. As we have pointed out at the beginning of the chapter, innovation is the result of the dynamic interplay of users and producers of knowledge at different stages of the innovation cycle. As such traditional 'mode 1' or linear based structures of innovation are evolving into more complex loose, 'mode 2', structures containing numerous stakeholders each with their own skills base in which innovation takes place within the wider social, economic and political context (Nowotny et al 2001). An emphasis in 'mode 2' is placed on practice based learning oriented towards specific and practical outcomes. An example of a 'mode 2' health innovation network is the KEMRI-Wellcome Trust Research Programme in Kenya (www.kemri-wellcome.org) which is seen as being:

"... fully integrated into the Kenyan research infrastructure, through its close relationship with KEMRI, in Kilifi, the Programme is embedded within Kilifi District Hospital, building its research programmes around local medical infrastructure and contributing to healthcare delivery. Researchers are also committed to engaging with the local community, to discuss their research and why it is being carried out".

As outlined in Box 6 further this Programme has numerous stakeholders involved and actively participating at various stages of the research process placing its innovation activities within the wider context of the local community healthcare needs as well as wider national and international health issues. Here the Programme is just one node within a much larger network of institutions working towards the creation of an atlas of malaria and its impacts in Africa.

The non-institutionally based collaboration with numerous other stakeholders throughout Africa on the MARA/AMRA Project, and beyond, has not only created useful 'risk' maps of malarial illness to inform malaria control policy in the region but also built the capacity of researchers within KEMRI-Wellcome and others in the region in geographical information systems (GIS) technology and statistical mapping methods. Such activities see knowledge transferred across geographical boundaries strengthening the loose organisational structure of the MARA/AMRA Project around the production and application of its innovation activities. Here capacity building is not confined – nor is it within KEMRI-Wellcome's other work – to being a linear process of those with the knowledge training those without the knowledge.

The focus is on the creation of stronger links between researchers and users to ensure that the maps created are used effectively and adequately within malaria control policy.

The KEMRI-Wellcome Trust is a nationally based initiative rooted in functioning and linked institutions. This solid base however enables it to operate regionally. Thus, even where institutions and organisations are initially set up on a national basis they can offer regional benefits and offer an alternative to new institutions which have weak or non-existent links to a wide range of other R&D and user organisations.

Box 6: KEMRI and MARA

KEMRI-Wellcome Trust Research Programme

The link between the UK's Wellcome Trust and Kenya's medical research community dates back to 1949 when the Wellcome Trust established a research laboratory in Nairobi's Kenyatta Hospital. KEMRI was established in 1979 as the country's main medical research institute. From the late 1980s formal joint work began between the two groups focusing on malaria research. The joint KEMRI-Wellcome Trust Research Programme has three main principles underlying its activities: internationally competitive research, strong clinical research focus and local applicability. Linked to this is a strong emphasis placed on capacity building. The Programme is built around partnerships with numerous actors including other international research institutes e.g. at Universities of Oxford and Liverpool, the hospitals of Kilifi District and Kenyatta National, the Kenyan Ministry of Health and the local communities in which its research centres are based.

The MARA/AMRA Project

The KEMRI-Wellcome Trust Research Programme is a member of a pan-African research project to map malaria risk and endemicity. The MARA/AMRA Project started in 1996. The KEMRI-Wellcome Trust Research Programme became a formal node within the Project in 1997 looking at malarial disease burden with a specific data centre. In the 10 years the project has been running, numerous other data centres have been set up within Africa providing a rich source of malaria data contributing to the development of 'risk' maps used in malaria control policy activities and the geographical modelling of malaria. It has allowed the first accurate assessment of the burden of malaria to occur for Africa. The project has set up a number of national centres, undertaken capacity building of researchers in GIS technology, climate change methods, databases and conducted end-user training workshops.

5.2.2 Networked health innovation partnerships

MMV is a health product development partnership that actively networks to strengthen

health innovation activities (see Box 7). The partnership actively attempts to develop R&D capacity (resolving difficult IP issues and building manufacturing capacity) to create useful malaria medicines particularly for developing countries. MMV places an emphasis on building up the regulatory environment for clinical trials of potential drug and vaccine candidates and works on access issues to ensure the market will be there once drugs and vaccines are developed. Like the IAVI partnership (Chataway and Smith 2006), MMV as an entity works as a broker of innovation across existing systems. It works beyond national boundaries bringing together disparate groups who share a common interest in advancing malaria medicine innovation but who before now had few avenues for interaction. Its focused activities could well result in more general R&D capacity building which will enable those involved to contribute to developments in other disease areas. Thus while capacity building is not the explicit objective of MMV, its activities do seem to result to some extent in capacity development for local partners.

Box 7: Medicines for Malaria Venture (MMV)

Set up in 1999 as a not-for-profit Foundation MMV works to "discovery, develop and deliver new antimalarial drugs" by bringing together the public, private and philanthropic sectors in partnerships to conduct research, produce and register drugs for the treatment of malaria in disease-endemic countries. It has activities that span the drug product development pipeline from basic research to delivery through public-private partnerships with groups from around the world. MMV has an in-house team, supplemented by contract research organizations, that manages its drug portfolio of over 20 projects. MMV has held 5 rounds of calls for proposals to identify new projects to add to its portfolio. It has projects that focus on different species of malaria and requirements for different patient groups and therapeutic pathways. Since 2003 MMV has closely collaborated with GSK, a major pharmaceutical company.

In contrast, the European and Developing Countries Clinical Trials Partnership Programme (EDCTP) was set up to consider the specific issue of building R&D capacity within developing countries through linkages with European researchers working on HIV/AIDS, tuberculosis and malarial drugs, vaccines and diagnostics. Although it has an explicit capacity building remit the EDCTP has experienced problems, unlike international partnerships such as MMV resulting in difficulties dispersing funds (see Box 8).

Box 8: The European and Developing Countries Clinical Trials Partnership (EDCTP)

Set up in 2003 this is a partnership between 14 European Union countries, Switzerland, Norway and African countries with the aim to develop new drugs and vaccines to fight HIV/AIDS, tuberculosis and malaria through joint research programmes that would share information and resources. An example of north-south and south-south collaboration and networking to build scientific capacity to conduct clinical trials in developing countries, the EDCTP was developed with developing country scientists involved at every step (Binka, 2004). However, despite this, and perhaps because of the size of the initiative – the EDCTP has been criticised for not processing trial grants quickly enough; some researchers who submitted trial proposals two years ago still have not received a reply (www.scidev.net, Sept 2006). A recent report (IAVI, 2006) highlights that of the €200million committed to the EDCTP published data suggests less than 5% of this money (only €8.3million) has been disbursed.

5.2.3 Southern-led African based health innovation networks

A number of health innovation networks extend beyond geographical boundaries linking groups at a sub-regional, regional level and at times even international level through the function of 'globalisation' so networks originating from within a like-minded group of individuals, within or between countries, can create links to form a sub-regional, regional or international group that takes its national or regional origins as a base. An example of such a group would be AMANET, the African Malaria Network Trust and the AAVP, the African AIDS Vaccine Programme (see Box 9). These groups work in different ways and have different goals but they were both conceived as 'African' initiatives with the goal of building African capacity and opportunity for health innovation.

A similar focus pervades South-South initiatives such as Brazil's work with Mozambigue and Angola to build stronger clinical research capacity. Brazil is to help strengthen Portuguese speaking African countries' public health research activities through educational linkages. Fiocruz is to coordinate a project which sees Brazilian researchers support a Masters course in public health research to be run at the Angola National School of Public Health. If successful the project will be rolled out to Mozambigue and other countries. The project. supported by the Angolan government and Capes, Brazil's federal research funding agency, allows Brazilian researchers to teach on the two year Master's course in Angola and for Angolan students to spend three months of their second year in Brazil doing research and writing their dissertations at Fiocruz. The course will begin in October 2006. Distance learning branches will be set up in Cape Green, Guinea Bissau and Sao Tome and Principe. The project will also provide the Masters students with free access to 10,000 online journals. Future plans for the project include renovating Angola's technical schools and libraries. The project builds on a programme at Fiocruz which during the 1980s and 1990s saw Fiocruz receive 30 students from Portuguese-Speaking African Countries and East Timor, supported by the Japanese International Cooperation Agency (JICA).

Box 9: AMANET & AAVP

The African Malaria Network Trust (AMANET)

AMANET started life in 1995 as the African Malaria Vaccine Testing Network and is a network of African organisations with external assistance aiming to develop African capacity to conduct malaria vaccine clinical trial work. The change to AMANET occurred in 2002 with recognition of a need for capacity to be built in other areas of malaria research activities with a more integrated approach to malaria research activities. AMANET's mission is to "Promote Capacity Strengthening and Networking of Malaria Research and Development in Africa". AMANET builds both human capacity through conducting training workshops and infrastructural capacity through provision of equipment and facilities. AMANET also funds clinical and field trials themselves. AMANET has a permanent secretariat based in Tanzania coordinating activities through scientific and trial site committees. The governance of AMANET occurs through a General Assembly and Board of Trustees format made up of representatives working in malaria research focusing on Africa.

African AIDS Vaccine Programme (AAVP)

A WHO-UNAIDS supported programme, the AAVP was initiated by a group of African scientists in 2000 who "adopted *"The Nairobi Declaration: An African Appeal for an AIDS Vaccine"*, pledging to use their personal and collective commitment and expertise in the development and implementation of *an African Strategy for AIDS Vaccines.*" (www.who.int). The secretariat is housed within the WHO-UNAIDS HIV Vaccine Initiative in Geneva providing technical, financial and secretarial support to the AAVP. Working around thematic working groups, overseen by a steering committee made up of 8 African scientists, the AAVP aims to accelerate HIV vaccine work to ensure development of effective HIV vaccines for Africa.

5.3 Making the Most of Health Innovation Networks

The value of health innovation networks can be found in their network activities, the emphasis placed on collaboration between groups with common purpose. The development of 'mode 2', which links academics, applied and product development researchers and user groups in health innovation efforts ensures more is achieved together than by going it alone. The need to integrate has become common within a number of industries particularly for health innovation in pharmaceuticals (Henderson et al. 1999) and with 'partnerships' seen as solutions to development problems (Crewe and Harrison 1998). We have moved into a 'shared power world' (Bryson and Crosby 2002) where actors are better served when better connected (Burt 2002) in an increasingly networked society (Castells 1996). The value of networks in health innovation can be found, as highlighted above, at all levels. Health innovation networks such as MMV prove useful at brokering knowledge between entities

across national boundaries at the international level. At the same time, the power and value of local networks on international activities is evidenced by the work of the AAVP. The examples highlight how important such networked relations are at providing a brokering mechanism for groups with common interests.

Many of the networks not only emphasise capacity building and strengthening of a wider health innovation system in which they are a part but create opportunities for this to occur as a result of the networked arrangements in which activities take place. The KEMRI-Wellcome Trust Research Programme and AMANET both build local capacity to conduct research and embed their activities within the communities and health sectors in which they work. The work of MMV places an immediate emphasis on networking to ensure successful development of anti-malarials. In order for this to occur training and other capacity building activities take place. Again, the benefits of linking research to innovation efforts are clear.

Health innovation networks are evolving across the continent on an international, subregional and regional basis. Using case studies we can look at the ways in which national structures and sub-regional and regional institutions can support and facilitate each other. Establishing solid relationships between national institutions and sub-regional and regional initiatives is vital to sustainability.

6. The International Community

The international community has a vital role in building health innovation systems in Africa. In an increasingly globalised world no one part of the world can operate in isolation. In building financial, human and institutional resource multiple international connections need constructing and sustaining. International policy needs to take into account the importance of building health innovation systems in Africa and international funds need to be targeted to the challenges of meeting related immediate and longer term goals.

In funding research and innovation the international community, particularly donors are often committed to supporting 'excellence'. However, what constitutes excellence is a thorny and contentious issue. To what extent should funding be directed to exciting basic science that will score highly on traditional indicators of excellence, i.e. highly cited peer reviewed publications and perhaps patents, and to what extent should efforts be directed at more applied work addressing pressing social, health and economic targets? What are the measures that can be used to measure excellence for this type of work? Should international donors support regional centres of excellence or is this a model that inevitably leads to 'ivory tower' establishments that are unable to forge the networks and connections needed to address the problems of African countries? The perspective we have adopted in this chapter is that there is scope for coordinating and integration efforts to build scientific and research capacity and building innovation capacity. There is no model that will yield results

in all contexts and support of high quality dynamic initiatives is crucial.

Another set of issues relate to how global 'vertical' or dedicated initiatives, which receive very significant amounts of donor funding, such as the GFATM, the Global Alliance for Vaccines and Immunisation (GAVI), and IAVI can be used to support the larger and broader health innovation system and health system goals of African countries. Whilst the impact of these initiatives has not always been judged to have a positive impact on national health structures and operations (Buse and Harmer 2007) there is good evidence to suggest that in some cases these initiatives have had a positive impact on capacity building in some areas.

IAVI presents an important capacity building example of the relationship between research 'for' developing countries and research 'with' developing country partners, not just research 'in' developing countries. The need for a preventative vaccine against HIV/AIDS is overwhelmingly evident as is the emphasis on the fastest and most effective way of achieving that target. However, a close look at the main PPP working on a preventative vaccine, IAVI, suggests that even here the distinction between 'for' and 'with' need not be so clear cut — IAVI has in fact had very positive impacts in terms of capacity building. In this case (see Box 10), political and ethical sensitivities around vaccine development and clinical trials are powerful arguments in favour of local engagement and voice at all levels (Chataway and Smith 2006).

Overall, this product-based approach to capacity building seems to have important lessons for those thinking about S&T capacity building policy. Capacity building can result from initiatives that focus on product development rather than on broader and more diffuse initiatives aimed at formal training. The tacit knowledge exchange around the vaccine and vaccine preparedness that has taken place as part of the IAVI work is particularly important as a lesson of experience for other S&T capacity-building initiatives.

The IAVI experience shows that some of the global initiatives do see that building capacity in developing countries is important because support and involvement is essential. At a meeting in 2006 at Wilton Park in the UK two other global health initiatives, the GFATM and GAVI also called for more 'systems' building in developing countries. The reasoning here is different. GAVI and the GFATM both consider that their operations have had very significant success. However, their future and the sustained success of their operations depend on better health services and systems in developing countries. Investment at this level of national and regional systems is now essential. Thus, there does now seem to an opportunity to build momentum for investment in systems building in developing countries. There is considerable scope for creative policy aimed at fostering capacity in health innovation and health systems.

Box 10: The International AIDS Vaccine Initiative (IAVI)

IAVI was set up in 1996 with the aim of promoting the creation and distribution of an effective preventative AIDS vaccine. IAVI acts as a sort of venture capitalist, investing in promising vaccine candidates and offering support for the expensive clinical-trial stage of drug development. IAVI also engages in high-profile public relations and grassroots advocacy work, particularly vaccine preparedness work, to promote the need for a vaccine and to provide insight into technological possibilities. A crucial part of IAVI's work is developing strong links – partnerships – with developing country institutions to run clinical trials and vaccine preparedness work or planning for vaccine manufacturing and distribution.

IAVI has achieved significant capacity building through its partnerships. IAVI's role in capacity building is paradoxical but successful. Capacity building is not a core priority but it is strategically important. Capacity building has been essential to IAVI for three principal reasons. First, for scientific reasons it is essential that clinical trials be conducted among those populations for whom the drug is intended. Second, building support for a vaccine requires local political support and this is built through active engagement. Third, the majority of IAVI's funding now comes from bilateral and multilateral funding agencies and these agencies clearly favour a capacity-building approach wherever possible.

IAVI partners in Kenya, Uganda, and Rwanda have all received very significant investment in training and infrastructure, and have benefited in particular from close and constant communication via telephone, Internet, and faceto-face meetings with leading scientists and managers. IAVI's African partners say it is the constantly focused activity around a set of tasks associated with vaccine development that has been particularly valuable. For partner organizations in Uganda, Kenya and Rwanda, new prospects have opened up as a result of this engagement and hey can now aim realistically to be centres of excellence for the development of vaccine clinical trials.

7. Conclusion and Policy Recommendations

At present, as we have shown earlier, the institutional set-up and range of policy perspectives in health innovation has a number of 'disconnects'. These disconnects exist everywhere and not only in Africa, but they are bigger in countries with weaker resource bases. In Section 2 we summarised the issue as a worrying and endemic gap between social policies on the one hand and industrial and innovation policies on the other. To put it bluntly, health policy and national health 'systems' tend, if at all, to treat innovation as irrelevant – for health product procurers, health products can be obtained just as easily or with just as

much difficulty anywhere in the world. This leads, not only to importation of most drugs, but often importation of the most basic hospital and clinic equipment and instrumentation.

We write in Section 2 of the lack of understanding between those who research and make policy in the world of health care and those whose interest is in health innovation and production of pharmaceuticals. Obviously then, institutions reflect this gap, and policies so far have not integrated social policy and the production policy. In fact health policy tends to deal with partial analysis of healthcare systems (Mackintosh and Koivusalo 2005) with little acknowledgement of wider areas of activity such as S&T research. At the same time S&T policy has not generally focused on health related matters because health has not been strategically important to national growth in many countries (Freeman and Miller 2001).

Increasingly, however, there is recognition that S&T, particularly biotechnology related research and development (R&D), is an important part of the health system and that developing countries must develop their own R&D capacity if they are to achieve sustainable health systems and the Millennium Development Goals are to be reached (Csaszar and Lal 2004; Mugabe 2005). Mahoney and colleagues have developed the idea of a 'health innovation system' around the six determinants of health innovation, summarised in Section 2 of R&D; manufacturing; internal markets; export markets; IP; and regulation. The large health product development projects (like IAVI and MMV) have, in some respects, kickstarted integration through doing it, focused on the big killers. Other studies, like the Rockefeller Report on Intellectual Property suggest, just as do the literatures reviewed in Section 1 that working on all fronts at once is key. For example, the ability to build capabilities in partnership working and managing large projects or sub-projects depends on existing or developing the systems-making connections in R&D, regulation, IP etc are necessary. But what matters most is pulling them together. Developing them separately without dialogue or connection, is not only slower, but will not work if the idea is to link the satisfaction of health needs with the capacity to deliver them.

In the following section we focus on some key policy recommendations that are relevant for better integration of the social and technical aspects of health innovation systems.

7.1 Linking Health Policy and Health Innovation Systems

Overall, we would still argue that countries with strong health innovation foundations, if they choose to, are well placed to succeed in developing and sustaining good health systems, and vice versa. Countries with better health innovation systems can participate in south-south efforts to improve conditions in weaker countries and regions. Recent academic analysis is focusing on ways in which innovation and industrial policy and social provision impact on one another and can be constructed in ways that are mutually supportive.

One policy action that the African Union and NEPAD might consider is initiating an expert group to develop analysis and promote policy initiatives and mechanisms to integrate health

related industrial and innovation policy on the one hand and healthcare policy on the other hand. The expert group would formulate policy plans and stimulate activities. The group would include policy makers, private sector actors and academics.

Another suggestion is linked to a capacity building action already outlined in the African Union and NEPAD Africa's Science and Technology Consolidated Plan of Action. As part of its science and technology capacity building the Consolidated Plan suggests Short-term Executive Workshops for Senior Government Officials. We suggest that some of these workshops be designed around building health innovation systems and specifically around the need to bridge the gap between different areas of policy.

7.2 The Importance of Building on and Integrating Global Programmes

From Africa's side, local institutions could be encouraged to explicitly work to build better conditions for learning from these huge global initiatives and global partnerships and construct a myriad of global connections – avoiding passive sub-contracting and actively learning in order to imitate and innovate.

One policy recommendation is for NEPAD and the African Union to pursue further discussion with international Global Health Programmes such as GAVI and the GFATM about how these initiatives could best support health innovation capacity building in African countries. Discussions along the same lines might also be pursued with some of the large public private partnerships such as IAVI and MMV.

7.3 The Importance of Balancing Innovation and its Regulation

Another policy challenge is to ensure that the pressures for innovation are in balance with those for regulation and governance. The High-Level Panel on Modern Biotechnology of the African Union and NEPAD in their report Biotechnology in Africa's Development which was focused on biotechnology but may well have more general import, pinpointed one danger: "The evolution of [Africa's biotechnology] regulatory systems has been largely influenced by international debates that are often not directly associated with the technological needs of the continent. The continent, through its regional economic communities, needs to adopt an evolutionary approach where regulatory systems develop hand in hand with technological opportunities and applications". It goes on to advocate risk taking and care at the same time, not to allow the risk to stop innovation happening.

The balancing act will require great policy finesse, and also significant resources. Regional initiatives will be needed to support local efforts. Efforts should build on WHO initiatives. Concerted efforts should be made to develop systems that are enabling rather than constraining and should be consistent with the detailed policy recommendations developed in the report on Biotechnology in Africa's Development.

7.4 Capacity Building for More Integrated Innovation Systems

We have argued that national institutions and organizations can use networks and partnerships to develop health innovation and provision. This analysis of capacity building possibilities builds on work that NEPAD has already carried out on thinking related to centres of excellence in Africa and we would endorse the policy perspectives and actions outlined in the document 'Centers of Excellence in Science and Technology for Africa's Sustainable Development'.⁶

We have also emphasized the importance of building on dynamic initiatives and trying to maximize national and regional capacity from initiatives which show promise. This thinking around building regional networks of excellence and grounding them where appropriate in national and regional institutions needs further development. Universities can clearly play a key role in interacting with and supporting networks and a clear policy recommendation is that Africa's academies of science consider ways to promote and extend health innovation networks in conjunction with African universities. By adopting more 'mode 2' approaches and by prioritizing links with other researchers, with users groups and with policymakers, African universities could make a fundamental contribution to the development of more sustainable health innovation systems.

Universities can also clearly play a key role in providing training in innovation policy and practice that could improve health innovation over the medium and longer term. The Consolidated Plan of Action outlines plans for postgraduate training in innovation and one policy recommendation would be to offer a modular strand of training on health innovation systems and integration with health systems.

7.5 Integrated Policy Making

There is need to identify and back 'micro-systems of innovation' whilst concurrently reforming national institutions and policy to provide facilitative innovation environments. This approach requires rethinking the way in which much policy is made. Policy formulation itself needs to become a more dynamic and interactive process. One policy recommendation, then, is for the African Union and NEPAD to support exercises such as Foresight which might help identify promising initiatives and technologies. Foresight exercises tend to work best when based on the involvement of substantial numbers of researchers, scientists and policy makers and it may well be that regional Foresight initiatives might be appropriate.

Notes

- 1. Absorptive capacity refers to the ability to search and make use of new knowledge and new technology.
- 2. For example where industrial and innovation capacity is being created but does not address local health and social needs.
- 3. http://www.who.int/medicines/areas/quality_safety/regulation_legislation/en/.
- 4. See http://www.scidev.net/en/news/sickle-cell-drug-mired-in-controversy.html. Accessed 18 August 2008.
- 5. Meeting at Africa Genome Education Institute, October 2006
- 6. Prepared by John Mugabe for AMCOST in November 2003

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Technological Trends and Opportunities to Combat Diseases of the Poor in Africa

J. Chataway, K. Chaturvedi, R. Hanlin, J. Mugwagwa, J. Smith & D.Wield

Abstract ____

Scientific and technological breakthroughs do not necessarily lead to accessibility of a new product to the public. There is no automatic and smooth transfer from laboratory to product, and followed by delivery to the consumer. In order to have useful innovation and product development, issues such as funding, regulation, production and delivery need to be resolved not only by African governments but also the international community, industry and civil society.

In this chapter we address following questions on the issue of transfer (or translation): which technologies do health experts think have the greatest potential to address Africa's health challenges? what are the main barriers and challenges to developing or accessing those technologies; and, what can be learnt from the existing initiatives which are aimed at producing, supporting or promoting the procurement and application of science and technology (S&T)? It is important to note that the changes are complex and go beyond the concept of simple transfer and thus need to be systematic.

To that end, we have proceeded as follows: summarised the recent work of other groups on these questions; added the findings of our own Delphi survey; examined in detail three types of key technological trends and opportunities to see how they might be developed, and also to consider the constraints to be overcome. A key premise of this chapter is that there are three basic sets of challenges in developing technologies for diseases of the poor in Africa. First, that scientific and technological challenges are key to addressing specific diseases. Secondly, that it is essential to address market failures and construct policies to improve the supply of and demand for appropriate new health technologies and innovation. Thirdly, that greater attention be paid to the 'social technologies' - the organisational and institutional mix - involved in producing and distributing technologies.

Introduction

Scientific and technological advances have had numerous and profound impacts on public health in both advanced and developing countries. One recent example is the development of Highly Active Anti-Retroviral Therapy (HAART) which has transformed the chances of those people living with HIV/AIDS (Badri et al. 2004). While these therapies do not cure the disease, they certainly increase life expectancy and are seen as being partly responsible for the reduction in the international AIDS death rate (The Economist 2008). Again, advances in water purification also mean that it is now possible for more people to access safe drinking water (Strestha et al. 2006), while innovations in genomics mean advancement in the development of drugs, vaccines and diagnostics (WHO 2002). A 2002 report by the Joint Centre for Bioethics at the University of Toronto outlined the top ten biotechnologies for improving health in developing countries. At the top of the list were modified molecular technologies for affordable and simple diagnosis of infectious diseases (Daar et al. 2002).

In order that these and other technological advances have a greater impact on the health of the poor in Africa, a number of constraints need to be understood and overcome, and they include technical, economic, institutional and political. The development of HAART has not resulted in immediate access to this technology by those who needed it in many African countries (Montaner 2006), Access to such HIV/AIDS treatment in Africa has required resolution of funding, regulatory, production and delivery issues by not only African governments but also the international community, industry and civil society. At organisational and institutional level, frameworks for developing an HIV/AIDS vaccine are fast evolving with new challenges emerging all the time. Thus early in 2008, scientific challenges resulted in calls for, and movement towards a return to laboratory science and away from clinical trials in the AIDS vaccine field (Independent 2008). Major new investment in health research, including although not as significantly for neglected diseases¹, affords exciting opportunities and has built momentum (Hotez et al. 2008). What can be learnt from existing initiatives aimed at producing, supporting or promoting the procurement and application of these advances? And, how can African policy makers and the international community best move forward such initiatives and provide access to these technologies? Addressing these questions is the starting point to mapping the current status of current technological trends and opportunities to combat the diseases that afflict the poor in Africa.

1. The Current State of Science and Technology for Health in Africa

There is an increasing realisation of the importance to build infrastructure in science, technology and innovation for the development of nations in Africa. This is likely to translate into progress towards the United Nations' (UN) Millennium Development Goals (MDGs) aimed at reducing poverty, disease and hunger in the world. NEPAD has a whole programme devoted to Science and Technology, the Commission for Africa Report (2005) highlighted

the importance of science, technology and innovation for Africa's development and the UN Millennium Project set up a Task Force to investigate the role of science and technology for development. In order to overcome the competing policy demands and ensure an emphasis is placed on science and technology (S&T), the UN Millennium Task Force on Innovation (2005) emphasised a deliberate and systemic approach to the inclusion of, and application of, S&T highlighting the learning process of innovative activity. Chapter 1 of this volume articulates the arguments for Systems based approaches in more detail.

Some African countries have already adopted a systemic approach to S&T. South Africa, Kenya and Egypt have all introduced S&T policy initiatives that work to build a 'national system of innovation'. By this system, policy decisions enable the creation of a network of public and private institutions throughout all areas of the economy which work towards the creation and diffusion of S&T. For example, since 1996 when South Africa launched a White Paper on S&T, the country has placed an emphasis on networked multiple stakeholder involvement, competitiveness and collaborative research in areas of heath research. This means that there are focus areas for S&T innovation in biotechnology and nanotechnology as well as collaborative research projects around HIV and malaria vaccines. As a result it has been argued that South Africa is producing a 'health innovation program' within its national innovation system (Mahoney and Morel 2006).

There has been a massive increase in international support for work on neglected diseases. Bilateral and multi-lateral initiatives were spawned over the last decade and new global health partnerships have attracted billions of US dollars in financial support in recent years. Many of these initiatives are based to some degree on awareness of the importance of all three fundamentals of building new technologies and innovations to address diseases of the poor.

Despite this, Africa still has relatively low levels of research and development (R&D) and health innovation. Almost no African country reaches the investment target of 1% of GDP in R&D set in the Lagos Plan of Action (AU/NEPAD 2006). NEPAD and the African Union's Science and Technology Consolidated Plan of Action outlines other features of low levels of investment:

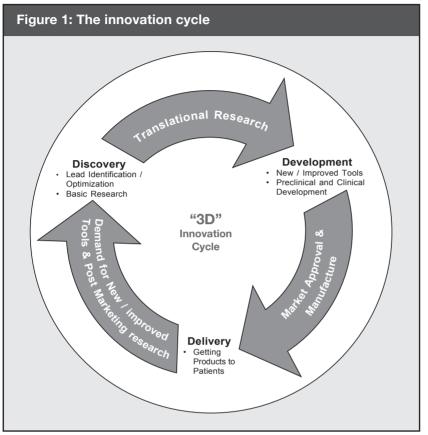
"Africa's low investment in science and technology is also manifested in declining quality of science and engineering education at all levels of educational systems. Student enrolment in science and engineering subjects at primary, secondary and tertiary levels is also falling. The continent is also loosing some of its best scientific and technical expertise to other regions of the world. In many countries infrastructure for R&D has been neglected and is decaying. Institutions of higher education, particularly universities and technical colleges, are in urgent need of renewal after many years of neglect and disorientation from local and national priorities." (AU/NEPAD 2006) The quote highlights the poor situation of African nations' S&T infrastructure. The lack of emphasis and attention placed on S&T in investment, economic and education policy is highlighted above. However, there has also been neglect of science and technology in health policy too (the emphasis being placed on the output of the health system – health*care* and its delivery) and vice versa (S&T policy did not include health components traditionally); a situation being compounded by small and competing budgets. For example, the World Health Organisation in its World Health Report (WHO 2001a) defines the health system in terms of 'healthcare' while the Commission for Macroeconomics and Health (2001) highlighted the lack of emphasis placed on health within science and technology policy. The emphasis has traditionally been on seeing each of these areas as separate to each other with only minimal inputs and linkages between them.

1.1 The Innovation Cycle – Building Sustainable S&T

A key lesson from the success of a number of countries in East and South East Asia is not just the need for investment in S&T, and in education, but the key role of problemoriented innovation – the applied S&T that can solve problems and bottlenecks with new products and processes. One important lesson from South East Asia is that a problemoriented focus – whether on new product development or on better or cheaper ways of delivering services -- seems to result in improved innovation. Scientific and technological capabilities are crucial and require resources. But these capabilities must be focused and honed on key innovation goals – improved or cheaper treatments, for example.

As the concept of a systemic approach to S&T suggests, successful innovation of technology requires more than the creation of a technology. It is important to acknowledge the complex interplay of numerous contextual factors. Innovation does not occur within a linear framework through which inputs of skills and resources at the discovery phase will automatically lead to the production of a technology product, process or service. The innovation process is in fact highly complex involving actors and linkages between industrial, education and healthcare sectors.

In recognising the complex nature of innovation, it is therefore important to consider technological innovation at all stages of the innovation cycle (discovery, development and delivery; WHO 2006). This will ensure technologies move from bench to bedside. In order for successful technological advance to occur it is important to consider the inputs, influences and obstacles that occur when a technology is researched, produced and delivered. The three stages and their linkage in health are best illustrated in Figure 1.



Source: WHO (2006)

Discovery, development and delivery are all stages within a cycle of innovation; they do not occur in a linear fashion but include multiple feedback loops between the stages while once a technology has been delivered, end-user feedback provides inputs on which further discoveries and adjustments to a technology can be made. In many developing countries there exists a gap within the innovation cycle, however, due to the lack of market demand for the development of products, processes and services appropriate to the disease burden of a country. No one firm or other economic unit sees investment in research and technology as in their interest or domain. That means that needs are not automatically met with investment and product development. There is a lack of incentives to ensure the linkage is made in the cycle between the delivery stage and further discovery activities. One way to incentivise investment in these areas is through the use of public-private partnerships, institutional arrangements that link the public and private sector to share the risks and benefits of R&D activities. Where investment in science and technology does occur as a result of public sector investment, that investment is often modelled on traditional notions of scientific excellence which may result in good theoretical understanding, but not on

deliverables (Chapter 1, this volume). These are just one set of a number of barriers that exist in ensuring a continuous cycle of innovation occurs. Box 1 highlights the various barriers that exist through the case study of diagnostics for tuberculosis in resource poor settings.

Box 1: Tuberculosis diagnostics in resource poor settings

Two billion people or 30% of the world's population are infected with Tuberculosis (TB). The disease results in eight million new infections and 2 million deaths every year. South Africa has the highest incidence of TB of any country in the world. TB is an infectious disease which commonly affects the lungs. Accurate diagnosis of TB is difficult in resource poor settings. The microscopic examination of sputum (mucus from the lungs) is still the only widely available diagnostic tool for identifying TB in most developing countries. However, under field conditions sputum smear microscopy shows a sensitivity of only 40-60%, partly due to the difficulty of maintaining well-equipped laboratories to perform it and the need for specialized training but mainly due to the inherent low sensitivity of the test. Poor sensitivity is exacerbated in the presence of HIV co-infection (falling as low as 20%) because it becomes difficult to see the bacilli within the sputum.

New diagnostic tools for TB detection have been developed and introduced in developed countries. However, they have generally not been adopted in resource-limited, high-burden countries due to cost, complexity, lack of laboratory infrastructure or inadequate performance in endemic settings (e.g. failure to adequately discriminate between diseased patients and latently infected or vaccinated subjects). Novel technologies successfully introduced into developed countries require adaptation to match the needs of developing countries. The perception of companies involved in diagnostic tool development that this will not lead to an adequate return on investment has hampered subsequent introduction of such tools in high-burden regions.

Much of the basic research and discovery led activities into new diagnostics for TB is therefore conducted within the academic setting or by small start up companies who lack the funds to translate their discoveries into finalized products. Lack of sufficient market data has exacerbated this situation in the past in not providing sufficient incentive to larger pharmaceutical companies who have the money to conduct costly product development and move a new diagnostic tool to market. At the same time there is a perception that distribution of new diagnostic tools will be difficult, expensive and the costs hard to predict.

In order to move TB diagnostic tool development forward a number of partnerships have been set up that bring together public funds and private sector expertise (e.g. STOP TB Partnership and the Foundation for Innovative New Diagnostics, FIND) to ensure new products are screened and that new product developments are initiated and introduced into the market. These initiatives ensure the provision of market data and advocacy and communications activities, the support of product specification process and co-funding of product development as well as facilitation of access including assisting and building up local regulatory processes. As such, these initiatives provide a means to complete the innovative cycle not only eliminating the gap at the translational research and market approval and manufacture level but also work to create demand for these products through their communication activities.

Source: Adapted from Stop TB (2006)

Innovation also occurs at multiple levels: macro, sectoral and micro (Chataway et al. 2007) and therefore it is important to develop policy relevant for innovation at all levels. Innovation requires an enabling macro level environment created through effective regulatory frameworks and national policies that strengthen the innovative environment. At the sectoral level a health system needs the capacity to take up and absorb any new technological products, processes or services that are produced and delivered through the micro level institutions and organisations working in health innovation activities. At each of these levels there is a dynamic and ever evolving interplay between actors from different sectors (health, education, industry etc.).

Considering innovation's procurement, development and application through such a systemic lens that acknowledges the cyclical and multiple layered nature of the innovation process will better enable sustainable and long-term successful implementation of chosen technologies. The process of innovation is not only cyclical and layered but further complicated by the interplay that occurs within it. Innovation usually occurs in a path dependent fashion (previous patterns of investment, resource deployment, technological trajectories and accumulated skills limit the scope for new technology to be discovered, developed and/or delivered). More targeted health innovative activity requires a specific catalyst or dedicated manipulation of policy and the wider environment.

The policy and infrastructural environment of a country's 'health innovation system' – the network of institutions, organisations, rules and norms that conduct innovative activities to find solutions to the country's health problems – described above will impact the ability of the country to innovate – to choose, discover, develop and introduce (new) technological advances. There is also no single tried and tested way of developing a health innovation system to ensure technology innovation can occur. Every country has different capabilities and capacities that each work in different ways and are influenced by different sets of economic, social and political contexts affecting innovation. Thus, creating new approaches, new technological platforms and introducing new innovations is far from straightforward. Excellent analysis of the challenges involved has to some extent already informed efforts

to create new technologies. Recent policy thinking about 'market failures' and incentives from governments and other actors is sophisticated and challenging. Public private partnerships (PPPs) such as the International AIDS vaccine Initiative (IAVI), Medicines for Malaria Venture (MMV) and others are fully aware that developing science and technology in ivory towers and expecting smooth and unproblematic translation to product development is extremely unproductive. Yet, the challenges in creating new technologies that really address the problems are huge. Those involved in analyzing these challenges and those trying to develop and deliver new treatments are aware that the 'social technology' needed to address the medical and health needs of the world's poor is lacking. Radical improvements in the understanding of how we create new paths through research, product development and delivery are needed. New approaches to encouraging new forms of communication and institutional/organisational mixes to bridge the various gulfs in thinking and action are required.

2. Mapping Recent Advances

There have been attempts at identifying technologies that appear to provide significant opportunity in combating diseases of the poor in Africa (cf. Daar et al. 2002; Grand Challenges in Global Health 2005; Jamison et al. 2006a; UN Millennium Project 2006). In particular, increased importance is being placed on biomedical and biotechnical advances in the life sciences, biotechnology and other technological advances over more systemic and social based technological advances to control diseases affecting developing countries. Of note are two reports which highlight these differences: the 2002 'Top Ten Biotechnologies' report (Top 10 report; Daar et al. 2002) from a group at the University of Toronto and the more recent Disease Control Priority Project's second report (DCP2; Jamison et al. 2006a).

Daar et al. (2002) outline the results of an in-depth survey of 28 eminent scientists and health policymakers to identify priority technologies to be used to improve the health of populations in developing countries. The report listed the following 10 biotechnologies as having the potential to improve health in developing countries: molecular diagnostic tools such as PCR (polymerase chain reaction); recombinant vaccines; vaccine and drug delivery systems; bioremediation (for environmental improvement); sequencing pathogen genomes to identify new anti-microbials; female controlled protection against sexually transmitted infection; bioinformatics; nutritionally enhanced genetically modified crops; recombinant therapeutic proteins and; combinatorial chemistry for drug discovery.

Jamison et al. (2006a) outline – amongst other things – the science and technology with the potential for future disease control in terms of biomedical research. The new technologies that it lists are: genomics, proteomics and cell biology; stem cell and organ therapy; information technology; diagnostics and hospital practices (surgery); human development and child and maternal health; neuropsychiatry; nutrition and genetically modified crops; social and behavioral science and; health systems and health economics.

What is important to note at this point is that the Top 10 report is exclusively dealing with technological advances relating to biotechnology² acknowledging the potential of genomic based solutions outlined in the 'Genomics and World Health' report (WHO 2002). It is principally an exercise in foresight that places the emphasis on scientific progress. The DCP2 report does place an emphasis on biotechnology based solutions but it does not focus exclusively on them. The focus of this report is on disease control more generally and how to reduce the incidence of disease within developing countries. In particular the emphasis is placed on where to allocate scarce resources within the health system. As such this report acknowledges that potentially useful technologies include process based technologies and social systems focused on human development and strengthening health systems.

Finding solutions to the chronic health problems that affect many African countries (as a result of diseases such as HIV/AIDS, TB and malaria) involves improved capacities to conduct scientific research to produce new drugs, vaccines and diagnostics. However, the argument put out in the DCP2 report suggest that equally important process based technological advances are required to ensure the technological products can be delivered appropriately and effectively. The DCP2 report highlights the importance of focusing not only on the development of purely scientific and technological product and processes as a means of combating disease but also on the need to have good organisational and institutional mixes; the importance of good 'social technology'.

Decisions about a choice of technology can be made based on a wide range of factors. Decisions about how a technology is sustainably developed and delivered can involve complex trade offs such as between short term gain (immediate results e.g. reduced disease burden) and longer term health returns (building sustainable health systems and processes). Trade-offs are also required between specific health related S&T e.g. development of drugs and vaccines for HIV/AIDS and other less 'technical' options that are also important e.g. clean water and improved sanitation.

The trade-offs (and their implications for the degree of focus on biotechnology based technological advances alone) require consideration if useful and relevant scientific and technological opportunities are to be advanced that have the potential to combat diseases of the poor in Africa. Thus in 2006 we conducted a mapping exercise that used these two reports as a base and aimed also to consider the opportunities relating to social innovation as well as science and technology. The mapping exercise consisted of an extensive literature review and a Delphi-type survey of prominent scientists and health policy makers the details of which are given below.

2.1 Survey Process

Using principally survey techniques – particularly an adapted Delphi technique – we aimed to gain an insight into what the major experts in public and international health, science

and medicine believe are the scientific and technological advances with the greatest potential to address Africa's major health challenges as well as the barriers to their advancement. The survey data was added to material gained from a literature survey and analysis in order to develop an overview – particularly working using case studies – of initiatives and areas of attention that offer hope or need scrutiny by African policy makers and the international community in order for the identified scientific and technological advances to be maximised.

Over 100 key experts from around the world were emailed twice using a similar format to a 'Delphi' survey. The experts included those particularly from Africa who are key medical and biological scientists as well as those involved more generally in the field of public and international health and specifically the diseases of poverty. We also contacted key actors from global health initiatives and those working in interesting new initiatives such as drug trial centres, multi-disciplinary clinical ventures, vaccine initiatives, etc. The response rate was not as high as expected with a 15% response rate to the first email and a 10% response rate to the second. A restricted time scale was the principal reasoning for the low response rate. The respondents were not always the same people on both occasions. Respondents came from a range of specialisms both from within the traditional and social sciences.

The first round of the survey consisted of an email requesting the respondent to rank in order of importance what they saw as being the five recent advances in the life sciences and related technological innovations that offer greatest potential to address Africa's major health challenge. We also asked respondents to list the key barriers to advancing these technologies in, and for, Africa in the next few years. A number of the responses were followed up with telephone calls to discuss the responses in more depth.

The replies were analysed and a list produced outlining the most frequently and highest ranked responses received by those that responded to our survey. These were then tabularised (see Table 1) alongside the technological advances identified in both the Top 10 and DCP2 reports.

Table 1 was then sent out by email to all 100+ experts who were asked to review the table and pick out five of the technologies listed that they saw as having the greatest potential to address Africa's health challenges, and to list their reasoning for the choices they had made.

Table 1: Recent health technologies with potential to address Africa'shealth challenges		
Top 10 Biotechnology	DCP2	Our Survey
Molecular diagnostic tools such as PCR (polymerase chain reaction)	Genomics, proteomics and cell biology	HIV/AIDS treatment in the form of anti-retroviral drugs
Recombinant vaccines	Stem cell and organ therapy	Insecticide treated bed- nets for malaria
Vaccine and drug delivery systems	Information technology	Artemisinin based malaria drugs
Bioremediation and environmental improvement technologies	Diagnostics and hospital practices (surgery)	Information technologies
Sequencing pathogen genomes to identify anti-microbals	Human development and child and maternal health	Vaccines
Female controlled protection against sexually transmitted infection	Neuropsychiatry	Diagnostics
Bioinformatics	Nutrition and genetically modified crops	
Enriched genetically modified crops	Social and behavioral science	
Recombinant technology for therapeutic products (e.g. insulin)	Health systems and health economics	
Combinatorial chemistry for drug discovery		

The results gained are outlined below. The exercise aimed to feed back those advances most mentioned by experts first to obtain a sense of whether there is consensus. However, and as importantly, the exercise also attempted to move beyond lists, by looking at reasoning for choice, in order to gain more in-depth insight into the implementation and access issues that require attention.

2.2 Survey Results

The survey is not intended to be representative or statistically significant but to get a snapshot view of current thinking and trends. The survey was also not intended to supersede the work conducted by University of Toronto or the Disease Control Project. Instead the survey was designed to complement these studies and see if attitudes and perspectives had moved beyond biotechnology related advances in the way that the DCP2 report suggests. Thus the results of our survey and the discussion that follows are presented here in conjunction with the results of the Top 10 and DCP2 reports. Table 2 outlines the results of the survey. Two of the advances highlighted in our survey are more disease specific than those mentioned in other reports: HIV/AIDS treatment and malaria treatment/prevention. Rather than emphasising general life science based technological advances the respondents in our survey highlighted the importance of combating HIV/AIDS and malaria due to the high disease burden inflicted by these diseases on Africa's populations with one respondent saying the starting question that needed to be asked was, *"what is the evidence of the effect of having the technologies in place".*

As such respondents felt:

"I believe vaccines would be directly pertinent to the three leading infectious disease burdens of HIV, TB and malaria (as well as a few other cause infections) and an affordable, effective, and practical vaccine would directly avert a large amount of morbidity and mortality."

"HIV/AIDS treatment via ARVs – most immediately beneficially effect for those infected with HIV."

In particular the main disease specific technologies put forward included antiretroviral (ARV) treatment for HIV/AIDS, vaccines for HIV/AIDS and malaria together with malaria drugs based on artemisinin. In the first round of the survey we also received a large number of inclusions of microbicides against HIV/AIDS and long-lasting insecticide treated bednets for malaria. Other less frequently cited technologies which are also less traditionally 'scientific' in make up were cell phones, the internet, residual spraying for malaria control, clean water and sanitation.

Other respondents chose to focus on generic life science based technological advances. The decision to focus on generic technological solutions was highlighted by one respondent who in the second round picked the category of 'genomics, proteomics and cell biology' as the main technological advance with most potential arguing *"these cut across all subjects, and carry potential for use by local scientists to address their own national problems."*

Table 2: Health technologies ranked in order of potential to address Africa'shealth challenges

Top 10 Biotechnology	DCP2	Our Survey
Molecular diagnostic tools such as PCR (polymerase chain reaction)	Genomics, proteomics and cell biology	Vaccines (including delivery systems
Recombinant vaccines	Stem cell and organ therapy	Diagnostic tools
Vaccine and drug delivery systems	Information technology	HIV/AIDS treatment in the form of anti-retroviral drugs
Bioremediation and environmental improvement technologies	Diagnostics and hospital practices (surgery)	Nutrition and genetically modified crops
Sequencing pathogen genomes to identify anti-microbials	Human development and child and maternal health	Health systems and health economics
Female controlled protection against sexually transmitted infection	Neuropsychiatry	Sequencing pathogen genomes to identify anti- microbials
Bioinformatics	Nutrition and genetically modified crops	Malaria treatment (with Artemisinin) & prevention (with bed- nets)
Enriched genetically modified crops	Social and behavioral science	
Recombinant technology for therapeutic products (e.g. insulin)	Health systems and health economics	
Combinatorial chemistry for drug discovery		

Four main generic life science advances were mentioned most frequently in our survey. Recombinant vaccines and their delivery systems were seen to be important because they "[w]on't be the answer to everything, but there are still huge gaps in infectious disease control, resulting in great disease burdens" and are "[I]ikely to provide protection for a variety of diseases in a safe manner." It was felt that "[t]here will be no effective treatment at individual and community level if we do not have the respective diagnostic tools and strategies at the point of care (i.e. not in any specialized centre, possibly even in the North)." GM crops and "better nutrition and crop yields would not only yield better food security and reduce hunger (another MDG) but also help improve performance at school and generate at the family/village level excess marketable produce which can start to create wealth to reduce poverty." The fourth generic advance that was identified was sequencing of pathogen genomes to identify microbials.

In fact the reasoning for a technology's inclusion by respondents differed slightly in each

of the two Delphi rounds. Predominately in the first round of the Delphi many of the respondents to our survey highlighted how burden of disease was one of the main factors influencing their ranking decisions. Ranking decisions in the first round were also based on the degree to which technologies were also readily available for introduction. In the second round, the reasoning given was much more placed on optimism and the need to improve difficult current situations as quickly and as efficiently as possible.

Such reasoning echoes that found by the researchers of the Top 10 report who reported the following factors as being important in assisting biotechnological advance:

- Impact
- Appropriateness
- Burden
- Feasibility
- Knowledge gap
- Indirect benefits

The need to consider multiple reasoning in choosing technology is illustrated by this quote taken from an interview of one respondent:

"ARV trials are getting quite exciting and showing promising results. Certainly potential is there but treatment and care needed includes HIV/AIDS prevention, counselling and testing, nutritional management, and, of course, access to ARV drugs. Money needs to be invested in education, training and healthcare resources as well as in developing new drugs. Besides, national and local policy leadership is a big issue."

The difficult choices required in deciding which technologies to focus on were also highlighted by another respondent:

"I'm having real trouble with the lists. I think it's very tough to compare, for example, "health systems and health economics" with, for example, "recombinant technology for therapeutic products" and tougher still to compare "human development and child and maternal health" with "sequencing pathogen genomes to identify anti-microbials". Of course, none of the rest of it makes much difference unless you have a health system (of some kind -- maybe more private sector than public but still a system) or a commitment to human development so I suppose those things have to go to the top of any list."

An emphasis throughout the survey – and as illustrated by the above quote – was also placed by respondents on the need for integrated approaches – the need to focus on more than one of these technological advances at any one time:

"It is the combination of ACT [Artemisinin-based Combination therapy] with the

use of bednets that will make a huge difference. I deliberately put them together as only the integrated approach of combining the curative and the preventive approaches will lead to success"

"I believe the shortage in many countries of capable health workforce and weak health systems, if they were addressed successfully, would enable the delivery of a range of cost-effective interventions such as bednets. The effective use of health systems/ health economics would lead to the use of other valuable technologies. Without the systems and economic tools, the justification for prioritizing these technologies may not be so clear and the resources to deliver them may not be developed."

The inclusion of health systems and health economics was therefore identified as both a barrier and an advance in dual measure. Weak health systems and poor economic tools were seen as hindering the ability to introduce and use other potential technological advances. Stronger and more effective health systems were seen to provide an enabling environment necessary to ensure that technologies were developed and their opportunities realised. Functioning health systems were seen as an overarching requirement for all the other activities and technological advances to take place. An emphasis was not so much placed in this respect on science and technology but more on the need for innovation in the area of health systems and their analysis. More specifically these answers relate to the importance of 'social technologies' or the importance of the right organisational and institutional mix throughout the research-development-access continuum.

Thus our mapping exercise has highlighted three types of technological advance with the potential to combat diseases of the poor in Africa. We have identified a number of generic life science and biotechnology based advances in the form of vaccines, diagnostics, genome sequencing and GM crops. Secondly we have identified a number of disease specific interventions for malaria and HIV/AIDS. And thirdly, we have identified the importance of 'social technologies' or the organisational and institutional mix that is necessary to ensure successful development and/or uptake of the generic scientific and disease specific technological advances.

This final set of technological advances relates particularly to the reference by respondents to the importance of health systems and health economics. This reference is a worrying reminder that problem-oriented R&D has to include analysis of the problem of how to deliver new health innovations. Just as products must now be designed for use as well as for cheap manufacture and recycling, health technologies must be designed in function of their use in difference types of location.

As such, this initial assessment of new technologies highlights the need to think hard about policies and practices that pull together new science and technology, like 'sequencing of pathogen genomes' with choice factors such as 'the burden of disease'. This requires radical

new ideas that link science, technology and innovation communities with health practitioner communities, locally, nationally, regionally, and internationally.

3. Mapping Technologies and their Application

As highlighted above, in reviewing our survey results and the Top 10 and DCP2 reports, we can identify six life science based technological advances and one 'social technology' advance (health systems and health economics) that have the potential to address Africa's health challenges from diseases such as HIV/AIDS, tuberculosis, malaria, cholera etc. These can be grouped into the following categories:

- 1. Generic life science based technological advances:
 - recombinant vaccines;
 - diagnostic tools;
 - sequencing of pathogen genomes to identify anti-microbials; and
 - genetically modified crops.
- 2. Disease specific technological advances for HIV/AIDS and malaria:
 - Vaccines for HIV/AIDS and malaria;
 - Malaria drugs;
 - HIV/AIDS drugs; and
 - Microbicides.
- 'Social' technology innovations particularly in the form of functioning health systems and their analysis. These relate to the need for the correct combination of funding, infrastructure and skilled personnel who are linked into supporting networks.

Each of these will now be introduced before more in-depth analysis in Section 3.4 of their potential and impact, status and constraints impacting their advance. The discussion of these technologies in this section uses the work of the Toronto group's Top 10 report as a base and updates this information where appropriate. The decision to include in this discussion the concept of a 'social technology'³ is due to the importance of advances in the (social) interactions between and within innovation communities and those working within the health system as much as the importance of having a new drug, vaccine or diagnostic available.

3.1 Generic Life Science Based Technological Advances

The Top 10 report highlights the importance of biotechnology based technological advances and the potential of a number of these to combat diseases of the poor in developing countries (see Table 3). Our mapping exercise highlighted three of those listed in this table which are deemed to provide an opportunity to address the main health related MDGs of combating poverty, reducing child mortality and improving maternal health. These, together with GM crops which the Top 10 report also highlighted and which is seen as necessary to contribute to the MDG on improving children's nutrition, will now be discussed. We will consider the current status and (the extent to which they are available and being used in Africa).

Table 3: Priority biotechnologies identified in the Top 10 report					
Technology	Advantages	Examples			
Recombinant Vaccines	Reduced risk compared with attenuated vaccines & rational vaccine design	Malaria subunit vaccine RTS,S (with AS02 adjuvant) in phase 3 clinical trials in children in Mozambique			
Improved vaccine and drug delivery methods	Needle-free technologies reduce need for trained personnel, risk of HIV infection controlled, release systems help overcome non-compliance heat-stability & eliminates need for refrigeration	Temperature-stable, controlled-release formulations of synthetic peptide analog of hepatitis B antigen and trehalose ester derivatives			
Sequencing of the genomes of pathogens and their vectors	Boosts search for novel drugs and vaccines & improves understanding of disease mechanism	Ten strains of West Nile disease vector <i>Culex pipiens</i> , one strain of malaria-carrying <i>Anopheles gambiae</i> have same point mutation in acetylcholinesterase for insecticide resistance			
Molecular diagnostics	Early detection, timely intervention, helps prevent spread of infection & avoids waste of resources on inappropriate treatments	Dipstick assay for the detection of <i>Salmonella typhi</i> -specific IgM antibodies, same-day results, small volume of serum needed, stability of reagents and simplicity of assay allow use in absence of laboratory facilities			
Recombinant proteins	Synthesis by transgenic plants and animals & potentially cheaper than mammalian cell culture	Cheaper biosynthesis of antimalarial artemisinin by <i>Escherichia coli</i> engineered to express yeast mevalonate isopreniod pathway proteins			
Combinatorial Chemistry Rapid generation of many varieties of chemical compounds; Increased efficiency, potentially lower costs, fewer by products		Two new classes of drugs inhibit <i>Leishmania</i> <i>mexicana</i> cysteine protease, found from combinatorial library of 150,000 compounds			

Source: Lambo (2005) and based on Top 10 report findings

3.1.1 Recombinant vaccines

Biotechnology has helped in the development of recombinant vaccines with many advantages over conventional technology, and has been applied to develop new and improved diagnostic assays which are cheap, rapid, sensitive and strain specific. The classic types of vaccines are all limited in their dependence on biological products, which often must be kept cold, may have a limited life, and can be difficult and expensive to produce. The development of recombinant vaccines – those using chromosomal parts (or DNA) from a different organism

inserted into a foreign cell⁴ - has generated hope for a new generation of man-made vaccines.

Vaccines stimulate an immune response in the body and can therefore reduce the chances a person has of an infection contracting a serious level of infection. Vaccines are the ultimate prevention tool being responsible for the total eradication of smallpox and the virtual eradication of polio in the world. However, vaccine science is complex and not every infection and disease has a vaccine against it. This is particularly true of the big killers, HIV and malaria while the tuberculosis (BCG) vaccine was developed nearly 100 years ago and its effectiveness is questioned (Novelli 2006).

Traditionally vaccines were either killed or weakened (attenuated) forms of whole pathogens. With modern recombinant technology it is possible to be much more precise in controlling vaccine characteristics. It is therefore possible to work with only specific parts of an infectious organism (in the case of subunit vaccines) through the antigens. One such vaccine is the hepatitis B vaccine. One of the first recombinant vaccines to be approved for human use is made using recombinant yeast cells genetically engineered to include the gene coding for the hepatitis B antigen. Because the vaccine contains the antigen, it is capable of stimulating antibody production against hepatitis B without the risk that live hepatitis B vaccine carries by introducing the virus into the blood stream.

Other molecular biology tools have made it possible to identify which proteins are conserved among different strains of a virus or bacteria, or which are responsible for virulence of pathogens or oncogenesis in tumours. These proteins may be good candidates for vaccines. There are also novel approaches being taken to produce what are known as naked DNA vaccines which use a plasmid (a circular piece of DNA that self-replicates) as a vehicle to carry a pathogen into the body against which the body produces antigens to stimulate immunity. These are novel because they would not require a cold chain mechanism which currently hampers much immunisation effort in Africa. Plant vaccines also offer hope. The most promising option here is not necessarily vaccines being developed in plants which are then eaten but where antigens are expressed from plants such as tomatoes or potatoes and then processed into a dose regulated form such as a capsule which again requires no cold chain and can easily be taken involving no needle pain. As medical knowledge has increased researchers worldwide are working towards developing new vaccines and therapeutics for cancer, tuberculosis, melanoma, AIDS, influenza, and malaria based on r-DNA.

3.1.2 Diagnostic tools

The use of accurate diagnostic tools to detect pathogens through associated molecules such as DNA and proteins in cells and blood is vital in controlling disease. As such the group of experts surveyed in the Top 10 report voted accurate diagnostic tools as "the most prominent biotechnology for improving health in developing countries in the next 5-

10 years." In particular the report mentioned advances in PCR, monoclonal antibody and recombinant antigen technologies as having the potential to revolutionise the diagnostic tools that are available for disease control in developing countries.

Several enzymatic amplification processes, generally categorised as nucleic acid amplification techniques, have been developed and introduced as commercial products in developed countries. The most widely used are PCR, TMA (transcription modified amplifications) and SDA (strand displacement amplification). PCR allows for the production of multiple copies of a specific DNA sequence quickly, safely and accurately. This technique can be conducted within hours rather than days and can be used to identify more dangerous pathogens to work with very safely (e.g. HIV). The technique can also identify pathogens that are difficult to produce in laboratory conditions in the case of malaria and tuberculosis. The rapid and accurate diagnosis of tuberculosis remains a major challenge for all developing countries and particularly for Africa with TB in HIV positive individuals, in children and in patients with extrapulmonary form of TB. PCR is increasingly being used to test for drug resistance at the same time as identifying the disease pathogen. However, the level of sophistication, complexity (requiring trained laboratory personnel) and cost associated with the technique restricts its general application in resource-poor settings.

Anti-body coated dipstick tests (see Box 2) that diagnose disease are increasingly used both within the clinical healthcare setting particularly in developing countries where electricity and water are in difficult supply (they are single-use test kits) and where more advanced medical centres are located at long distances from a community. Developments in the areas of monoclonal antibodies (a number of identical mass produced cells from a single parent cell) and recombinant antigens (mass produced antigens that are created by genetically engineered organisms e.g. bacteria or yeast) are also used as the base for dipstick tests (such as PATH's HIV1 dipstick test) as well as ELISA (enzyme-linked immunosorbant assay) screening where basic laboratory equipment is available to detect antigens and antibodies.

Although PCR and the other technologies have provided opportunities for the creation of simple to use, rapid test kits, the cost of these kits and PCR can be expensive. The cost of PCR testing is being reduced through the development of methods to test for more than one disease at a time (multiplexing) and by modifying the storage and processing techniques it requires, however the cost of these technologies may make these diagnostic tools beyond the reach of many governments with limited budgets and competing demands on funds. There has been successful transfer of PCR technology to developing countries through the work of the Sustainable Science Institute in San Francisco and the Swiss Tropical Institute in Tanzania with the local modification of equipment and the recycling of reagents (Harris and Tanner 2000).

The DCP2 report highlights how other non-biotechnology related advances are also occurring in the diagnostic tools area which include advances in imaging techniques such as magnetic resonance imagine (MRI) scans, computer tomography and ultrasound. These have the opportunity to revolutionise healthcare in the developing world although the cost of these technologies make them out of reach for many healthcare providers in the developing world.

Box 2: New dipstick test

The development of a pioneering new diagnostic tool for trachoma could help to eradicate the most common cause of blindness due to infection.

Dr. Helen Lee and Claude-Edouard Michel of the Diagnostic Development Unit at the University of Cambridge, and collaborators, have developed and trialled a rapid dipstick test that can diagnose the presence of infection within half an hour. The new 'point-of-care (POC) test' was developed specifically for use in developing countries, as it is cheap, quick and simple to perform, and requires no expensive equipment or skilled labour.

Dr Lee and team then compared the accuracy of this new dipstick test with the gold standard polymerase chain reaction (PCR) test in a trial in remote trachoma-endemic villages in Tanzania. The trial [in 2004 and 2005], involving 664 children aged 1-9, showed that the dipstick test was more accurate in identifying the presence of infection, correctly predicting over 97 per cent of cases, against 43.6 per cent for the current method.

The findings could profoundly influence the future diagnosis and treatment strategies for trachoma worldwide.

Source: www.wellcome.ac.uk

3.1.3 Sequencing of pathogen genomes

PCR technology enables the efficient sequencing of pathogen genomes. The opportunities afforded by this form of genome sequencing and that of parasite genome sequencing provides the base for much modern health research. As such the Top 10 report highlighted it as a 'priority area' while WHO devoted a whole report to the potential impact of genomic research on world health in 2001 (WHO 2002). Genes regulate the organisms within the biochemistry pathway and it is from this base that most diseases can be defined. As such the sequencing of genomes provides a means of understanding how a disease is caused or the makeup of a parasite and how it may be controlled. Sequencing – via a process called the Sanger or Dideoxy method – is the discovery and recording of the nucleotide sequence within an organism's DNA. Knowing the sequence of a genome is the first step to understanding its biology and finding ways of controlling it.

Genome sequencing is not only used in diagnostic tools such as PCR. Genome sequencing is also providing an input into the production of vaccines and drugs by providing information as to the gene sequence characteristics of important proteins. It is also possible to compare

genomes of disease carrying strains and non-disease carrying strains of organisms to find the differences that can be used as a way forward in drug and vaccine production.

Genome sequencing provides the opportunity to map the genetic layout of disease pathogens, parasites, humans and animals (see Box 3). This provides a means of determining genetic variability around the world between different species, countries and population groups. Sharing genetic information between researchers through free websites such as HapMap (www.hapmap.org) provides a means for all scientists throughout the world to be able to access this information. Similarly, creating gene banks where large pools of generic data are created is another source of data sharing which can be used as a base for research. This is particularly important in the emerging field of bioinformatics whereby data is assembled using computer based models and tools to search genetic data for clues about genetic makeup and how to control and identify disease.

Unfortunately there are numerous scientific obstacles and a lack of understanding still around how genes are expressed (Bentley 2004). Along side this are institutional roadblocks that limit the access and knowledge around genomic sequencing. Currently the big genome projects are based in the UK and the USA and the lack of genomic based research in the developing world has created the phrase 'the genomic divide'. The global genome mapping project, HapMap, includes developing countries such as Nigeria while South Africa has invested in setting up a bioinformatics institute and encourages private health biotechnology firms to set up around innovation centres. On the whole however, the amount of basic research, such as around genome sequencing, within biotechnology that is conducted in Africa is small.

Box 3: Pathogen genomes

"The parasite genome is very plastic," explained Dr Manolis Dermitzakis, coleader of the project from the Wellcome Trust Sanger Institute, "and carries the scars of its battle against its three main challenges - our rapidly evolving human immune system, the defensive responses of the mosquito and the insecticides and drugs we use to challenge it."

"Our variation studies bring biology to the parasite genome, uncovering the secrets of Plasmodium without - but as a prelude to - work in the lab. Our overview of evolution points to those gene variants that are responsible for disease effects - some were expected, but some are surprises."

Humans infected with malaria often carry several variant strains. A consequence is that vaccines to combat malaria are very difficult to develop and may become ineffective if the parasite switches its coat. Moreover, the range of parasite diversity means that resistance to new drugs can become rapidly established from small numbers of existing resistant organisms. Widespread resistance to chloroquine has developed in only 50 years. The Plasmodium map of variation can be used alongside maps of human variation, such as the HapMap or that of copy number variation published in Nature recently by a team from the Sanger Institute, to understand how the genome of each has been moulded by the activities of the other.

"The human genome carries imprints of our history of infection by malaria", commented Dr Mark Walport, Director of the Wellcome Trust. "Similarly the genome of the malaria parasite shows how it interacts with the human immune system. Understanding these interactions is key to the development of effective vaccines against malaria."

The new map was developed with biological expertise from researchers at St George's, University of London and the Weatherall Institute of Molecular Medicine, University of Oxford, John Radcliffe Hospital, Oxford. It is a snapshot of Plasmodium evolution, and provides a wealth of information for the malaria community, for example, by identifying genes that evolve too rapidly to be good drug targets. It shows researchers where to search for new treatments and where to avoid.

Source: www.sanger.ac.uk

3.1.4 Genetically modified crops

Improved nutrition can significantly improve the life chances of infants in the developing world where malnutrition affects one in five people. One way of doing this is to genetically modify staple foods such as cassava, maize, potatoes and rice. Traditionally to improve a species of plant, farmers have cross breed two species to mix the genes and introduce new genes into a plant. Genetic modification is a modern, biotechnological equivalent by which a plant's composition is modified by artificial means. This enables genes from one species to be inserted into an unrelated species. Gene technologies can produce new varieties more quickly than conventional breeding (Nuffield Council on Bioethics 2003). The usual method is to insert a gene into an organism so that as that organism grows the genes are taken up by the cell in which its placed. One example of this is Golden Rice, a variety of rice that was modified to contain added vitamin A and iron.

Up to now, most GM crops have been grown with just two characteristics – herbicide tolerance and insect resistance. Herbicide tolerance allows, in principle, farmers to kill weeds but not crops, sometimes using less herbicide over the whole growing cycle. Similarly, insect resistance allows, in principle, farmers to kill insects without damaging crops, sometimes allowing fewer applications in total, lowering labour and insecticide. However, other characteristics are possible with genetic modification, such as drought resistance, ripening control, fat content, and nutrition.

There are arguments against the use of GM crops. These focus on issues of risk to humans,

animals and the overall ecosystem balance in the production and consumption of GM crops. At times these become part of a wider discussion around the way new technologies should be regulated (Tait and Chataway 2007). This has led to resistance on the part of many people to the introduction of GM crops including the refusal of some countries to receive food aid from GM sources (Scott 2004). Proponents of GM crops however argue that they could have significant potential on farming production and food production similar to the impact of the 'green revolution'.

One example is that of Vitamin A enhanced (Golden) rice has been produced with the primary aim to help prevent vitamin A deficiency (VAD), which affects 14 million children under five and is a prime cause of blindness. About 250 million children had sub-clinical deficiency, one-third of whom live in rice eating areas of Asia. There are arguments about whether golden rice is just a technofix, but public-private partnerships between companies and researchers are ongoing, linked to building regulatory systems so that clinical trials can ascertain whether the vitamin A in the rice will be taken in by the body. Research is also taking place on vitamin A sorghum, including via a large consortium, the African Biofortified Sorghum Project, funded by the Grand Challenges in Global Health Initiative of African, American and Japanese institutions to enhance sorghum with iron, zinc and vitamin C (AU/NEPAD 2006). Others are working on nutritionally enhanced cassava and protein enriched potato.

3.2 Disease Specific Technological Advances for HIV/AIDS and Malaria

During our mapping exercise HIV/AIDS and malaria were two diseases that featured prominently as those contributing to the significant burden of disease affecting many countries in Africa. WHO (2005) estimates that 3.2 billion people a year are affected by a bout of malaria and 1.2 million are killed. The highest mortality is amongst children and those living in Africa where 90% of all malaria related deaths occur. About 39.5 million people are infected with HIV/AIDS in the world. Of the 4.3 million new infections estimated to have occurred in 2006, 65% were in Africa. The region now has 24.7 million HIV/AIDS infected people (WHO/UNAIDS 2006).

Research into finding treatments and preventive technologies for these two diseases has traditionally been hampered by low levels of funding and investment, particularly by the private sector in the industrialised world – where much of the expertise and funding lies. The increase in funding sources through philanthropic organisations e.g. the Bill and Melinda Gates Foundation, and the development of new financing mechanisms e.g. International Financing Facility for Immunisation are providing ways forward. There are also increasing calls for African governments to take increasing responsibility and build their capacity to do so (Dickson 2008; Hanlin, 2008).

Very significant amounts of money are being spent on HIV/AIDS research. In the period 2002 -2006, the EU spent 74.3 million Euros, however the US is by far the biggest country

donor contributing 86% of all public funds raised for HIV vaccine research and 74% of all microbicide investment. Overall, the US National Institute of Health spends approx US\$2 billion annually on HIV/AIDS research although of course not all of this will be relevant to developing countries. The science of antimalarial drug research has moved rapidly in the past decade through a large networked approach with funding increasing considerably. The European Union committed approximately 43.1 million over the period 2002-2006 (IAVI 2006). Total expenditure on malaria R&D in 2004 was estimated at US\$323 million predominately due to contributions from the US National Institute on Allergic and Infectious Diseases and the Bill and Melinda Gates Foundation. The combined investment of these two groups constituted 49% of malaria R&D investment. Three quarters of this money was given to entities conducting research and research managers (particularly the partnership groups of Medicines for Malaria Venture [MMV], Program for Appropriate Technologies in Health (PATH's) Malaria Vaccine Initiative and WHO's Tropical Disease Research group).

Funding shortfalls for both HIV/AIDS and malaria R&D exist and few African countries contribute significant national funds to promote such R&D investment with the exception of South Africa which has heavily funded HIV vaccine development activities and to a lesser extent microbicide research (de Francisco and Matlin 2006). Even once these products are developed there is still however a major constraint to be overcome that is more than simply financial. All drug, vaccines and diagnostics require strong access pathways and this requires good distribution networks and demand for affordable, effective, easy to use products. These access issues also need to be considered during discussions around developing specific disease related technological innovations.

Technologically and scientifically there have also been barriers to advancing treatment and prevention options. These will be discussed in more depth in Section 3.4 however it is important to note here that, although great strides have been made in the areas of drug treatments for HIV/AIDS and malaria, hope is provided by advances in other directions as well. These come in the form of anti-AIDS drugs being used as a preventative (pre-exposure) prophylaxis, improved condoms (both male and female), cervical barriers (such as microbicides) and male circumcision (Padian et al. 2008; The Economist 2008). Advancement in vaccine science for both malaria and HIV/AIDS has been much slower. It is expected that a malaria vaccine will be produced in the coming years with a number of malaria vaccine candidates having undergone and in the process of Phase III testing. An HIV vaccine is however still much further off. The lack of success in preventative biomedical advances such as vaccines and microbicides has led to a call for 'combination prevention' whereby known preventative methods (such as condoms and circumcision) are combined with treatment of HIV/AIDS (Cohen 2008). Again however, the emphasis here is on treatment and prevention of two of the 'big three' (HIV/AIDS, malaria and TB) at the expense of other neglected diseases.

3.2.1 Malaria drugs

The malaria burden on Africa demonstrated above is made worse by high levels of drug resistance hampering treatment efforts. In recent years many countries in Africa have had

to change their first line malaria drugs due to growing resistance particularly of *Plasmodium falciparum* malaria to traditionally used treatments using chloroquine and even more recent Sulfadoxine/Pyrimethamine treatment introduced in the wake of chloroquine resistance. The WHO now recommends the use of artemisinin based treatments. Artemisinin drugs first introduced in South-East Asia a little over a decade ago have proven to be well tolerated and the most potent of antimalarials. However, artemisinin drugs have a very short half-life and thus a multiple dose regimen of seven days is required to achieve an acceptable cure rate. When artemisinin drug with a partner drug that has a longer half-life improves the efficacy of the artemisinin. It also reduces treatment duration with the artemisinin and the likelihood of development of resistance to the partner drug.

The R&D required to produce these new combination therapies and the uncertain return on investment has reduced the degree international pharmaceutical companies are willing to invest in producing malaria drugs. To incentivise investment new innovative partnerships are being used. One example is the work of MMV, a not-for-profit organisation which aims to "bring public, private and philanthropic sector partners together to fund and manage the discovery, development and registration of new medicines for the treatment and prevention of malaria in disease-endemic countries." (www.mmv.org). MMV currently has over 20 projects in its portfolio, representing what is widely viewed as the largest antimalarial drug research portfolio ever. Following a fifth call for proposals which closed in February 2006, MMV's Expert Scientific Advisory Committee recommended seven new projects be added to the portfolio, subject to contract and availability of funding. These projects include one development project, four discovery projects and two natural products projects. MMV has included two fixed combinations of artesunate, a semi-synthetic derivative of artemisinin, with other known antimalarials to create chlorproguanil-dapsone-artesunate and pyronaridine artesunate in its portfolio which show promise as new affordable ACT drugs for malaria treatment (see Box 4).

Box 4: Malaria drugs

Chlorproguanil-dapsone-artesunate (CDA) in sub-Saharan Africa

GlaxoSmithKline (GSK), the World Health Organisation's Special Programme for Research and Training in Tropical Diseases (WHO-TDR) and MMV are collaborating in the development of the drug – a new-fixed dose artemisinin combination therapy, combining chlorproguanil, dapsone and artesunate, known as Chlorproguanil-dapsone-artesunate (CDA). CDA, which could be a major weapon against malaria, is a fixed-ratio three-drug combination of Lapdap[™] with an artemisinin derivative, being developed to treat uncomplicated Plasmodium falciparum malaria. A Phase II dose-ranging study in adults and children with acute uncomplicated malaria has been completed using sites in the Gambia and in Malawi, and the choice of artesunate dose for the fixed combination is now finalised. A Phase III clinical development programme prepared according to International Conference on Harmonization (ICH) guidelines and the UK Medicines and Healthcare products Regulatory Agency (MHRA) is underway in several African countries. In addition, a longitudinal 'Phase IIIb' trial is being designed at present, and discussions around the design of a possible Phase IV programme are underway.

University scientists have already collaborated with GSK and other partners to develop the anti-malarial, Lapdap[™]. This drug has a short half-life, which creates a short 'resistance selection window' or exposure period, to the parasite, helping to preserve its anti-malarial efficacy. CDA has been created by adding artesunate to Lapdap to create a fixed-dose therapy and should bring greater therapeutic benefits including more rapid parasite clearance from the blood and reduced risk of drug resistance.

Pyronaridine and Artesunate (PANDA) fixed dose combination

Pyronaridine-Artesunate is a new fixed-dosed combination based on artemisinin combination therapy, currently the most effective type of antimalarial treatment. The novel formulation technology applied to both drugs by Shin Poong of Seoul, Republic of Korea, MMV's partner in this development programme, has resulted in Good Manufacturing Practice quality tablets. Single, repeated doses escalation, interaction and food effect components demonstrated that the combination was well tolerated, with pharmacokinetics showing improved bioavailability and supporting once-daily dosing. PANDA has completed its large Phase II studies with 470 patients in Asia and Africa. While data are being processed for final analysis and reporting, planning has started for a multi-centre large Phase III trial in Africa and in South-East Asia in both children and adult patients. These studies will be followed by another study in younger children which will assess efficacy of a new paediatric formulation. If the Phase III trials confirm the phase II results, regulatory filing to the European Medicines Agency (EMEA) and the Korean Food and Drug Agency was expected by the end of 2007 with the new antimalarial ready to market in 2008

3.2.2 HIV/AIDS drugs

HIV antiretroviral drugs or ARVs disrupt the action of the virus. There are various combinations of these drugs which act at various different stages of the lifecycle of HIV (see Box 5). The virus mutates very quickly and as such it is often necessary to change the drug regimen being used to ensure it is most effective and resistance does not occur. Usually a cocktail of drugs is used such as HAART which involves treatment with at least three active antiretroviral medications. Treatment is highly effective but only if continued for life as it is not a cure.

Unfortunately there are a number of factors that hamper ARV access in Africa related both to distribution but also production. Médecins Sans Frontières (MSF) (2006) lists the following factors as hampering delivery of ARVs in developing countries:

- Shortage of health workers and the high costs charged to patients for the drugs and clinic visit;
- Too few children receiving ARVs because of the lack of diagnosis and treatment tools as well as the lack of availability of strategies to prevent mother-to-child transmission;
- Failure to coordinate TB and HIV control programmes and a lack of tools to diagnose and treat TB in HIV patients and;
- Newer formulations and combinations of drugs are often not available or registered in developing countries resulting in a lack of access to the best drugs that are available.

A related issue to the availability and cost of drugs relates to the form ARV drugs take i.e. whether they are patented and so registered to the company that made them who have sole rights to produce and market them (such as those listed in Box 5) and generic (non-patented) variations which are significantly less in cost. Generic drugs have reduced the cost of first line drug regimens (as opposed to second line regimens which are given commonly when first line drugs do not work as a result of resistance or TB) by 99% to an average cost of US\$132 a year per patient. 50% of those taking generic drugs are taking drugs produced in India. Since 2005 India has started enforcing Trade Related Intellectual Property Rights (TRIPS) legislation which subject new drugs to up to 20 years patent protection. Groups such as MSF argue that this has the potential to drastically effect drug supplies to HIV patients around the world, including in Africa, through increased prices (www.msf.org). Efforts such as WHO and UNAIDS' '3x5' initiative and William J Clinton Foundation's collaboration with drug manufacturers are however improving drug access in Africa.

Box 5: HIV drugs

Each type, or "class", of ARV drug attacks HIV in a different way. There are four main types of drug currently available:

- The first class of anti-HIV drug was the nucleoside reverse transcriptase inhibitors, also called "nukes". These drugs work by stopping the HIV genetic material being converted from RNA into DNA. Examples of such drugs are AZT (ZDV, zidovudine, Retrovir®) and Tenofovir (Viread®).
- Another class of drug blocks the same step of the life cycle, but in a different way. This class is the non-nucleoside reverse transcriptase inhibitors, or NNRTIs. Three NNRTIs have been approved: Nevirapine (NVP, Viramune®), Delavirdine (DLV, Rescriptor®) and Efavirenz (EFV, Sustiva®).

- 3. The third class of antiviral drug works at the time when the new virus within the body matures and blocks the raw material for new HIV virus from being cut by the protease enzyme that enables it to be assembled into a functioning virus. Ten protease inhibitors have been approved.
- The newest class of ARV drug includes fusion inhibitors. They prevent HIV from attaching to a cell during one of the first stages of the HIV life cycle. Only one fusion inhibitor has been approved: Enfuvirtide (T-20, Fuzeon®)

Source: Adapted from www.aids.org/Factsheets/403-What-is-Antiviral-Therapy.html

3.2.3 Microbicides

In the absence of a vaccine, novel biomedical methods for the prevention of HIV transmission such as microbicides are being seen as an important potential weapon against HIV infection. "Microbicides have the potential to give many women in developing countries the power, for the first time, to control their risk of contracting HIV and other sexually transmitted diseases" said Hilary Benn, the UK's international development secretary. Jonathan Weber, professor in genito-urinary medicine and communicable diseases at Imperial College London, backed that view: "We desperately need new methods to prevent HIV transmission in the face of rising prevalence of infection globally. "As we have still not been able to develop an effective HIV vaccine, vaginal microbicides are now the most promising bio-medical intervention for the prevention of HIV infection on the horizon." (BBC news Tuesday, 23 March 2004).

Microbicides are chemical agents with the potential to be used topically by women within the vagina to prevent HIV and other sexual transmitted diseases. Candidate agents that block the HIV virus binding to cells currently being investigates include several high molecular weight anionically charged sulphated polymers such as PRO 2000 (a naphthalene sulphonate polymer). PRO 2000 has been extensively studied in vivo and is now in phase III trials in women at risk of HIV infection in Africa. In addition, research attention is being directed at the possibility of using oral antiretroviral therapy, specifically tenofovir, for pre-exposure prophylaxis (PrEP) to prevent HIV infection (Weber et al. 2005). As of June 2008, there were 11 candidates in clinical development, three of which were being evaluated in ongoing phase II/IIB or phase III trials (see Table 4).

Table 4: On-going microbicide clinical trial projects					
Phase	Candidate	Partners	Countries		
3	PRO 2000/5 gel	Indevus, MRC, DFID (Funder)	South Africa, Tanzania, Uganda, Zambia		
2B	Tenofovir gel	CAPRISA, USAID, LIFElab, Gilead, FHI, CONRAD	South Africa		
2/2B	PRO 2000/5 gel (P) and BufferGel®	NIAID, Indevus, ReProtect	Malawi, South Africa, United States, Zambia, Zimbabwe		
	Dapivirine (TMC120) gel	IPM	Belgium		
	Ethanol in Emollient Gel	NIAID	Kenya		
	HEC/CS/N-9†	CONRAD/USAID	USA		
	Tenofovir/PMPA gel	CONRAD, IPM/USAID	Dominican Republic, United States		
1	Tenofovir gel	NIAID	United States		
	UC-781 gel	NIAID, CONRAD	United States		
	UC-781 gel	UCLA, NIAID, CONRAD	United States		
	UC-781 gel	CDC, Thailand Ministry of Health, CONRAD	Thailand		
	UC-781	CONRAD	United States		
	UC-781	CONRAD, CDC, Emory University	United States		
	VivaGel™ (SPL7013 gel)‡	DAIDS/NIAID, NICHD, Starpharma	Puerto Rico, United States		
N/A	Placebo ring±	IPM	Kenya, South Africa, Tanzania		

Source: http://www.global-campaign.org/candidates.htm. Accessed 15 August 2008

Global Partnerships and networks of collaborators enabled such a rapid development of the field. The Alliance for Microbicide Development, an alliance of scientists, product developers and advocates, began in 1998 to coordinate and promote investment in, and development of, microbicides. Four years later saw the formation of a public-private partnership, the International Partnership for Microbicides (IPM), to assist with financial and regulatory issues.

Partnering with academia and industry is helping to move science along much more rapidly

than any single group could accomplish alone. Advocacy has increased and financial support, prompted by the Bill and Melinda Gates Foundation, has increased from national governments, WHO, European Union for finding a vaccine. A structured technology platform like MMV or IPM that combines different disciplines and expertise to facilitate understanding the biology of difficult diseases, has accelerated the discovery of promising new mechanisms and compounds.

3.3 'Social' Technology Innovations

Ensuring successful innovation of generic and disease specific technologies as outlined in Section 1 is not straightforward. The organisational and institutional mix within which technologies are produced and distributed also requires attention. Our mapping exercise and review of the literature highlighted the importance of what we term 'social technologies'. It argued for the importance of a systemic approach to technological innovation. It is important to consider integrated approaches that take into account the whole innovation cycle and not only discrete aspects of it at any one time. The first step towards this, and as pointed out by many of the survey respondents is, the need for better health systems.

3.3.1 Health systems

David Weatherall and his colleagues in the DCP2 report write "As well as the mainstream biomedical sciences, research into providing health care for the future will require a major input from the social and behavioural sciences and health economics." Although not a technological advance as per the biomedical advances discussed above, the importance of functioning health systems can be seen as a 'social technology' that has the potential to address Africa's health challenges in a way biomedical technological advances cannot. This is because, as one respondent to our survey put it, "the strengthened health system is the "magic gun" for all the "magic bullets" that will be developed." A strong health system (the institutions and mechanisms within which healthcare is produced, financed, governed and provided) is required for all the biomedical technological advances to succeed.

Many developing countries, particularly in Africa, suffer from health systems that lack resources (funding, infrastructure, personnel) and knowledge (skilled personnel). This has implications on how medical research is conducted, what health technologies are produced as well as when and in what manner these technologies are made available and accessible to those that need them. Take the example of HAART used at the beginning of this study. HIV/AIDS as a disease is evolving all the time, constant research is required to ensure that drugs that are available to treat the disease are effective. Research that considers the effectiveness and efficacy of AIDS drugs is being carried out in research institutes in a number of African countries but a few such as the Kenya Medical Research Institute (KEMRI) have sufficient trained staff and access to technology to measure CD4 counts, viral loads and drug resistance. And even here there are issues around ensuring a pool of well-trained researchers are available from the countries educational establishments.

KEMRI benefits from international partnerships with groups such as the Wellcome Trust and Swiss Tropical Institute which assists in capacity building activities but not all countries have these links. And although the research is being conducted not everyone in Kenya has access to AIDS drugs when they need them. This is due to issues on the demand and supply side. At times there is not the supply of drugs that are required and where supplies are available they are not able to guarantee the same drug regimen is available. This makes it difficult to ensure compliance with drug taking as it becomes confusing for AIDS sufferers as to which drugs to take, when. More specifically, however, on the demand side are issues of cost. Very rarely are anti-retroviral drugs given for free and when they are the cost of purchasing the drugs to the provider can mean that only the cheaper older lines of the drugs are affordable.

Strengthening health systems requires an in-depth analysis of all aspects of their performance (financing, production, governance and provision). In order to 'fix' health systems it has been suggested that an integrated and systemic approach is required:

"institutions and agencies concerned with improving the currently grim health outlook in Africa must take a more systemic approach -- turning at least some of their attention to apparently mundane matters within the health system, such as infrastructure, training, capacity building, human resources, and health planning, that form the foundation for future advances in the well-being of Africa's citizens." (De Savigny et al. 2004)

A well known example is the work of TEHIP in Tanzania which worked to strengthen district health care planning activities through linking data collection techniques regarding burden of disease with budget calculations along with capacity building of staff in the techniques. This project took an integrated approach to strengthening the health system in order to address the district's health challenges.

Another example of strengthening the health system through integrated approaches is provided by Ethiopian malaria control activities. Supported by several development organisations, the Ethiopian government is undertaking an integrated malaria control approach. The emphasis is not simply on provision of anti-malarial drugs to treat malaria but on prevention through the distribution of insecticide treated mosquito bednets and its working to strengthen treatment activities through the use of rapid diagnostic test kit provision for health posts as well as recommending and improving access to an artemisinin based drug for which the malaria parasite has not developed resistance yet.

Strengthening and building effective health systems is only one part of the answer. It is important – as stressed in Section 1 – to build up the whole process to ensure technologies move from bench to bedside. This requires a holistic approach taking the idea of an innovation cycle as the starting point for more problem-orientated innovation that stresses the linkages and disconnects between the different actors and institutions involved in the whole innovation

process. Most important for health innovation is to strengthen the links – to work out how to build better links via innovation practices – that is, to work out how integrated approaches can solve health problems. Strengthening one element in isolation from the others is a means to an end, but not the end itself.

In stressing the importance of social technologies it is not possible to put together a list of what is required; there is a lack of evidence as to 'what works' unlike for many of the diseases currently affecting the poorest populations in Africa while 'what works' in one place may not meet the requirements in another. Attempts have been made to outline what is required to ensure a functioning health system (WHO 2001; Jamison et al. 2006b) in terms of the determinants or 'pillars' that make up the 'system': information and infrastructural inputs, management, human resources and financing. Thus some countries may require an emphasis being placed on data collection in order to match health system and health research responses to disease burden or a better medicines supply chain. Other countries may require stronger leadership and policy support or ways to retain and train medical staff. Then there are countries that need to balance the needs and financing of public sector health care provision with the often used but unregulated private sector suppliers. Many countries require a combination of these activities. This also requires - particularly when a holistic innovation systems lens is used - interaction with those placed outside of the realm of 'health' or even 'research' and 'science and technology'. A functioning health system requires interactions with systems of education, finance, regulation and law, politics etc.

3.4 Potential and Impact of New Technologies on Health Systems

In the previous section we listed three broad types of technological advance with potential to address Africa's health challenges. These all have the chance to reduce the burden created from diseases such as HIV/AIDS, TB, malaria and cholera etc. To be successful in the introduction, adoption and development of any of these technologies it is however necessary to consider various technological constraints affecting their implementation and development. At the same time, and as highlighted by the implications of 'social technologies', there is a need to consider the importance of building robust health innovation systems that provide a way to create enabling environments that will empower the integration of new science and technology with the potential to address Africa's health challenges.

The successful introduction and uptake of technologies relies on a complex relationship with social, economic and political forces. There are numerous examples of technologies that have not successfully been introduced or produced due to inabilities to understand or contend with forces external to the technology itself. AIDS vaccine research has been constrained by scientific uncertainty while the female condom has been plagued by a combination of its design and subsequent attitudes towards it. Even where a product is available and efficacious, for example in the case of polio vaccination efforts, traditional beliefs and attitudes amongst communities, reiterated at times by community leaders, has also hampered progress. Thus, it is important to consider both:

- 1. Constraints affecting each technology in its advance;
- 2. The wider enabling environment constraints.

These will now be discussed in turn.

3.4.1 Constraints affecting a technology's progress

Sequencing of genomes as a technology has great potential in providing the first step towards addressing the health challenges faced by Africa. As highlighted above, the opportunities afforded by being able to isolate and understand individual genes has provided the catalyst for breakthroughs in diagnostic PCR technology as well as malaria drug development. Unfortunately issues exist regarding the capacity of African science bases to become involved in this technology. However a number of African countries are using and developing the technologies, such as PCR, that result as a consequence of information gained from sequencing genomes. As was highlighted above, the Top 10 report placed diagnostic tools as having the greatest potential to address health challenges. This is because many diagnostic tools currently exist and are in use throughout the world. PCR technologies and new developments in diagnostic testing are transforming the speed at which disease diagnosis and detection occur. However the cost of these technologies sometimes makes them less available to developing countries. A variety of new recombinant drugs and vaccines are available and some cost less to produce than older varieties, however, recombinant vaccines are still not available for HIV, malaria and TB (although progress is being made) and issues of resistance hamper some development efforts. One of the biggest issues affecting drug and vaccine development however is their delivery systems. This issue is linked to the need for stronger health systems, the 'social technology' listed above. Allied to the need for stronger health systems is an increasing awareness of the social determinants of health⁵ of which hunger and poverty is one. The potential offered by GM crops as a means of increasing (more nutritious) food production is seen as a means of working to reduce hunger and poverty in developing countries.

Thus each of these different technological advances are at different stages of existence and have differing potential impact in terms of reducing burden of disease. This is not only in terms of their impact in controlling disease through providing treatments but also in terms of prevention activities. The TEHIP example given above provides a case where decisions regarding what areas of disease control should be focused on where weighed against budgetary constraints and current burden of disease within the local health districts. These kinds of priority setting issues are important when considering which of the above technologies has the potential greatest impact on Africa's health challenges but made more difficult by the lack of predictability in science (see below). The Council on Health Research for Development (COHRED) has worked extensively with the Alliance for Health Policy and Systems Research to consider successful priority setting of health research agendas following the work of the Ad hoc Committee on Health Research⁶. If choices have to be made as to which of these technologies a country should focus its attention undertaking priority setting activities are the first step to take as exemplified by the South African government who set up a foresight process following the identification of research priorities using the Essential National Health Research approach.

3.4.2 Enabling environment constraints

The potential these technologies have to address Africa's health challenges is dependent on a number of constraints that they face at the various stages of their development. A number of these have already been made mention to above and have also been covered in Chataway et al. (2007). These and other constraints that affect the impact these technologies will have on addressing Africa's health challenges will now be discussed in a little more depth.

The unpredictability of science

A very important constraint can be the strict process of priority setting. This can limit the areas where major advances are discovered. Science is not always predicable but can occur very much the result of chance. This was the case for Jenner in discovering that smallpox could be vaccinated against using cowpox and how, more recently, penicillin was discovered. Science requires a degree of freedom to explore but also a degree of connectivity as science also requires interaction and dialogue between scientists and researchers. A further science related constraint is the more practical constraint faced by rising drug resistance by pathogens. There is a need for flexible policies to work with these to ensure for example that new drugs and vaccines can be introduced as and when required before resistance comes to dominate. Secondly, science is not always the responsibility of, or possible at, national level. Leading edge science (like a new vaccine for HIV/AIDS) relates at times to a global risk, not a national one. However, getting local capacity to test for vaccines and drugs is a national level activity. There needs to be the flexibility, integration and understanding to provide for this.

Skills availability

The continent suffers from an overarching constraint in respect of the skills sets available in the areas of health and science and technology. In R&D activities there is a lack of trained staff to work in laboratories and little opportunity for such experience in the educational setting. In the healthcare setting there is an increasing lack of staff who are willing to work when more money can be made working in other occupations or other countries. This reduces the capacity, particularly in the public sector, for healthcare providers to distribute and use these technologies. There are also gaps in capacity at the policy level which impacts the quality of the decision making and governance process within which these technologies are advanced. The heavy burden HIV/AIDS is having on the continent is also playing a part in affecting the numbers of the health and science and technology workforce. The issue of skills is not simply one of individual level human capital, in many instances there is a need to build team-orientated and project management approaches; there are times when groups of experts with various specialisms are required to ensure problems are overcome in a clinical, R&D, project management and policy level.

Make or buy decisions

In the case of diagnostics and some vaccines and drugs the technologies are available and decisions have to be made about whether it makes sense to buy technologies or develop domestic manufacturing capabilities. South Africa, Kenya, Nigeria and Egypt have built strong diagnostic, drug and vaccine manufacturing capabilities at present. However, ensuring manufacturing capability requires serious financial investment and the prospects of markets. There are also issues regarding economies of scale of production that make it difficult to ensure the sustainability of manufacturing capability for some drugs in Africa. This is one reason the World Bank has argued that production will remain in the hands of a small number of large manufacturers and as such most countries should buy in pharmaceutical products such as ARVs produced from elsewhere (Rovira 2004). However, a number of firms are starting to produce generic ARVs particularly through joint ventures. One example is Quality Chemicals in Uganda produce ARVs in a joint venture with Cipla Pharmaceuticals of India from June 2007 (Anderson 2006).

The same decisions come into play when decisions are made regarding the development of a country's own basic research and development facilities. In trying to encourage the development of R&D South Africa has set up innovation hubs, centres around which incentives and subsidies are given to companies wishing to invest to start up an R&D company, particularly in the area of biotechnology. In other places public-private partnerships are emerging that are providing a means to build scientific capacity on the ground (Chataway and Smith 2006) suggesting solutions can be found to this constraint around a decision to get involved in production of R&D.

Purchasing power

Constraints relating to purchasing power can be found in both the supply and demand. On the supply side there are constraints in terms of ensuring that the infrastructure and equipment are able to be purchased to do good quality basic research and to have first class manufacturing capability. Recently Zambia announced that it was unable to afford new diagnostic tools and was having to rely on older methods to conduct medical tests (Ngandwe and Tallaksen 2006). As has been highlighted above public private partnerships have been suggested as a means of moving forward in this area. However the impact of the private sector on health care has been, and continues to be hotly debated (Soderlund 2003). Similarly there are constraints created from purchasing power issues on the demand side. In many countries there is a lack of purchasing power within the general public who

have to access healthcare services. These exacerbate issues of equity of, and access to, healthcare.

Regulation and quality control

Whether a decision is made to conduct basic research or manufacture in-country or import ready produced technologies from outside, products are required to be of high quality and well regulated. Unfortunately, regulatory and quality assurance networks tend to be weak in many countries and regionally. The situation is improving in areas such as clinical trials of new drugs and vaccines where a demand is being placed on all those involved having been trained in Good Laboratory Practice or Good Clinical Practice and some laboratories have been given international accreditation to conduct clinical trial work e.g. the Kenyan AIDS Vaccine Initiative in Kenya. However, the quality of many manufactured drugs both those imported and manufactured locally can be poor. The efforts of Dora Akunyili, Nigeria's Head of the National Food and Drug Administration and Control, show that improvements can be made but it has been argued that there is a need for more emphasis on cooperation and training to build regional regulation and to use WHO's pre-qualification process to ensure quality, safety and efficacy of medicines (Gray 2004).

Policy environment

Having policy makers who understand the value of a functioning health system goes a long way towards ensuring that goal. Similarly, it is important that policy makers understand and value the potential of these technologies in order for them to push the requirements needed to ensure these technologies are produced and delivered. Secondly, there is a need for them to work together to realise that it is not just an issue of science or of healthcare delivery but of gaps within a wider system of health innovation (see Chataway et al. 2007).

Access issues

One aspect of the access issue relating to the last element of the innovation cycle is how to ensure compliance with treatment doses and regimens by both medical staff and patients themselves. One mechanism to overcome this has been the development of pre-packaged drugs to aid correct treatment action. This relates to a wider issue of general awareness and understanding regarding technology. A number of studies have found that communities and policy makers alike may not understand the mechanisms of technological advance, say for example the process of clinical trials (cf. Leach and Fairhead 2005). There can also be little understanding regarding the need for, or value of, new technologies. Gaining understanding is not the only issue that hinders good delivery. Ensuring any of the technologies listed above are delivered requires a combination of constant and reliable delivery mechanisms, safe and regulated supplies as well as trained staff to deliver and use the technologies. These require a functioning and effective health system i.e. a system that is able to effectively finance, produce, govern and deliver healthcare and its related activities. This also makes

clear that access issues are multiple and are not just limited to the last stage of the innovation cycle. Access is required to all information, skills and personnel throughout the innovation cycle. Without these it will not be possible to build functioning and effective health innovation systems.

Thus although these technologies have much potential to address Africa's health challenges and many are available for use and delivery having been successfully developed there are a number of constraints that hold up their ability to address these health challenges. The next section will consider these issues and come up with a number of policy recommendations.

4. Conclusion and Policy Recommendations

A very significant momentum has built up in relation to the problem of neglected diseases in Africa and particularly in using scientific and technological tools to further capacity to treat disease and ill health. In the last decade there has been an explosion of new initiatives in this area. The challenge now is to make sure that this momentum is continued and leads to the construction of the kind of capacities that will enable Africans to benefit from good health on a more sustained basis.

Below we have put together some of the main policy recommendations of ways African countries can move forward. There is no universal 'one size fits all' formula. Nothing that has been outlined in this study may be suitable to be taken up by all countries in Africa.

Successful development of health related technologies or technology based health products requires productive organisations and institutions, it requires the right 'social technology'. It requires a consideration of all issues and activities that relate to innovative technology in a systemic way. It is necessary to consider not only the constraints affecting a particular technology's progress but also the wider enabling environment constraints listed in Section 3.4.

There is no one framework or model of activities that each country can undertake nor is there a single checklist of areas that each must consider. Each country, each initiative and each new technology has, and will, evolve in individual and quite separate ways with different types and strengths of linkages and interactions being made that both stimulate and detract from innovation.

One set of key and current policy issues for African countries is where future improvements might be made quickest and to best advantage. Deciding which scientific and technological advances to choose and how best to provide the 'social technology' to aid their development requires strong strategic planning and priority setting activities.

Undertake strategic planning and priority setting that starts with foresight activities to identify

the best mix of scientific and social technologies.

In thinking about health innovation systems a move is made from thinking in terms of discrete areas of activity and towards the wider architecture of actors and linkages required to ensure a technology is developed and/or introduced. This creates a means of ensuring not only that technology is developed or delivered but that it is also taken up and used – something that currently is not often considered. Currently, an emphasis is often placed on getting treatments out using top-down approaches that tend to ignore the complexity on the ground when attempting to introduce a technology.

Create Health Innovation and Development Platforms

Health Innovation and Development Platforms would most likely be problem-oriented platforms rather than science-led or health system pulled. They would build on, but also go way beyond the idea of cross-functional teams in product development. In the same way that the new global initiatives for technologies – e.g. for vaccines or new drug regimes for TB, have emerged, these new platforms would be ambitious and would need to include science, technology and innovation capabilities as well as health systems capabilities. They would be dedicated to improving coordination and understanding of different product development and treatment efforts and would be a way for the African Union and NEPAD to play a direct role in policy making in the development of health innovation and coordinated capacity building in health systems. These platforms will need to be very ambitious but are very necessary if the 'problem-orientation' is not to stop with new innovative products that cannot be delivered. Designing new health delivery systems would then be a part of the innovation process reducing the disconnect between innovation of technology and development of healthy populations.

Platforms should allow for regional and international level activities

In order to access all the resources and capabilities a platform might require there would need to be mechanisms through which linkages could be made to regional and international actors. In many instances there are likely to be large overlaps and similarities between different country's platform mechanisms and objectives. There would need to be explicit approaches to build more universal principles and to learn from one location to another so as not to have to 'reinvent the wheel'. One way of achieving this would be to regionally organise the platforms to make the most of regionally available expertise. The NEPAD and African Union frameworks provide one mechanism through which to organise such platforms. Similarly the ability to make linkages with international organisations and countries outside of the region will need to be encouraged.

Notes

These are defined as those diseases that predominately affect the poorest populations who lack the purchasing
power to buy the medicines needed. The diseases also receive less attention from international pharmaceutical
companies and donor funding. There are increasing calls that this definition be used in a narrower sense to refer
only to a list of diseases (excluding the 'big three' of HIV/AIDS, malaria and tuberculosis) such as schistosomiasis,
lymphatic filariasis, onchocerciasis, and trachoma (Hotez et al. 2005).

- The definition of 'biotechnology' used throughout the reports and our survey relates to a wide definition of biotechnology as any technological application of biological or living organisms.
- This is usually defined to refer to technologies that facilitate, or are facilitated by, communication and social processes. Our use of this term differs slightly in that we denote an organisational and institutional mix that is one part of the process of ensuring successful innovation.
- 4. Recombinant DNA (rDNA) technology is a field of molecular biology. The practice of cutting, pasting, and copying DNA dates back to Arthur Kornberg's successful replication of viral DNA in a breakthrough that served as a proof-of-concept for cloning. This was followed by the Swiss biochemist Werner Arber's discovery of restriction enzymes in bacteria that degrade foreign viral DNA molecules while sparing their own DNA. Arber effectively showed geneticists how to "cut" DNA molecules. This was followed by the understanding that ligase could be used to "glue" them together. These two achievements launched rDNA technology research.
- 5. As evidenced by the setting up of the WHO Commission on Social Determinants of Health.
- See www.cohred.org and www.alliance-hspr.org & the work of WHO's Ad hoc committee on health research concerning future intervention options e.g. 1996 report, "Investing in health research and development" Geneva: WHO.

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CHAPTER 3

Indigenous Knowledge (IK) and Innovation Systems for Public Health in Africa

H.O. Kaya

Abstract _

The majority of people in Africa, especially the poor, depend on indigenous knowledge and innovations (IKIs) for survival. Current research and development (R&D) in sub-Saharan Africa shows that nearly 65% of the poor in this region depend on traditional medicine for their basic health care needs. Most of the governments in Africa are increasingly recognizing the importance of IKIs for sustainable community livelihood and development. However, existing policy and legislative frameworks are ineffectual because they do not fully protect and promote the use of IKIs. Thus the benefits of Intellectual Property Rights (IPRs) have not trickled down to the local communities. The situation is compounded by the limited number of researchers needed to sustain R&D in IKIs, and that most of the R&D still depends on donor funding. Furthermore, the use of reverse pharmacology has not been exploited in ways that would help to develop costeffective plant medicines. The paper proposes the following recommendations: first, African countries should develop policy and legal frameworks which will, among other things, promote value adding, benefit sharing, the use of reverse pharmacology, increase funding for R&D activities, as well as promoting regional and international networking. Secondly, there is a need to increase the number of researchers in the field of IKIs. Finally, in order to broaden and sustain public awareness, IKIs should be mainstreamed into the formal education systems at all levels.

1. Introduction

1.1 Definitions of Indigenous Knowledge and Innovations

Available literature on indigenous knowledge does not provide a single definition of indigenous knowledge (IK) and innovations. This is largely because the topic is broad and so lends itself to different perspectives across the various disciplines. Indigenous knowledge (IK), sometimes referred to as traditional knowledge (TK), or just local knowledge (LK), generally refers to the age-old, long-standing traditions and practices of certain regional, indigenous, or local communities. Traditional knowledge also encompasses the wisdom, knowledge, and teachings of these communities, most of which has been handed down from one generation to the next, or from person to person. While some forms of traditional knowledge are expressed through stories, legends, folklore, rituals, songs, and even laws, others may be expressed through other means. This knowledge distinguishes one community from another, often reflecting each community's interests, with some communities depending exclusively on their traditional knowledge for their survival.

According to the Convention on Biological Biodiversity (CBD) adopted in Rio de Janeiro in June 1992, IK refers to "the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles" as well as "indigenous and traditional technologies" (CBD Art. 8(j) and 18.4). The main charateristics of such knowledge is that it is (i) held collectively, although certain types of TK may be the purview of specific individuals or subgroups within the community; (ii) largely undocumented and hence transmitted orally from generation to generation; and (iii) an evolving form of knowledge according to which communities respond to new challenges and needs. Alternative definitions are provided in Box 1 below.

Box 1: Sample Definitions of Indigenous Knowledge

IK and innovations refer to a distinctive body of knowledge, skills including practices, and technologies that have been developed by local communities over many generations outside the formal educational system, and enable communities to survive in their specific natural and cultural environments (Mascarenhas 2004).

Indigenous knowledge and innovations refer to the knowledge belonging to a specific ethnic group, and is thus 'knowledge at the local knowledge that is unique to a given culture or society and forms the basis for local-level decision-making in agriculture, health care, food preparation, education, natural resource management, and a host of other activities in rural communities' (Lukaba 2007).

Indigenous knowledge is the information base for a society, which facilitates

communication and decision-making. Indigenous information systems are dynamic, and are continually influenced by internal creativity and experimentation as well as by contact with external systems (Flavier et al. 1995).

Indigenous innovation is the process by which individuals or groups discover or develop new and better ways of managing resources, and of building on and expanding the boundaries of their indigenous knowledge. This means that successful local innovations often involve new ways of community organization, or new ways of stakeholder interaction (Peteru 1995). The World Health Organization (2000) defines public health as an aspect of health services concerned with threats to the overall health of a community. It generally includes the surveillance and control of infectious diseases and the promotion of health behaviors among members of the community. Public health therefore is not simply about the absence of disease but entails mental, physical, and emotional well-being.

Sindiga (1995) states that plants and animals which have been used as sources of medicines in both ancient and modern times continue to play a vital role in health care systems of local communities. Wild and domestic animal components such as hooves, skins, bones, feathers and tusks form essential ingredients in the preparation of curative, protective and preventive medicine. It is thus not surprising that a significant portion of the currently available nonsynthetic and/or semi-synthetic pharmaceuticals in clinical use is comprised of drugs derived from plants, microbial, animal and mineral products.

In this chapter, therefore, the role and opportunities of IKIs in the African public health care systems are discussed. In order to promote their integration in modern public health care systems and also to realize their full potential in improving public health care in Africa, some policy recommendations are made at the end of the chapter.

1.2 The Value of Indigenous Knowledge and Innovations in Public Health Care

The World Health Organization (2000) estimates that the majority of the population in most non-industrial countries, including Africa, still relies on traditional forms of medicine for everyday healthcare. Medicinal plants and, to a lesser but important extent, animal products, also form the material for these traditional medical practices. Kitula (2007) states that traditional health and medical systems are based on world views or cosmologies that take into account the mental, social, spiritual, physical and ecological dimensions of health and wellbeing. This is so because traditional health and medical systems have organized frameworks for classifying plants, animals, landscapes and climatic conditions in relation to their effects on health and diseases.

Furthermore, in most traditional societies, food and medicine are often used interchangeably;

while food is medicine, a good diet is the basis for good health. Among the Batswana, for example, indigenous vegetable food plants such as "Lerotho" (Spider Flower), "Thepe" (Amaranth) and "Monyaku Makopuntji" (Pumpkin Mellows) are also used as medicine against various sicknesses (Pitso 2008).

It is on the basis of this that indigenous health and medical knowledge in Africa continues to be the basis for developing integrated modern and indigenous health and medical care programmes. For instance, conservation and horticulture programmes are emerging in different parts of the continent as vital strategies for the revitalization of indigenous health and medicinal practices. The IKS Centre of Excellence at the North-West University in South Africa, in collaboration with local communities, schools and the Council for Scientific and Industrial Research (CSIR), is facilitating the establishment of Indigenous knowledge-based vegetable and herb gardens in various local communities in the North-West Province (South Africa).

Kaya et al. (2007) emphasize the need for coordinated efforts to develop policies, mechanisms and also to make available the necessary resources for preserving and protecting the rich African biodiversity which provides vital health and medical care for the majority of the world's population.

Indigenous knowledge is not only valuable for the sustainable livelihood of African local communities but also very useful for the modern pharmaceutical industry and agriculture.

Ten Kate and Laird (1999) have indicated that biogenetic resources and their associated IK provide significant inputs for pharmaceuticals, cosmetics, agriculture, food additives, industrial enzymes, bio pesticides, and personal care industries. The contribution of IK to modern medicine has been estimated to contribute nearly US\$43 billion. This was the market value of plant-based medicines sold in OECD countries in 1985. The commercialisation of IK to inform drug development is widespread world-wide, as indicated in Box 2 below.

Box 2: Examples of commercialization of traditional medicines for public health

A significant part of the US\$60 billion world market for herbal medicines is based on indigenous knowledge. For example, India currently exports more medicinal plants than herbal products, due to difficulties in getting formulations cleared by the United States Food and Drug Administration (FDA) and nonacceptance by medical insurance companies (particularly in Europe). However, the situation is changing such that India is entering world markets for herbal products aggressively and significantly. India's exports of medicinal plants and herbal products are about US\$8 million annually and are expected to grow. The Indian Maharishi Ayurveda Products is planning to enter the roughly US\$4 billion Japanese market with a portfolio of 120 ayurvedic products comprising food supplements, aromatic oils, cosmetics and body care products.

Source: Muya (2006)

The World Health Organisation (1999) has shown that nearly 80 per cent of the world's population depends on traditional medicine for primary health needs. For example, in India, 600,000 licensed medical practitioners support the classical traditional health systems and over one million traditional community-based health workers (Nuar 2001). It is also generally observed that two thirds of the world's population could not survive without the foods provided through indigenous knowledge related to plants, animals, insects, microbes and farming systems. In sub-Saharan Africa, about 90 per cent of the food is produced using customary farming practices (Daar et al. 2002).

The World Bank (2004) has also shown that in most African countries, traditional medicine is used by nearly 70-80 percent of local populations to deal with their basic health care needs. There is scientific evidence to support the fact that over 120 pharmaceutical products are derived from plants, and 74% were first utilised by indigenous cultures. A few examples in Africa are provided in Box 3.

Box 3

Box 3 a: Bioprospecting of the Hoodia Plant (Rodolo, 2007)

The San people of Southern Africa found in Namibia, Botswana, Angola, Zambia and Zimbabwe have for many centuries used the hoodia plant as an appetite suppressant, especially during hunting expeditions where little food was available for many days. The plant received international interest since 1937. In 1997 the CSIR licensed an active plant isolate. P57 to a British biotech company, Phytopharm, which conducted double blind clinical trials of the chemical, confirming its appetite suppressing qualities. The Working Group of Indigenous Minorities in Southern Africa (WIMSA), representing the San people in the region, and representatives of CSIR in June 2001 agreed that CSIR will pay 6% of all milestone payments (estimated at \$0.9-\$1.4 million) received from Phytopharm, and 8% of all royalties from products developed from P57. The royalties to the San people will be paid into a Trust Fund, i.e. the San Hoodia Benefit-Sharing Trust, which has representatives of CSIR, the regional San Councils, WIMSA, and an observer from the South African Department of Science and Technology. The drug has since gone through phase IIa trials and has clinical promise in the growing market for anti-obesity compounds.

Box 3b: Niprisan® Production in Nigeria (World Bank, 2004)

The National Institute for Pharmaceutical Research and Development, Abuja, Nigeria conducted scientific and clinical investigations on the use of standardized herbal extract for treating sickle-cell disorder. The herbal medicine called Niprisan showed very good efficacy and safety profiles such that it was subsequently licensed to an American company for multiplication. The product was officially launched in May 2006 by the government of Nigeria. Evidently, the experience with Niprisan shows that the natural multi-component preparation is necessary for the efficacy and safety of herbal medicines

Box 3c: Endod: The African Soap Berry (WHO, 2002)

Dr. Aklilu Lemma and co-workers at the Institute of Pathobiology, Addis Ababa University investigated the molluscicidal properties of the montane forest shrub, Phytolacca dodecandra (Endod, also known as the African soapberry) in 1964. The crushed fruits and leaves have traditionally been used as soap for washing both clothing and the body. Dr Lemma observed that the snails which are vectors in spreading the bilharzia disease among people were absent in streams where people washed clothing with Endod. The team identified saponins as the active ingredients for both the lathering, and the molluscidal properties. The saponins were biodegradable and harmless to most other forms of life. In 1990, while at the University of Toledo in the United States of America, Dr. Aklilu Lemma suggested that Endod could perhaps be used to kill zebra mussels in the Great Lakes area of the United States and Canada. When this hypothesis was tested, the University of Toledo scientists found that the saponins were effective and the use of Endod to kill zebra mussels was patented by the University of Toledo to work in 1995 (US Patent No. 5,252,230).

The World Health Organisation (2002) has further shown that Indigenous knowledge and innovations (i) contribute to problem solving strategies for local communities, especially the poor; (ii) help the poor meet their food requirements (iii) offer local opportunities for strengthening local experiences, judgments and practices and thereby increasing the impact of development programmes; (iv) enhance indigenous approaches to development, leading to greater sustainability; and (v) form the building platform for the empowerment of the poor.

2. Current Status of Research and Development (R&D) in IK and Innovations in Africa

Several natural products are undergoing rigorous scientific study for remedies traditionally

used by various indigenous cultural groups, most of them being plant-derived. It is widely accepted that traditional medicinal uses (ethno medical information) of plants inform the presence of a biologically active constituent in a plant. Thus traditional medicinal uses constitute 'leads' that are a shortcut to the discovery of modern medicines. Generally, most often cited work indicate that from 119 known useful plant-derived drugs, 74% of the chemical compounds used as drugs have the same or related use as the plants from which they were derived (Farnsworth 1990; Alves and Rosa 2007).

There are several efforts in Africa which are targeted at R&D on IK and innovations for improved public health care. For example, the South African Government has established the National IKS Office (Department of Science and Technology) which is responsible for sponsoring the Medical Research Council (MRC) Indigenous Knowledge Systems Lead Programme (Rodolo 2007). The National IKS Office has disbursed financial support for cutting edge laboratory equipment for the validation of traditional medicine in areas of toxicity, efficacy and pre-clinical trials. Under this initiative, the processing of traditional medicines into capsules, tablets and creams is underway. (See Box 4 below)

Box 4: The Indigenous Knowledge Systems (Health) Lead Programme

The Medical Research Council of South Africa (MRC) has established the Indigenous Knowledge Systems [Health] Lead Programme (IKS) whose aim is to promote, develop and protect indigenous knowledge systems and its innovative systems of health through education, research and development, systems research and through policies that would be beneficial to all. The mission of the Programme is to promote and advance indigenous knowledge systems through research and development by making it a valued health model in the global environment and to redress health traditions, which until now have neglected health priorities and issues. The vision of the Programme is to become a centre of excellence in traditional medicines research, training and development both locally and regionally and to be competitive globally. Consequently, its specific objectives are (i) coordination and development of health research in indigenous knowledge, (ii) institutional and community networks and support, (iii) development of an enabling clinical trial environment, (iv) innovations and commercialization in traditional health systems, (v) policies governing intellectual property and benefit-sharing, (v) research programmes that are appropriate and relevant, and (vi) support and funding academic research

Source: Rodolo (2007)

Elsewhere, the Kenya Medical Research Institute (KEMRI) is working with traditional healers to develop antimalarials isolated from plants. The KEMRI scientists are testing and evaluating hundreds of plants being used to treat malaria at its Centre for Traditional Medicine and Drug

Research. Botanists from Kenya's National Herbarium are actively involved in this important endeavour (Kitula 2007).

In Tanzania, the Tanga AIDS Working Group (TAWG) collaborates with traditional medicines and bio-medical practitioners to combat the HIV/AIDS pandemic in various local communities. The TAWG is working with the Council for Scientific and Industrial Research (CSIR) in South Africa to validate traditional herbal remedies identified and used by TAWG. The World Bank IKS programme is facilitating the partnership (World Bank 2004).

2.1 R&D Challenges in IK for Public Health Care

Kimenyi (2003) has indicated that there are still gaps regarding how African indigenous knowledge and innovation systems impact on public health care. Research and development (R&D) activities in this area face numerous challenges, which include (i) finding an enabling and conducive environment for R&D, (ii) limited human capital and infrastructure, (iii) the absence of or declining funding for R&D; and (iv) limited exchange and networking within the south and with the north. These issues are discussed in detail below:

Enabling environment for R&D

Muya (2006) states that although policy and legal instruments exist in some African countries such as South Africa and Nigeria, most African countries have not created a conducive environment for promoting R&D in IKIs in public health care. Even in those countries with established policy frameworks, the implementations are still weak. Furthermore, the number of researchers in IKIs, which is a new field, is still relatively low. This is compounded by the absence of human capital development in this area. There are few academic institutions in Africa teaching IKS as a discipline at all levels (Ohenjo et al. 2006).

Funding of R&D

In most African countries, national governments are the primary sources of funding for research and development, with foreign donors and foundations largely contributing the bulk of funding. The private sector, especially pharmaceutical companies, is also usually active in terms of promoting programmes which offer opportunities for identifying medicines from the rich African plant bio-diversity (Nakashima et al. 2002). The World Health Organisation (2000) adds that, generally, most African countries invest less than 0.5% of their GDP on R&D. This affects the quantity and quality of R&D, scientific and technical education and training (STET), and science and technical services (STS). This is compounded by existing institutional weaknesses found at all levels of research and development.

Indigenous Knowledge and Innovation Exchange and Sharing

Although IK and innovations are readily shared among members of a community, sharing

across communities is limited. Further, since IK is predominantly tacit or embedded in practices and experiences, it is most commonly exchanged through personal communication and demonstration: from master to apprentice, from parents to children, from neighbour to neighbour, from priest to parish. Thus the process of recording, transferring and disseminating this form of knowledge is still a challenge (World Bank 2004).

Correa (2000) emphasizes that local, regional and international institutions have important roles to play in facilitating the effective and sustainable use of IK and innovations for public health care in Africa. For instance, building partnerships and networks at all levels, including community one, will support the protection and promotion of IKS, as well as facilitating the development of policy and legislative frameworks necessary for the coordination of IKIs across national and regional domains. The incorporation of IK and innovations in the school curricula will also ensure that the value and importance of IKIs is understood and appreciated among learners who will be equipped with the necessary intellectual and research tools to recognise, conserve and develop IKIs for sustainable livelihoods. The development and promotion of support institutions (including CBOs and NGOs involved in IKIs for public health and medical care) will also constitute an important strategy.

3. Indigenous Knowledge, Bio-prospecting and Benefit Sharing

Bio-prospecting, defined here as the quest for natural products exploited for commercial gain by pharmaceutical, agricultural and biotechnological industries, explicitly targets traditional knowledge holders. This is due to the increasing recognition that the accumulated indigenous knowledge and practices of indigenous communities are a powerful resource that can greatly facilitate the task of identifying useful new varieties of domestic plants or animals, isolating novel biological components, or developing innovative technologies and techniques for commercial use.

However, Neelakantan (2006) argues that such recognition has not resulted in the acknowledgement of the need to share the benefits with the local communities, especially the knowledge holders. The patenting of domestic plant varieties, traditional medical products and other biological resources whose identification and use are embedded in IK continue to be a source of grave concern for developing countries and indigenous communities. By giving foreign companies or individuals patents to exploit IKIs for commercial benefit, the entire process turns the owners of traditional knowledge into beggars.

Turmeric (*Curcuma longa*), for example, is an old traditional plant which has, for centuries, been used to heal wounds in India. The drug from this plant became a patented invention in the US. Consequently, it became illegal for Indians residing in the US to use turmeric for

this purpose. Similarly, a European patent on the fungicidal properties of the "neem" plant privatized the botanical knowledge of Indian farmers who have used this natural pesticide in their fields for generations. Consequently, both of these patents were revoked, but only after long and costly challenges were mounted by the government of India (Dutfield 1999).

Patents are only one of several legal instruments that constitute the current regime of Intellectual Property Rights (IPRs). In the case of indigenous knowledge holders, IPRs have been a source of problems, rather than being solutions. IPRs are expected to protect local communities against the interests of companies that engage in bio-piracy, that is, the unauthorized exploitation of biological resources and indigenous knowledge. In order to counter the granting of patents to foreign companies in ways that disadvantages indigenous peoples, the World Trade Organization has been taking action under the agreement on Trade Related aspects of Intellectual property Rights (TRIPS). However, nothing in the TRIPS Agreement has been expressly designed for the protection of indigenous knowledge. The World Intellectual Property Rights Organization (WIPO), for example, has recently created a commission on genetic resources, traditional knowledge and folklore, whose mandate involves the investigation of innovative measures to accommodate the exceptional characteristics of indigenous knowledge systems. Since IPRs protect knowledge by setting rules for their commercial exploitation, ironically they may merely facilitate the appropriation of traditional knowledge by the global marketplace. For a long time, biodiversity in both developing and developed countries has been accessed by outside researchers with little or no returns to conservation activities to local communities (Ng'etich 2005).

Following the development of CBD, issues of sharing benefits arising from bio-prospecting have become significant. However, until now, certain critical issues remain unresolved, particularly in relation to how to proceed with legalizing and formalizing the bio-prospecting process in ways that would ensure that bio-prospecting is done with the full consent of the originators of traditional knowledge (Possey 2002).

Muya (2006) adds that traditional medicine continues to be viewed by the pharmaceutical industry as a source of "qualified leads" in the identification of bioactive agents for use in the production of modern synthetic drugs. Bioprospectors express optimism that they can help to implement the 1992 Convention on Biological Diversity (CBD) by encouraging biodiversity, conservation and stimulating capacity building in developing countries. Many indigenous peoples and local communities, however, are sceptical of existing bio-prospecting agreements. Those concerned with the development of bio-resources for human health recognise that when local custodians of biodiversity benefit from their sustainable use by others, conservation opportunities increase. The CBD codifies this benefit sharing principle, but the absence of applicable instruments to equitably compensate all stakeholders within a country leaves it largely untested.

The World Health Organisation (2000) has shown that up until now, many legal and practical

issues relating to the protection of IPRs are not yet fully understood, let alone been addressed. In order to achieve a better understanding of and wider consensus on these issues, it is necessary to address basic conceptual problems and test practical solutions for the protection of traditional medicine. There is a need to continue the debate with various stakeholders, that is, practitioners of traditional medicine, representatives of the medical community, the pharmaceutical and biotechnology industries, intergovernmental organizations, and related stakeholders. This is due to the fact that lasting solutions can only be found if all the stakeholders work together, in good faith, and bring their specific expertise and experience to bear on the challenges of promoting the use of IKS for sustainable livelihoods.

Saray (2001) has observed that the pharmaceutical companies operate as multinational corporations and have all the means to establish dominance in the industry through various mechanisms. Their activities result in (i) flooding the African local markets with cheap drugs which suppress local knowledge systems and innovations, (ii) the pursuance of patents which often exclude the IK holders, thereby cutting them from the benefits of their knowledge and innovations; and (iii) Bio-piracy which makes the African countries and their IK holders and innovators much poorer as their IK resources are exploited for profit.

3.1 Protection and Regulation of IK and Innovations for Public Health Care

Indigenous knowledge and innovations (IKIs) continue to be recognized as an important tool for sustainable development including the provision of sustainable public health services. This is largely because they are accessible and affordable to marginalized communities. However, the indigenous resource base is being threatened by an increasing interest from international pharmaceutical prospecting companies. For this reason, Intellectual Property Rights offers a great opportunity to protect the rights of knowledge owners by offering legal mechanisms for the allocation of the ownership of knowledge and the sharing of benefits among competing claimants. The guarantee of ownership rights to African local communities would also safeguard the future of IK and innovations, thus helping resolve preservation issues. This is because as beneficiaries and owners of knowledge, the local communities will strive to protect their IK resources.

Collective ownership and the use of various forms of IK and innovations are a feature that is not compatible with most of the existing intellectual property regimes which give rights to individuals and corporate actors with legal identification. Without their own "legal" regulatory institutions to "protect" knowledge and resources, knowledge in most indigenous groups is either shared by the various members of the group, or remains the preserve of individuals such as traditional health practitioners or specific elders. Where specific individuals retain knowledge, the retention is not a product of legal design, but rather of secrecy. It is, therefore, difficult to defend or protect it legally. More recently, herbal medicines have been patented, either domestically or internationally. This has made them unaffordable to the poor in the

developing countries including Africa, because they have become expensive in the countries controlling the patents (Dutfield 2000).

3.2 Reverse Pharmacology for Value Addition to Innovation in IK for Public Health

Patwardhan (2005) shows that several major drug groups have emerged due to scientific studies on drugs which were traditionally known as traditional medicine. Important examples include histamine and acetylcholine from ergot, curare derivatives, amine-modulating drugs based on the clinical phenomenology of *Rauwolfia serpentina*, and many others. However, these efforts have been sporadic and lead to inordinate delays from the moment of clinical observations to new drug development. Therefore, a newly developed, organized and time-bound scientific endeavour called Reverse Pharmacology (RP) requires full exploitation to release results quickly. Reverse Pharmacology is the science of integrating documented clinical/experiential novel hits into leads by trans-disciplinary exploratory studies (*in vitro* and *in vivo*), at multiple levels of biological organization. These leads are further developed into drug candidates by relevant science for safety, efficacy and quality by experimental and clinical research. The scope of RP is to understand the mechanisms of drug actions, to obtain leads for medicinal chemistry and to introduce safe and effective natural drugs, based on vast experience of traditional medicine (Vaidya et al. 2006).

Using RP, new product development has occurred over the last two decades. For example, *Mucuna pruriens* for Parkinson's disease, Picrorrhiza kurroa for viral hepatitis, *Tinospora cordifolia* for immunopotentiation, *Commiphora wightii* for rheumatoid arthritis and *Curcuma longa* for precancerous mouth lesions. The path of Reverse Pharmacology is cost-effective, creative and generates safe natural drugs from Traditional Medicine. Evidence-based traditional medicine can therefore globally emerge with new natural drugs, with scientific data on safety and efficacy (Patwardhan 2005).

4. Conclusion and Policy Recommendations

In this Chapter the importance of IKIs for public health care in Africa has been discussed. Given that a large proportion of Africa's poor depend on IKIs for their livelihoods, that is, medicine, food and nutrition, the paper has advanced and articulated the reasons for the full exploitation of these knowledge and innovation systems in order to influence better public health care. The paper has also shown African countries' awareness of the value of Indigenous Knowledge and Innovations for public health care. This is despite varying degrees and focus. It is important for African countries to strengthen policy and legal instruments to add value to IKIs for improved public health care.

Furthermore, the paper has demonstrated that funding for R&D initiatives remains weak and sporadic. This is because most African R&D institutions rely heavily on external financing support. It is, therefore, suggested that African governments should go beyond merely developing IKS policies but should get fully involved in funding all IKS initiatives including R&D. This is due to the fact that IKIs play a significant contribution towards improving human health on the continent. In addition, capacity building (in the areas of both natural and social scientists in IKIs related issues) and the development of strategic partnerships within the south and northern partners should be encouraged and supported. This is based on the increasing realization that knowledge generation and value addition to IKIs require deliberate and concerted efforts between south-south, north-south and south-south partnerships. In the same vein, universities, national and regional R&D institutions should initiate new projects and programmes into this field.

In the 21st Century, Africa needs to seize this opportunity to develop and implement policies which promote and add value to indigenous knowledge and innovations for better and improved public health care. The recommendations are summarized as follows:

- African governments should develop policies and appropriate legislative frameworks to protect and support IKIs.
- Research and Development in IKIs should focus on aspects that are directly related to the public health care of the population in order to achieve greater well-being of the people.
- Partnerships and networks should be established by all IKIs stakeholders to enhance the critical mass of researchers on IKIs.
- African governments, the private sector and other role players in IKSIs should increase investment in R&D for sustainable community livelihood and development.
- A conducive environment should be created for R&D to validate and affirm the efficacy of IKIs in public health care.
- Appropriate benefit sharing mechanisms should be created and intellectual property regimes should be developed to protect IKIs.
- Indigenous knowledge and innovations should be streamlined into the formal education systems at all levels to ensure sustainability.
- New scientific approaches like reverse pharmacology should be explored and used in order to add value to IKIs for better public health care delivery.

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The links between agriculture and health: an intersectoral opportunity to improve the health and livelihoods of the poor

C. Hawkes & M. Ruela^a

Abstract _

Agriculture and health are linked in many ways. First, agriculture is essential for good health: it produces the world's food, fibre and materials for shelter; in many countries it is also an important source of livelihood among the poor. At the same time, agriculture can be linked with poor health, including malnutrition, malaria, foodborne illnesses, human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), livestock-related diseases, chronic diseases and occupational ill-health.

Health also affects agriculture: people's health status influences the demand for agricultural outputs, and in agricultural communities, poor health reduces work performance, reducing income and productivity and perpetuating a downward spiral into ill-health.

This paper presents an overview of the bidirectional links between agriculture and health with a focus on the developing world. It develops a conceptual framework that brings together the various links between agriculture and health into a single broad framework. The framework comprises the core components of the agricultural supply chain (producers, systems and outputs), key health concerns and the mechanisms of common interaction between the agricultural and health components: income, labour, environment and access — all key social determinants of health.

These links between agriculture and health present an opportunity for the two sectors to work together to find solutions to each other's problems. Yet the

^a Bulletin of the World Health Organization, 2006;84:985-991. Article published with permission fom the authors and Dr Fidelis Morfaw (WHO). health and agricultural sectors remain poorly coordinated. Leadership from global health and agricultural institutions is needed to build policies and good governance to facilitate integration, while capacity building is needed at all levels to help translate the conceptual links into comprehensive action on the ground. Health and agricultural researchers likewise need to work more closely together to achieve common goals.

1

Introduction: Identifying Critical Links Between Agriculture and Health

It is well established that population health is strongly influenced by society and the environment. Social and environmental determinants of health include income, employment, access to food and social capital, and exposure to agents in air, water and soil (Lebel 2003; Marmot 2005). Although these determinants have been much studied, one important aspect of society and environment has as yet been inadequately addressed: agriculture.

Agriculture is essential for good health — it produces the world's food, fibre, and materials for shelter, and can produce medicinal plants; it is also an important source of livelihood for many of the poor in developing countries. At the same time, agriculture can lead to poor health (Hawkes 2006). As pointed out over 15 years ago by Lipton and De Kadt in their review of links between agriculture and health, agriculture is linked to the main causes of death and disease — malnutrition, infectious diseases and chronic diseases (Lipton and Kadt 1998).

Examining health in an agricultural context is therefore important because agriculture presents not only opportunities for improving health but also risks to health. It is equally important because health affects agriculture. In agricultural communities, poor health reduces income and productivity, further decreasing people's ability to address poor health and inhibiting economic development more broadly, while in the population at large, malnutrition and disease patterns influence market demand for agricultural products.

The links between agriculture and health are thereby bidirectional: agriculture influences health and health influences agriculture. This bidirectionality offers an incentive for the two sectors to work together — to orient agricultural systems to benefit health, and health systems to benefit agriculture.

The recognition of the importance of intersectoral work to health is not new (Bos 2006). It was articulated recently by the Bangkok Charter for Health Promotion. "An integrated policy approach," it states, is "essential if progress is to be made in addressing the determinants of health" (WHO 2005). In agriculture, the emergence of joint animal and human health concerns such as avian influenza, and epidemics among agricultural communities such as that of human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS),

have heightened the need for integrated action with the health sector.

Yet despite this opportunity and some awareness, the health and agricultural sectors remain poorly coordinated: health considerations play little part in the decisions farmers make about production or those that agricultural ministries make about policy, and likewise agricultural policies have a limited role in the health sector (Lipton and Kadt 1998). There are reasons for this disjuncture, some resulting from lack of awareness, others from distinct policy conflicts. But whatever the challenges, these divisions are undermining efforts to overcome ill-health among impoverished communities, and giving short shrift to agriculture's role in alleviating many of the world's most serious health problems.

The objective of this paper is to highlight the potential advantages of closer interaction between the health and agricultural sectors by presenting a conceptual framework of agriculture-health links, and illustrating how these links operate in specific settings in the developing world.

2. The conceptual framework: how is agriculture linked with health?

The conceptual framework (Fig. 1) was developed following a review of the scientific literature on agriculture and health, including existing models with agriculture–health components, such as the ecohealth approach (Lipton and Kadt 1998; Lebel 2003). The search was undertaken in three databases (PubMed, ISI Web of Science and CAB Direct) for publications from 1980 onwards, limited to those in English. The initial search terms were "agriculture" and "health", later refined by searching for particular health conditions and agricultural practices.

2.1 Key Health Conditions: Significance to Global Public Health

The first step in the development of the framework was to identify the key health conditions and risks, diseases and groups of diseases, associated with agriculture. In the currently available literature, the following health problems — all of which affect the poor in developing countries — were identified as being linked in some way with agriculture: malnutrition, water-associated vector-borne diseases, foodborne illnesses, HIV/AIDS, livestock-related illnesses (zoonoses), chronic diseases and particular occupational health risks. (It is likely that other health conditions are also linked with agriculture, but they have not yet been explored in the published literature.) The framework thus specifies and unites an array of key global health concerns, which interact when present in the same context.

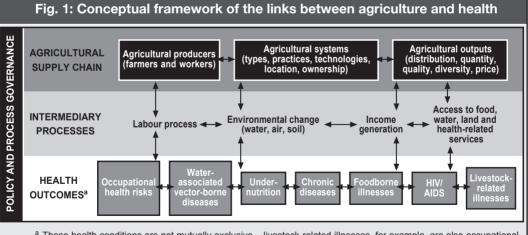
2.1 Key Agricultural Components: The Supply Chain

The second step was to look at how agriculture is associated with these health conditions. Scientific studies tend to focus on one part of the agricultural supply chain (e.g. agricultural producers and occupational health risks; agricultural outputs and foodborne disease).

But by considering the different types of literature together, it becomes clear that the entire agricultural supply chain has implications for health: agricultural *producers* (i.e. both farmers and agricultural workers) are particularly vulnerable to malnutrition and disease because they often have limited resources; agricultural *systems* influence human health through interactions with the environment which affect agricultural outputs; and agricultural *outputs* — food, fibre, materials for shelter and some medicinal plants — are essential for human health but also present risks. Producers, systems and outputs also represent potential points of intervention to achieve greater synergies with health.

2.3 Key Intermediary Processes: The Social and Environmental Determinants of Health

The final step in the development of the framework was to identify the common processes mediating the relationships between the agricultural supply chain and the different health conditions. From the literature, it emerged that four interlinked social and environmental determinants of health are critical: income (amount, type, stability, distribution and control of) labour (amount available, type, location, energy and time expended), access to food, water, land and health-related services (e.g. medicines, bednets and hospitals) and environmental changes in water, air and soil. The role of the intermediary processes, together with the rationale behind the identification of the health conditions, is elaborated on in the next section, which looks at each component of the agricultural supply chain.



^a These health conditions are not mutually exclusive – livestock-related illnesses, for example, are also occupational health risks. The list of health outcomes is not necessarily inclusive. Other health conditions are also likely to interact with agriculture, but these have not yet been identified as such in the published scientific literature.

3. Rationale and Explanation of the Bidirectional Links

3.1 Agricultural Producers

Working as an agricultural producer (as a farmer or labourer) is a determinant of health, largely via the intermediary processes of income and labour (Lipton and Kadt 1998). Agricultural households earn income from agriculture, which in turn influences their ability to purchase and gain access to food, water, land and health-related services and thus determines their overall health status. By affecting their access to food, the amount, type, stability and distribution and control of income also has important implications for the nutrition of agricultural households (Pinstrup-Anderson et al. 1984; Kennedy and Bouis 1993; Bouis 2000; Oshaug and Haddad 2002).

The labour supplied by agricultural households interacts with health in several ways. First, labour influences nutritional status by affecting energy expenditure and the time available for child care and food preparation(Pinstrup-Anderson et al. 1984; Kennedy and Bouis 1993; Bouis 2000; Oshaug and Haddad 2002).

Second, farming exposes producers to a range of occupational health hazards, such as dehydration, accidents, zoonoses, and acute and chronic pesticide poisoning (Cole 2006). Third, the amount and type of agricultural employment has implications for the spread of and exposure to disease (e.g. HIV/AIDS) because it influences migration and the search for alternative income sources (Gillespie and Kadiyala 2005). All these interactions are affected by gender relations in agricultural communities.

In the other direction, malnutrition and poor health in agricultural communities affect people's ability to gain a livelihood from agriculture by affecting their capacity to work and generate food and income. The problem is graphically illustrated by the case of HIV/AIDS, which has devastated agricultural communities in sub-Saharan Africa. The resilience of communities to these negative shocks depends partly on intermediary social determinants such as access (including cost) to health-related services and food.

3.2 Agricultural Systems

Agricultural systems vary hugely — by commodity type, practices and technologies used, location and ownership system. The types and severity of diseases associated with the agricultural system thus vary with these different factors. In livestock production, for example, different animals are associated with different zoonoses (e.g. working with dairy cows and sheep is a risk factor for brucellosis). The influence of agricultural systems on health is particularly notable via the intermediary process of environmental change (WHO 2002; Nugent and Drescher 2004; McMichael and Butler 2005). As exemplified below, water-associated

vector-borne diseases are a particularly important group of diseases affected by this interaction.

In the other direction, health affects agricultural systems: poor health reduces the ability of producers to innovate, invest in and operationalize changes in agricultural systems — including changes that promote health (Lipton and Kadt 1998).

3.3 Agricultural Outputs

Agricultural outputs affect health in a variety of ways. The major output — food — can carry foodborne illnesses and affects nutrition. Foodborne illnesses are caused by unsafe food that may originally have been contaminated during agricultural production. For example, pathogens on raw fruits and vegetables may be the result of irrigation with inadequately treated wastewater, and aflatoxins may be present in staple crops (as exemplified below) (Unnevher 2003; Scott et al. 2004; Walker et al. 2005). Nutrition is influenced by the quantity of food available, its quality and diversity, its price and how it is distributed, which in turn are influenced by agriculture and the policies that govern it (Pinstrup-Anderson 1984; Kennedy and Bouis 1993; von Braun and Kennedy 1994; Bouis 2000; Kataki and Babu 2002; Hawkes and Ruel 2006).

Agricultural outputs are also linked with chronic diseases. Agricultural policies can create incentives or disincentives to the production of different foods, tobacco and alcohol, and in turn determine their prices, thus affecting the environment in which people make choices about these products, and their subsequent level of exposure to risk factors for chronic disease (Nugent 2004; Elinder 2005).

Another agricultural product is medicinal plants, many of which are believed to be effective in the treatment of certain diseases (Rao et al. 2004). Incorporating production of medicinal plants into agricultural systems, such as agroforestry, has the potential to address some of the problems related to over-harvesting of medicinal plants in the wild, while meeting the demand for these plants on global export markets (Hawkes and Ruel 2006).

In the other direction, health affects people's abilities, needs and desires to consume different amounts and types of food, which in turn affects demand from agricultural systems and the types of products. Even if a health condition is not present, the risk of ill-health may create or reduce demand for outputs with specific qualities. Concerns about foodborne illnesses or diet-related chronic diseases, for example, can reduce demand or create demand for certain foods over others.

4. Consequences of links between agriculture and health in specific settings

Two examples are presented below to illustrate the consequences of these bidirectional links for the health and livelihoods of vulnerable groups in local settings, and the potential for

innovative, linked solutions.

4.1 Water Resource Development, Crop Production and Malaria

The development of water resources for agriculture is a good example of how practices characterizing an agricultural system interact with the intermediary processes of environment, income and labour to affect health. Irrigation, multipurpose dams, and ponds for livestock and fish can benefit health by increasing food yields and production, and generating higher incomes for the producers; on the other hand, they can also create conditions suitable for the propagation of insect vectors and intermediate hosts of pathogenic parasites, thus introducing or intensifying the transmission of water-related vector-borne diseases, such as malaria, schistosomiasis and Japanese encephalitis (van der Hoek 2004).

Mutero et al. (2004) compared the impact of these interactions on malaria in Mwea Division, Kenya, between villages with and without rice irrigation. They found that villages with rice irrigation had a 30–300 times higher prevalence of the local malaria vector, yet paradoxically, a lower prevalence of malaria (0–9% compared with 17–54%). One potential explanation for this so-called "paddies paradox" was that households engaged in irrigated agriculture had higher incomes and were thus more able to pay for malaria treatment and bednets. But although average cash income in the villages using irrigation was higher, poverty was rife in all villages and there was no evidence that people in the villages with irrigation made greater efforts to protect themselves. The suggested alternative explanation came from another agriculture–environment component: that in the irrigated villages, mosquitoes were more likely to feed off the cattle kept for economic reasons, thus diverting them from humans as a source of bloodmeal and reducing disease transmission.

In the other direction, malaria affects agricultural producers by reducing their ability to work. A study in an area of intensive vegetable farming in Côte d'Ivoire showed that malaria led to absences from work of between 0–26 days in a 10-month period; this in turn was directly correlated with reduced overall yields and revenues (Girardin et al. 2004).

The links between malaria and agriculture present opportunities for innovative approaches to address poor health and livelihoods (Mutero et al. 2006). Management of agricultural water has been shown to reduce morbidity and mortality from malaria (Keiser et al. 2005). In a case reported from Sichuan province, China, a shift in irrigation techniques to an annual cycle of wet crop/dry crop rotation resulted in a reduction of vector breeding to a level lower than that required to sustain malaria transmission (Qunhua et al. 2004). Other potential approaches include keeping cattle as deliberate bait, and combining health interventions (that is, distribution of bednets) with irrigation programmes.

4.2 Aflatoxins, Agriculture and Health

Aflatoxins are a good example of how contaminated agricultural outputs have implications

for the health of local and global populations. Aflatoxins are highly toxic metabolites produced by a fungus which develops during the production, harvest and storage of staple crops. Eating foods contaminated with high levels of aflatoxins leads to acute aflatoxicosis, and regular consumption even of low levels is associated with stunting and underweight among children and the development of hepatocellular cancer in low- and middle-income countries (Gong et al. 2002; Hall and Wild 2003; Bhat and Vasanthi 2003).

In West Africa, studies by Gong et al. and Egal et al. have shown that 90% of children in Benin and Togo were exposed to aflatoxins in maize and groundnuts, which led to a measurable impairment of child growth (Gong et al. 2002; Gong et al. 2003; Gong et al. 2004; Egal et al. 2005).

As a result of international trade in staple foods, the health impacts of aflatoxin can extend far beyond local communities (Unnevher 2003). This has led food-importing countries to define regulatory standards; if levels of contaminants exceed the standard, they will not be imported.

Such standards have implications for the livelihoods of agricultural communities in exporting countries. Otsuki et al. (2002) used a model to compare the impact of a regulatory standard proposed by the European Union in 1997 on African food exports, with the impact of the international standard (Otsuki, Wilson and Sewadeh 2001). They concluded that the regulation would have led to declines in African exports of cereals, dried fruits and nuts worth US\$670 million in exchange for one or two lives saved in the EU. This result implies that a balanced trade-off is needed between the direct health risks posed by aflatoxins and the indirect health risks presented by potentially lowered incomes in agricultural communities.

But again, when the interactive nature of the problem is taken into account, relatively simple solutions to these risks to health and livelihoods can be identified. For example, a recent study showed that low-cost agricultural interventions such as using wooden pallets for crop storage reduced exposure to aflatoxins in local communities in West Africa by more than half (Turner et al. 2005).

6. Conclusion: Applying the Framework in Policy and Practice

The conceptual framework and examples presented here show that agriculture can provide the environmental and/or economic conditions conducive to the spread of disease, but can also provide the conditions conducive to the prevention and control of disease. They demonstrate the importance of examining the links within a broad framework that considers the different pathways, given that the multiplicity of interactions can produce unexpected outcomes and trade-offs.

The conceptual framework can be used to advance intersectoral policy and practice in three

main ways. First, it can be used to communicate to decision-makers and the international development and donor communities the importance of examining the links between agriculture and health: failing to think systemically about these links may be undermining their efforts to improve agricultural livelihoods and address diseases of public health importance — avian influenza being one example. Second, it can be used to encourage researchers working at the intersection between agriculture and health to come together to form a larger and stronger community. Microbiologists working on food safety, social anthropologists examining the impacts of HIV/AIDS in rural areas, and public health nutritionists concerned about the healthiness of the food supply may not think they have anything in common, but they do: they all work on the interactions between agriculture and health. Moreover, bringing together workers in this surprisingly large field increases the evidence base from which lessons can be learned to solve linked problems. Third, the conceptual framework can be employed to encourage capacity building at all levels, including local settings. This approach is needed to identify where and how the livelihoods of the poor are most affected by the interactions, and where agricultural and/or health interventions would be most effective.

7. Policy Recommendations

The following four policy recommendations should encourage greater synergies between agriculture and health:

- First, individuals and institutions already active in the field of links between agriculture and health should compile and communicate evidence of successes and failures and share their knowledge and experience.
- Secondly, institutions concerned with global health and agriculture should build capacity, policies and governance structures to facilitate linked approaches, starting by setting up forums to bring the stakeholders together.
- Thirdly, agricultural and health researchers should together identify and prioritize research gaps and needs, and develop a joint research agenda;
- Fourthly, all stakeholders should invest in capacity building to help translate the conceptual links into comprehensive action on the ground. The goal is clear: healthier people and healthier agriculture.

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Regulating Information and Communication Technologies (ICTs) for Africa's Development: E-Health in Perspective

W. Bowman, B.W. Bell, Jr & M. Nyambura Ndung'u

Abstract _

Several African countries have adopted policies on Information and Communication Technologies (ICT). Most of all these policies give rhetorical acknowledgement to the importance of E-Health, that is, health services improved through the use of technology. However, the implementation of these policies tends to vary. As will be shown in this paper, very few nations progress beyond the stage of "window dressing" in order to implement such policies. With respect to E-Health, Uganda has made significant strides by equipping twenty-one Government hospitals with ICT facilities. In contrast. the government of Kenya has shown no indication in terms of providing the necessary support to implement E-Health. Thus only public hospitals have E-Health facilities in Kenya. Elsewhere, more fieldwork is needed to determine the status of E-Health in Nigeria, Ethiopia and Ghana, although the efforts to achieve this goal seem to be in the early stages. E-Health faces major challenges such as sustainability and infrastructural development. This chapter recommends that, rather than take on a large number of dispersed and uncoordinated projects, only a smaller number should be carried out with careful planning and comprehensive government support. Because E-Health initiatives rely heavily on the presence of a viable Internet "backbone" in secondary towns and rural areas, governments must work with the private sector and regional organizations to develop such infrastructure. Further, such projects require stable and well-distributed electricity supplies. In short, E-Health in Africa requires long-term planning and infrastructural investments by African governments.

1. Introduction and Background

This paper investigates the status of E-Health^{*i*} (Eysenbach 2001) in selected African countries. The paper covers two main parts which are further divided into sections. The first part defines and discusses the concept of ICT as well as providing background information of ICT in Africa. It also provides an overview of ICT policies including the legal, regulatory and policy frameworks relevant to E-Health across the African continent. The second part defines E-health and discusses its evolution. With specific references to selected countries, this part gives an overview of the countries' policies on ICTs in health. To that end, the authors conducted primary fieldwork, speaking with responsible officials in government ministries in the selected countries regarding E-Health projects and related facilities.

1.1 What are ICTs?

The definition of ICTs is the subject of some debate. According to the International Telecommunications Union, information and communication technologies (ICTs) generally refer to *old* technologies such as radios, televisions, fixed telephones, as well as *new* technologies including cellular telephones, computers, and the internet. Others define ICTs as "all hardware, software and services that relate to information processing, communication, and handling, as well as all business activities that depend substantially on the above" (Aduda and Ohaga 2001).

In Africa, ICT is generally defined much more broadly than in the Western world. For example, activists routinely cite telecommunications, broadcasting, radio, postal services and even print as some of the main components of ICT. The authors of this paper argue that ICT is not a discrete technology, but rather a blend of the old (landline telecommunications) and the new (computers and the Internet). In this chapter, the term ICTs refers to information and communication technologies such as the radio as well as the newer digital technologies including computers, satellite, mobile phones and the Internet. This paper also makes frequent references to "ICT policies." The policies generally cover three main areas: telecommunications, especially telephone communications, broadcasting (radio and TV) and the Internet.

1.2 Background on ICT in Africa

A yawning technological gap exists between the developing world and the industrialized nations. Most developing countries, including those in Africa, lack adequate access to technologies such as computers, the internet, fixed and mobile telephone lines and other related communications technologies. Thus Africa has the lowest telephone densitiesⁱⁱ (ITU 2001) and the lowest levels of Internet connectivity in the worldⁱⁱⁱ (Okpaku 2003). According to the International Telecommunications Union, for example, almost every sub-Saharan African nation is a "low access" nation in terms of digital access indicators with respect

to mobile and fixed telephones, literacy, computer and Internet access (ITU 2003). Further, ICT penetration levels also vary within countries with pockets of high and low access levels, particularly along rural-urban divides (Bridges.org 2001).

In response to this deficit, the past five years have seen numerous African governments making policy commitments to develop formal ICT policies in their nations. Indeed, by the year 2000, at least twenty-three African nations had developed or were in the process of developing formal ICT policies (UNECA 2000). Many observers believe that improving access to ICTs in developing counties will help promote economic and social development, as well as creating jobs and facilitating global competitiveness (Dzidonu 2002).

In the last few years, policymakers in both the developing world and the industrialized nations have focused on addressing the technological gap between the developed and the developing world that hinder the integration of developing nations into the new global economy (Kearney 2001). At the levels of both international and national governance, significant resources are being directed to the formulation of ICT policy in Africa. In March 2001, for example, the United Nations established an Information and Communication Technologies Task Force (UN ICT Task Force). This was done in part to support Africa's efforts to harness ICTs for poverty eradication, human development, the elimination of gender disparities, and the combating of disease (United Nations ICT Task Force 2004). Indeed, Goal 8, Target 18 of the United Nations' Millennium Development Goals urges the international community to distribute the benefits of ICT more equitably.

2. Comparative Analysis of ICT Policies in Africa

The research team reviewed the ICT policies of Botswana, Nigeria, Rwanda, Ethiopia, Mozambique, South Africa, and Kenya. While ICT policies were available in some countries, they were unavailable in others. In general, these policies paid significantly less attention to E-Health. Rwanda and Botswana have well-thought-out policies, with the least comprehensive one being that of Ethiopia, and Nigeria's policy seemingly ambitious but evidently difficult to implement given the size and population of the country.

In terms of planning and implementation, the Rwandan National Information and Communication Infrastructure (NICI) Plan is clearly the most effective. Mozambique has also done a sterling job of actually implementing the objectives laid out in its ICT plan. Like Nigeria, Kenyan plans are lofty, but far from implementation.

With regard to E-Health, the policies of Nigeria, Rwanda, Egypt and Mozambique lay out specific time frames for the accomplishment of specific objectives in the E-Health fields. In particular, the Mozambique strategy covers E-Health adequately, providing measurable benchmarks and indicators. An analysis of the policies alone only speaks to rhetorical intent. Policies by themselves give no indication of how much success a nation has achieved

in terms of implementation, although it may point to good planning of infrastructure in the country.

2.1 Selected African ICT Country Policies

Almost all of the ICT policies examined highlight the fact that the countries face similar challenges in terms of achieving the goals of their national ICT policies. For example, Rwanda's key developmental challenges are a low level human resource development, underdeveloped and under-funded social infrastructure and services, and a weak private sector. Similarly, Kenya lists the main challenge as harnessing the potential of ICTs for economic growth and poverty reduction, with a lack of comprehensive policy and regulatory framework, inadequate infrastructure and insufficient skilled human resources cited as specific challenges.

2.1.1 Botswana

The Botswana policy covers E-Health in a comprehensive manner. In other words, the policy provides very clear strategies of how E-Health goals will be accomplished. The policy creates incentives for private sector investment, while at the same time taking cognizance of the need for regulatory mechanisms. Along with South Africa, Botswana has used a variety of ICTs including the radio, TV talk shows, telephone support and mobile phones, to lower the spread and infection of HIV/AIDS.

Drafted in 2005, Botswana's ICT policy was developed by Botswana's Ministry of Communications, Science and Technology. The policy is aligned to Botswana's Vision 2016 -- the country's strategy to propel its social-economic and political development into a competitive, winning and prosperous nation.

2.1.2 Nigeria

Initially, the Nigerian policy does not mention anything about health in its opening statement, but offers detailed strategies for health later in the document. The policy recognizes the role of the private sector in creating health partnerships and offers incentives to private operators to invest in both health and education in achieving the laid down policies.

Formally known as Nigerian National Policy for Information Technology (IT) 'Use IT' (2001), this policy has the overall goal of making Nigeria an "IT capable country in Africa" and a "key player in the Information Society by the year 2005", using IT as the engine for sustainable development and global competitiveness. Silent on health, the policy's mission statement states that "IT will be used for Education; Creation of Wealth; Poverty Eradication; Job Creation and Global Competitiveness."

The policy is divided into 16 chapters. The first chapter deals with human resource development

while health is covered in chapter 5. Under the general objective, some of the policy intentions are to: (1) empower Nigerians to participate in software and IT development; (2) improve food production and food security; (3) improve healthcare delivery systems nationwide; (4) integrate IT into the mainstream of education and training; (5) encourage government and private sector joint venture collaboration; (6) create Special Incentive Programs ("SIPs") to induce IT sector investment; and (7) develop human capital with emphasis on creating and supporting a knowledge-based society.

Chapter 5 of the policy is dedicated to health. The policy statement states that the government shall invest in IT-based healthcare systems to ensure that Nigerians have access to good healthcare delivery. The overall objective is to use IT for the establishment of Health-care Information Systems (HIS) cutting across all healthcare systems with an aim of improving the efficiency of patient care and reducing the cost of healthcare delivery.

Section 5.3 focuses on Strategies of achieving the health objectives which includes

"...capitalizing on existing global IT infrastructure such as the free Healthnet Satelife "nearly real-time" email facilities, networking all healthcare institutions to collate information, share data and communicate on-line, establishing full Internet connectivity and access for healthcare professionals at all levels (primary, secondary and tertiary) and making IT skills acquisition mandatory for all healthcare professionals..."

2.1.3 Ethiopia

Ethiopia's policy places emphasis on the education sector while saying nothing about the health sector. It is encouraging to note, however, that there is a telemedicine project in Ethiopia which supports several rural hospitals. The policy, which is very brief, has eight statements, two of which are related to education and health. One of the policy statements is that "the development of human resource in information and computer sciences shall be promoted and supported and that an effective legal and regulatory framework which enables to integrate, speed up and monitor the development of national information infrastructure (NII) shall be provided."

The Ethiopian National ICT policy was finalized in 2005. Section 2 of the Ethiopian policy lays out the vision of the policy: "to exploit ICTs for the enhancement of efficiency and effectiveness at the civil services, optimization of the flow of information at all levels, and to maximally facilitate connectivity to the global information infrastructure and lay a firm foundation for e-business by the year 2010."

The policy aims to exploit the opportunities created by ICT in order to achieve rapid and sustainable socio-economic development, facilitate good governance and a healthy democratic system. There is mention of health in this section in a statement that the nation aims to

introduce and establish appropriate technologies for the handicapped.

2.1.4 Rwanda

Entitled an "Integrated Socio-economic and ICT Policy and Strategies for Accelerated Development," Rwanda's ICT policy was launched in February 2000. It aims to transform Rwanda into an information-rich and knowledge-based society and economy by the year 2020. Rwanda's "Vision 2020" comprises an overall vision for social and economic development of the country taking into account the developmental challenges it faces within the context of its key socio-economic indicators.

Rwanda has a strong ICT implementation strategy which incorporates a four-phase NICI planning process. Phase 1 of the strategy ran from 2000 to 2005 and is now in the process of implementation. Phase 2 spans the period from 2005 to 2010. The general consensus is that NICI I was partially implemented and was more of a road map. It is generally agreed that Phase 2 will be the core implementation plan.

Section 1 of the policy has identified Rwanda's key developmental challenges as being as follows: (1) a low level of human resource development; (2) underdeveloped and underfunded social infrastructure and services; and (3) a weak private sector.

The policy also recognizes the critical role that the private sector can play as a key partner in the process of moving Rwanda into an information and knowledge economy. The policy notes the government's commitment to facilitating the private sector through the creation of an enabling environment for policy programmes to be implemented. The policy further states that the Government is committed to the creation of a stable economic and investment climate that will assist both domestic and foreign private sector organizations in the development of the physical telecommunication and communications infrastructure and other ICT infrastructure. By infrastructure, the government means the information resources and systems "infrastructure" to support the activities of various sectors of the economy as well as in the development of human resources in ICT and other skill areas required by the information economy.

In the section of enabling legal, regulatory and institutional provision, the policy states that the Rwandan Government acknowledges that the development and the exploitation of ICTs in the economy and society as well as the development of the information and knowledge economy will need to be supported and facilitated by appropriate legal provisions and legislation, regulatory framework, and institutional structures. It further states that the government is committed to implementing relevant and appropriate sections of the "African Telecommunication Policy and Regulatory Framework Development Programme" prepared by the African Ministers of Communication during African Telecom '98 held in May 1998 in Johannesburg.

2.1.5 Kenya

Based on the Government of Kenya's Economic Recovery Strategy for Wealth and Employment Creation (2003-2007), Kenya's ICT policy was approved and gazetted in March 2006. The policy has four guiding principles, namely: infrastructure development, human resource development, stakeholder participation, and the creation of an appropriate policy and regulatory framework.

The Kenyan ICT policy gives considerable attention to E-Learning at the expense of E-Health. Section 3.3.5 mentions health for the first time, stating that the use of IT in health delivery systems reinforces fundamental human rights by improving equity and quality of life. It further states that the government will promote the use of IT in health delivery by "Providing IT facilities in all public health facilities; providing IT training to medical staff, setting standards and norms for IT in the healthcare system; developing legislation governing telemedicine and health information and finally establishment of national resource centres for IT in the healthcare system."

The Kenyan ICT policy recognizes the weak state of the regulatory framework. Nonetheless, despite the fact that the policy was gazetted in March 2006, there is no regulatory, policy or legal mechanism to fund any of the initiatives laid out in the policy document. Although the Kenyan ICT policy sounds promising from a rhetorical standpoint, nothing has been done to implement the guidelines laid out in that document.

2.1.6 Uganda

As of the information received in 2007, Uganda is comprehensively rewriting its ICT Policy. Uganda has made good progress on implementation. Uganda has broken ground on numerous tele-centres throughout the country. As indicated in other parts of this study, Uganda is in the process of computerising hospitals and schools and is working aggressively towards building an ICT backbone in secondary towns.^v Uganda was an early adopter of an ICT policy and has made significant progress towards implementation by utilizing public-private partnerships as well as NGO and donor support.

2.1.7 Mozambique

The Mozambique ICT policy is written in Portuguese. However, the Republic of Mozambique issued an Information and Communication Technology Policy Implementation Strategy (translated into English) which was approved by the Council of Ministers in June 2002. It provides a description of projects, their duration, implementing agencies, the estimated budget, and the status of funding. The Implementation Strategy states that the ICT policy has identified six priority areas, namely education, human resource development, health, universal access, infrastructure, and governance. The strategy provides the operational

framework to support the phased implementation of a series of short, medium and long term projects in the six priority areas specified in the ICT Policy. The strategy recognizes three major challenges to achieve the rapid spread of the use of ICTs in Mozambique, including the limited base of human resources with solid skills in ICTs and their availability throughout the country.

Mozambique's implementation strategy aims at overcoming these constraints in the longrun while defining, in the short run, programmes that maximize the use of available local skills and infrastructure. The Strategy proposes projects that apply ICTs to support actions in all six priority sectors, including: "...school networking; a variety of approaches to ICT training and education; dissemination of information on HIV/AIDS; and increased access through provincial centres for digital resources..."

Section 3.1 acknowledges that a limited ICT skills base in Mozambique and the concentration of persons with IT skills in Maputo acts as a constraint to the initiation and maintenance of ICT activities throughout the country. The medium term priority projects in Section 4 place emphasis on high-level ICT training, the expansion of community access through tele-centres for information access about HIV/AIDS, governance and the facilitation of local business.

The strategy argues that all the initiatives and projects must be based on the national telecommunications infrastructure, the backbone of the information society in Mozambique. "In this context, it will be possible to take advantage of the potential offered by ICTs for the national programme to help combat HIV/AIDS", the policy notes.

2.1.8 Egypt

Egypt's IT policy is known as the National Plan for Telecommunications and Information and was finalized in December 1999. One of the overall goals of the policy is the provision of the manpower needed for the communication and information sectors.

The policy plan has indicated some specific projects to be implemented in support of the various sectors. The Ministry of Communication and Information Industry Development is in charge of a project which aims to create a legal environment conducive for the growth of the communication and information industry. The Ministry of Communication also leads another project for the formation of a suitable investment environment.

There are also sectoral projects with follow-ups by the ministries. For instance, the Ministry of Health is in charge of developing a health information network for citizens as well as hospital information systems. A detailed implementation schedule is also included in the plan with time limits ranging from three to five years. More research follow-up is needed to determine whether these time limits have in fact been met.

The Egyptian plan has a section focusing on the creation of a suitable legal framework for the growth of the communications and information industry. The section further states the objectives of creating a suitable legal framework as follows: to develop the legal framework so that it is in line with the great progress in communications and information technology as well as what is happening in service liberalization to meet the challenges of globalization; developing and empowering intellectual property laws as the main motivation for the development of industries such as software systems and databases which depend on creativity; and finally, the creation of merit systems for the communication and information industry to help attract investments and increase [national/local] competitive power in international markets.

2.2 Nature of Policy Incentives for Private Sector Investment in African ICTs

The incentives for private sector investment are not clearly stated in most policies, but several of these policies attempt to provide an enabling environment for the growth of the sector. For example, Section 6.2.5 of Botswana's policy recommends a thorough review of various fiscal incentives in an effort to make ICTs both attractive and affordable. The policy further states that "These incentives should look at reducing the overall cost of purchasing ICTs as well as providing tax benefits for companies in the ICT field – particularly new businesses or SME's." In addition, local business and private sector training organizations will be encouraged to offer greater levels of ICT training in Botswana.

The Mozambican strategy emphasizes that the project for local ICT business facilitation will provide assistance to local entrepreneurs, adopting policies for incentives for the development of local companies, especially small and medium enterprises (SMEs). The projects for a Science and Technology Network, the System for Scientific Information, and the ICT observatory will ensure that leaders and institutions have the informational support necessary for planning and decision making.

The Nigerian strategy promotes E-Health and E-Learning by attempting to create an enabling environment to facilitate "...private sector (national and multinational) investment in the IT sector; to stimulate the private sector to become the driving force for IT creativity and enhanced productivity and competitiveness; to encourage government and private sector joint venture collaboration and to create Special Incentive Programs (SIPs) to induce investment in the IT sector..." Under the same Section 1.3, the Nigeria policy further states that one of the strategies shall be to encourage IT companies to invest in education and training through incentives such as tax rebates through government bodies such as the Industrial Training Fund (ITF) and Centre for Management Development (CMD). Nigeria is providing benefits for the private sector to build the national backbone through tax incentives and the creation of a "Backbone by Anyone" Project.

The Ethiopian policy encourages private sector investment by introducing appropriate

incentives and developing partnerships between government and the private sector in building and utilizing the "national information infrastructure." The section also states that the policy will encourage affordable acquisition, production and mass distribution of educational materials, basic electronic media, contents and facilities. The authors would welcome the opportunity to follow up on how well the selected nations have actually implemented these incentives for public-private cooperation.

2.3 The Role of Regulatory Agencies in Promoting E-Health

African government regulators are at different levels in promoting E-Health activities in Africa. The funding and creation of public-private partnerships to develop and expand ICT is a stated goal. Governmental budgetary allowances, in conjunction with private sector incentives, are developed to create an environment that encourages fair competition and pricing for domestic development and participation. In Uganda, for instance, the Communications Commission (UCC) regulates and promotes developments in the communications industry. With regard to promoting E-Health programmes, the main objective of UCC is to develop and improve rural communications services. The Uganda Rural Communication Development Fund (RCDF) was created in 2003 as an intervention to ensure that basic communication services of acceptable quality are accessible, at affordable prices, and at reasonable distances by all people in Uganda. Various projects have been funded under RCDF including Schoolnet Uganda.

The Nigerian Communications Commission (NCC) is the regulatory authority for the telecommunications industry in Nigeria. According to its enabling decree, the commission has created a regulatory environment for the supply of telecommunications services and facilities as well as the promotion of fair competition and efficient market conduct. It has further facilitated the entry into markets for telecommunications services and facilities of persons and organisations wishing to supply such services. The NCC also protects licensees and the public from unfair conduct of other providers of telecommunications services with regard to the quality of services and the payment of tariffs. This has made it possible to establish the existing E-Health initiatives.

The Communications Commission of Kenya (CCK) together with the government has promoted the development, sharing and integration of E-Learning resources to address the educational needs of primary, secondary and tertiary institutions. CCK has facilitated publicprivate partnerships to mobilise resources in order to support E-Learning initiatives, develop integrated E-Learning curriculum to support ICT in education and promote distance education and virtual institutions, particularly in higher education and training. The AMREF telemedicine project has received considerable support from CCK.

In Botswana, the results of the Benchmarking and e-Readiness Assessments Report conducted in 2004 indicates that the country has good levels of technical infrastructure and supporting legislation in place, providing a solid foundation for the acceleration of an integrated National ICT agenda. The policy notes that Botswana is currently in the early stages of its national ICT programme, with levels of ICTs in homes, communities and businesses being modest, and ICTs in healthcare, education and government remaining in their formative stages. Botswana has identified that there are still gaps to be filled in the use of ICT in health and education and that the government should take advantage of the good technical infrastructure and supporting legislation.

Section 4.4 of the Mozambique implementation strategy provides an overview of the policy and regulation and goes ahead to state that promoting wider access to telecommunications services at reasonable cost for most citizens is a fundamental underpinning of any ICT Strategy and is also a goal to be reached for the strategy implementation. However, the policy notes that "while the legal and policy framework in Mozambique is moving towards facilitating the competitive provision of these services, many constraints still limit their geographic expansion and economic accessibility and will continue to do so for the foreseeable future." It further states that the ongoing reform of the communications sector addresses these constraints in the medium to long term. Section 4.7 states that "School connectivity, literacy training, the delivery of HIV/AIDS information, the installation of e-mail and VSATs will be implemented in the provinces." It further notes that the regulatory reform is designed to reduce costs for users in remote zones and community access centres as well as in telecentres and Provincial Digital Resource Centres (CPRDs).

3. Defining the Concept of E-Health and tracing its evolution^a

The remaining part of this chapter considers the concept of E-Health as it appears in the policies of the studied countries as well as examining the ways in which E-Health is implemented by the governments of those countries, the private sector, donors, and also by community based organizations.

The term E-Health came into use in the year 2000, but is now used widely in both academic and practitioner circles.^{v/i} E-Health refers to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology (Eysenbach 2001). In general, E-Health encompasses the following four components: Telemedicine (using ICT to provide remote medical consultation), E-Learning (using ICT for remote Continuing Medical Education), E-Public Health (using ICT for remote health education to the population), and E-Preventive Medicine (using ICT to provide healthcare data for public health and preventive medicine programmes).

Telemedicine is a component of E-Health which can be defined as the investigation, monitoring and management of patients using systems which allow ready access to expert advice and to patient information, no matter where the patient or relevant information is located. Telemedicine utilizes telecommunications and computing systems to manage health-care delivery. Tele-medicine tools may have an important role to play in the improvement of the quality and efficiency of health systems in developing countries, as they offer new channels for communication and collaboration.

Improving the health of individuals and communities, and strengthening health systems, disease detection and prevention are crucial for development and poverty reduction. In public health, information management and communication processes are pivotal and can potentially be facilitated or limited by the availability of ICTs. Many advocates believe that the use of ICTs for health, or "E-Health," will prove to be fundamental in health care delivery and public health practice. Some key ICT applications in health include the following: 1) handling surveillance and epidemiological information; 2) disseminating personal and community information; 3) managing health services; 4) accessing knowledge and medical literature; and 5) facilitating clinical decision-making. E-Health is likely to have particular value in responding to shared global health challenges such as emerging epidemics or the health consequences of natural disasters, although this promise is yet to be validated in rigorous academic analysis.

3.1 The Status of E-Health in Africa: An Overview

Several African countries have passed national ICT policies. Almost all of these ICT policies give rhetorical acknowledgement to the importance of E-Health. However, these policies tend to vary dramatically in terms of actual implementation. Based on original interviews and data collection conducted by the authors of this study in August, 2007, Uganda is making progress in building an E-Health infrastructure. Twenty-one Ugandan hospitals have government-sponsored ICT facilities.

3.2 Illustrative Examples of E-Health Initiatives

3.2.1 AMREF Telemedicine Project (Kenya and Tanzania)

The African Medical & Research Foundation (AMREF) initiated a regional telemedicine project in 2004 targeting four rural hospitals initially in Kenya and Tanzania. The concept is to connect rural healthcare facilities to academic medical centres in the cities electronically in a regional 'health intranet,' enabling access to bodies of medical knowledge that were previously inaccessible. In this way, healthcare is taken to the patient rather than the other way round.

The AMREF telemedicine project provides expert second opinion to clinicians in those hospitals supported by the AMREF outreach programme. The primary goal is to improve

the quality and accessibility of specialist care. The secondary goal is the improvement of care through training using teleconsultation and continuous medical education (CME) courses. AMREF clinicians and consultant physicians consult on specific cases. Clinical staff from the rural hospital forward the case notes and supporting images of the patients to be 'seen' the following day by email. Notes may be scanned into images of handwritten notes or PC-based using proprietary software such as Telemedmail[™]. Consultants meet to prepare opinions and at an agreed time a teleconferencing connection is established. On completion of the consultations, the entire record is saved on a dedicated library file on the AMREF server. In this way, AMREF is able to access thousands of more patients in remote areas every year in an increasing number of hospitals in Eastern Africa.

The project's focus is on capacity building both at the sites and within AMREF Outreach offices. The aim is to develop clinical expertise in referrals, research and professional education and compilation of electronic case histories. The project continues to develop and evolve to reach a wider audience and keep up with the latest technology, expertise and medical needs. One of its major plans is the development of a virtual referral centre while establishing partnerships with academic medical centres.^{viii}

3.2.2 King Faycal Hospital Project in Kigali, Rwanda

In Rwanda, evidence of a telemedicine pilot was demonstrated at King Faycal Hospital in Kigali connecting two other hospitals in Rwanda as well as major hospitals in Belgium. Video conference facilities are in place with broadband Internet using fibre optic connecting all three medical Universities and other healthcare settings, particularly those providing pediatric care. Under the current project carried out by the power utility company, Electrogaz, to deploy fibre optic through the power transmission lines, the Government of Rwanda agreed to connect all health centres and schools which are located five kilometers from the transmission lines. The Rwandan health care system seemed to be at risk due to increasing demand, spiraling costs, inconsistent and poor quality of care, and inefficient, poorly coordinated care systems.

The King Faycal Hospital uses tele-health networks such as videoconferencing and wireless communications so that specialists can share information and prescribe treatment over long distances. It ensures that the few physicians available are put to the best use for the benefit of many Rwandans, including the medical students in various teaching universities of Rwanda. With the facility in place, students and practicing physicians can consult with other medical consultants from anywhere around the world. Efficiency of the medical services has increased at King Faycal Hospital due to the fact that through the telemedicine technology one doctor can attend to patients located in different hospitals such as Cyangugu and Ruhengeri.

3.2.3 Keneya Blown: Mali University Medical School (Bamako, Mali)

A project in Mali named "Keneya Blown," the "health vestibule" in the Bambara language,

was initiated in 2001 by the Mali University Medical School in Bamako and financed by the Geneva government and the Geneva University Hospitals. The telemedicine network has enabled various collaboration channels, including North-South, South-South, and South-North distance learning and tele-consultations. A promising perspective is the fostering of South-South exchanges of expertise through decentralized collaborative networks. For example, there is neurosurgical expertise in Dakar, Senegal, which is a neighboring country to Mali. A tele-consultation between these two countries is culturally and logistically feasible since physicians in Senegal understand the context of Mali better than those from northern countries, and a patient requiring neurosurgical treatment would most likely be treated in Dakar rather than in Europe. Similar projects using the same technologies are now being deployed in Mauritania, Morroco and Tunisia (Geissbuhler et al. 2003).

3.2.4 Ghanaian Ministry of Health's Community Health Information Management

In Ghana, the Ministry of Health developed a Community Health Information Management system (CHIM) to meet the challenge of the widening gap between increasing demand for health services and the scarce resources available according to the field study. The CHIM system is an ICT-based data collection and information-sharing system which is used for decision-making in the Ghanaian Ministry of Health in order to improve the utilization of the scarce resources available for an increasing demand for health services and is based on the software tool package Epi Info[™]. At present, Internet access is very limited outside Accra and other large urban areas in Ghana. Therefore, local health data is gathered and entered into the program by community health workers, stored on portable digital media, and brought to the capital city.

According to the survey, budgetary allocation for this programme is built into the overall budget of the Ministry and represents between 3% and 5% of the overall budget. There are no private E-Health facilities in Ghana. There are other major donors to the ICT program, including Ghana's bilateral and multilateral donors supporting the governmental budget, for example, the Danish International Development Agency and the European Union. The support for ICT is provided for information management, and not specifically for the ICT programme. Through the ICT programme, the Ministry is supporting 20 pilot districts with ICT infrastructure and personnel to be able to collect, store, and manage information at the district level.

The advantage of a digital health information system is that it strengthens management at the district level and decentralizes health management at the community level. The system also improves the surveillance and control of communicable and non-communicable diseases, especially malaria and AIDS. The system is benefiting all sectors and donors because it combines and compares national health insurance, education, water and sanitation, and other sector information for all stakeholders. Another project worth noting in Ghana is the District Health Information Management System (DHIMS). The mission of the project is to improve on the quality of data control in the health sector, serving the Dangme East District and Ghana Health Service/Ministry of Health.^a The project has been able to capture and analyze data in areas such as Expanded Programme on Immunisation, In-patient Morbidity and Mortality, and Out- Patient Department Mortality.

The project is funded by the Government of Ghana through the Ministry of Health. It is not possible to tell the amount of funds involved, because most of the equipment was brought in directly by the Ministry of Health and the personnel are being paid by Ghana Health Service through the overall budget of the district.

3.2.5 Uganda Chartered Healthnet (UCH)

Short for Uganda Chartered Healthcare, UCH is a project funded by SATELLIFE -- a USheadquartered charity organisation which initiated the research project in order to address health information needs, and also to provide critical and valuable information to health workers, including medical faculties, doctors, researchers and students. Launched in 1995, UCH's main objective is to provide Internet and email to the university community, specifically for health services. In 2003, another project funded by SATELLIFE, a Boston-based faculty of medicine, was initiated. Called Uganda Health Information Network and consequently Healthnet, the project was registered as an NGO to present a platform for implementing the project.

A field visit and interviews established that the project forms part of the reform and decentralisation process of the Ugandan Health Sector to link health work done at a national level with health work done at district levels. UCH started with a pilot project in two districts: Mbale and Rakai. The pilot is now complete and the project is transitioning from the pilot project phase covering only two districts to now cover the whole country. The project coordinator noted that UCH, as a research organization, is providing health information services to doctors, health-workers and other interested stakeholders. It is geared towards improving the way services are delivered, and its main objective is to ensure that the information needed by health workers is available in a timely and accurate way for better delivery of health services.

At first, UCH provided an email service, where health information retrieved from SATELLIFE (in USA) was disseminated to health workers in Kampala. As the number of commercial health-information providers increased, UCH changed its strategy and initiated a content provision and customized data analysis service to health workers through Personal Digital Assistants (PDAs). Health information is now exchanged via PDAs, WideRay Jacks (a device that configures retrieved information from databases to the PDA or vice versa), email, cellular networks and central servers.

The project coordinator further indicated that through the introduction of PDAs, Ugandan health workers are now able to request specific information, upload the request, and receive the desired information on a subsequent download. UCH has experienced improved and timely delivery of health reports to the Ministry of Health and has especially been beneficial to doctors and health workers in rural areas, who now have access to vital medicine and treatment information and are able to communicate quickly with other health workers and professional health institutions. UCH also delivers continuing medical education to health workers and doctors, availing the Uganda Clinical Guidelines on PDA for health workers. The health information includes drug information and treatment recommendations, current medical journals, disease monitoring, and patients' health records.

The use of ICTs has, among other things, resulted in doctors being able to diagnose tuberculosis and cholera epidemics much faster, as well as screening blood samples more efficiently, and storing patients' records in secure and easily accessible formats. According to a published technical report, "Data collection is improved through the use of this technology. Rakai and Mbale District Health Services report obtaining close to a hundred per cent compliance rate with their weekly Disease Surveillance reporting using the network, whereas the national average is 63%. They also report improved data quality at point of collection, more timely access to data for analysis and decision-making and more rapid response to emerging situations as benefits."^x

4. The Use of ICT in addressing HIV/AIDS

Given the scale and pace of the spread of HIV and AIDS, and the urgent need to 'shorten the learning curve,' electronic communication has a vital role to play in responses to the pandemic in both the developed and developing countries. ICT has now been recognized as an effective tool for the transfer and exchange of information and knowledge in the fight against HIV/AIDS. Accordingly, this chapter provides a dedicated section to the topic.

4.1 Global Experience in the Use of ICT for HIV/AIDS

The global experience on the application and use of ICT for HIV can be demonstrated by the AIDSWEB project, launched in 1998, as an initiative of the World Bank Institute's ICT for Education program (formerly the World Links for Development Program). This project seeks to explore linkages involving the use of ICT in HIV/AIDS educational and peer outreach activities. Project activities to date have included an e-mail based collaborative project, teacher exchange visits, adaptation of HIV/AIDS educational material for ICT platforms, HIV/AIDS and ICT workshops for schools, policymakers and NGOs, and material development.

In India, an estimated 5.1 million people are infected with HIV, accounting for 68% of the South Asian epidemic and 10% of the global epidemic. The country ranks second only to

South Africa in the total number of people living with HIV. The crisis has spawned initiatives from a variety of sectors, including federal government, state agencies, non-profit organizations, networks of HIV-positive people, and corporations. Nationwide surveys have shown that while over 1,200 implementing agencies in the country are attempting to respond to the HIV/AIDS crisis, there exist major information gaps, inadequate capacity and limited resources that impede the ability of these agencies to deliver quality services. Based on the results from the surveys, three barriers and consequent needs have been identified in the capacity-building arena: skill building, collaboration and information sharing, such as good practices, technical support, and access to resources.

The examples below illustrate some of the ways in which ICTs, including the old media ICTs of radio and television and the paper media, can be used to support efforts to combat AIDS and HIV in Africa.

4.2 Straight Talk Foundation Uganda

The Straight Talk Foundation in Uganda runs a programme to enhance an understanding of adolescence, sexuality, and reproductive health by promoting safer sex and life skills. Straight Talk uses radio, print and clubs to reach its target group. The radio show is aired once a week, for half an hour, on 14 FM stations nationwide. Delivered in both English and local languages, the programme addresses the needs of all youth in and out of school. The popular "Straight Talk" and "Young Talk" magazines, a newspaper and newsletter provide a forum where young people can write letters about their problems and receive advice from doctors and others who are well informed about sexual and reproductive health (SRH) issues. Straight Talk clubs in secondary schools and communities are avenues for open discussion about adolescent issues. Sensitization workshops are also used to target teachers and parents and are held for discussions on SRH issues related to children and adolescence.

The challenges include the barriers that cultural practices, beliefs and attitudes build in openly discussing sexuality issues with young people. Because of limited funds, the foundation cannot adequately meet increased demand for its programs by District authorities, school administrators, and young people. A major achievement for Straight Talk is that it has succeeded in reaching out to the adolescents in spite of cultural reservations from the adult audience (teachers and parents).^{x/} Its impact is measured through readership and listernership surveys, the tracking of feedback letters, and follow-up interviews with teachers and pupils.

4.3 AIDS Helpline

The AIDS Helpline was established by the South African Department of Health in 1992 in partnership with Life Line. The toll-free Helpline service was consolidated into a centralised call centre in Johannesburg in 2000. It is staffed by full-time, trained counsellors and can handle up to 24 incoming calls at a time. The calls are monitored through data capture

forms and automated electronic call counting. The service provides callers with basic information, counselling, and referral to services in all 11 South African languages and is available 24 hours a day, seven days a week. Telephone access in South Africa is high -42% of all South African households either have a landline or cell phone, and only 9.4% of households have no access to a telephone nearby.

4.4 Video and Television Based HIV Education

Tsha Tsha is an entertainment-education television drama series focusing on young people and dealing with love, sexuality and relationships in a world affected by HIV/AIDS. The series has been viewed as realistic, captivating, entertaining and educational. Setting the drama in a rural context was found to be a novel concept and appealed to rural and urban residents alike. There was an increase in knowledge and general awareness about HIV/AIDS with various self-reported shifts in HIV attitudes, beliefs, practices and behaviours. Tolerance and empathy for people living with HIV/AIDS were enhanced through the series, and this was related to an increased sense of responsibility for the wellbeing of others. The series offered a sustained engagement with the dynamics of living openly with an HIV-positive status and the problems and challenges involved in sharing one's status with others. Strong, positive images of young people confronting their HIV-positive status were provided and realistic and moving portrayals of a broad range of personal and community issues were confronted in the process. Tsha Tsha was also seen as providing positive role models for women, as well as positive examples of male-female interaction.

WE CARE is one of the TV programs that emphasize the importance of taking care of people with AIDS. This ten-minute episode AIDS education program was previously meant to educate children in primary schools about the HIV/AIDS pandemic and help them develop an attitude of caring for people with HIV/AIDS. This program started in October 2001 and was designed to support life skills learning within the 2005 curriculum.

Soul City Institute for Health and Development Communication, a health and development NGO, has been in existence for 16 years and has a regional programme which includes nine SADC countries focusing on HIV/AIDS related prevention and treatment messages conveyed via TV, radio and print materials.

5. The Role of Public-Private Partnerships in E-Health

Public-private partnerships (PPPs) have been a feature of so-called "public" services such as water and transport. PPPs have only recently extended into social policy areas such as health and education, generating significant trends in public finance in the past decade. PPPs are formal agreements that usually take the form of long-term flexible relationships that include an element of risk sharing and engage the NGO and commercial sectors in a variety of ways. In PPPs, the public sector defines the scope of business, such as specifying priorities, targets, and outputs) while the private sector delivers the business objectives, offering value for money to the public sector (Laroque and Latham 2003). In African ICT initiatives PPPs can fulfill a dire need for resource provision and management (Bovaird 2004). PPPs do not substitute for government action but imply a different governmental role to harness the resources of private partners (Jamali 2004).

5.1 E-Health PPP's in Africa

Within E-Health PPP's, the private sector supplier's role is usually to provide the E-Health information and expertise needed by healthcare professionals and managers to achieve the strategic healthcare goals of the national (or regional) healthcare system (Jones, 2002). In light of the fiscal constraints facing sub-Saharan African public health systems, appropriately structured and executed PPP's in E-Health can help address specific cost and investment challenges and deliver more efficient, quality-enhanced services (Nikolic and Maikisch 2006).

5.2 Detailed Survey of Selected E-Health PPP's in Africa

A subsidiary of the International Telecommunications Union's (ITU), Telecommunications Development Bureau (BDT) launched its first telemedicine project in Africa in 1998. A telemedicine link between the central hospitals of Beira and Maputo in Mozambique was established using existing terrestrial and satellite telecommunications systems by a group of partners, including Telecomunicaçoes of Mozambique (the country's main telecommunications operator) and WDS Technologies, a telemedicine equipment vendor from Geneva. The teleradiology software was designed by WDS Technologies and tested at the University Hospital of Geneva. The project enables the two central hospitals to rely on standard lowcost teleradiology equipment for the transmission, exchange, and visualization of images and radiographs (Mbarika 2004).

Afrox Healthcare Ltd (AHL) partners with the South African government to provide hospital care to low-income patients at selected chronic and acute care hospitals. Their operations create huge volumes of data that is transmitted internally between AHL hospitals and operations and the ageing AHL enterprise system. In 2002, AHL called in Microsoft to develop an open, extensible messaging platform system that would address internal and external communication challenges and provide operational efficiency. Microsoft's overall solution delivered integration of the enterprise through XML Web Services and Microsoft .NET Enterprise Servers, with the scale of this deployment of the .NET Framework in healthcare believed to be a world first for AHL and Microsoft South Africa. Significant savings per hospital site were projected, implying group-wide savings that would easily justify rolling the technology out to more facilities. Initial results suggest an 11 per cent time and cost saving in various areas, including a faster billing cycle. Annual savings per site were estimated at many millions of rands. Through this technological intervention, cost-efficient patient-led healthcare is becoming a reality (Microsoft Corporation 2007).

TRACnet, developed by Voxiva, is Rwanda's IT solution designed to collect, store, retrieve, and disseminate critical program, drug, and patient information related to HIV/AIDS care and treatment. Under the leadership of the Ministry of Health and the Treatment Research and AIDS Centre (TRAC), and also with support from the US President's Emergency Plan for AIDS Relief (PEPFAR), TRACnet has been deployed nationwide connecting every health facility providing anti-retroviral (ARV) treatment and related services.^{xii} A cellphone can be used, even where there is no electricity, to report on a whole range Issues including patients on treatment, drug stock levels and the other key data. Rwanda is the first country in Africa with a national-scale, real-time information system to manage its HIV and AIDS programme (GSM Association 2007).

Drawing on Rwanda's success, the \$10 million Phones for Health initiative has recently been announced. The Global System for Mobile Communications (GSM) Association's (GSMA's) Development Fund, PEPFAR, Accenture Development Partnerships, Motorola, MTN and Voxiva are initially focused on 10 African countries to harness mobile phone coverage for strengthening health systems. Phones for Health will allow field health workers to use a Motorola handset equipped with a downloadable application to enter health data. The data will be transferred (via GPRS or SMS channels) into a central database where it is mapped, analyzed by the system, and immediately made available to health authorities via the web. The system will also support SMS alerting and other communication tools for contacting field staff (GSM Association 2007).

The GSMA's Development Fund is providing support to develop the core applications for Phones for Health and support for the in-country implementations. Motorola will support the optimization of mobile phone based health applications on a range of Motorola phones. MTN is the lead operator for the Partnership for the initial country deployments. MTN will provide the hosting infrastructure for each country, in-bound 800 services, SMS and GPRS services to support the use of the applications. Accenture will provide overall project management and in-county deployment support. Voxiva will provide overall programme coordination and management, core application software, application management services, project management and training support to countries. And PEPFAR will provide initial support of \$2 million to this alliance for system expansion in Rwanda and Nigeria in 2007 (GSM Association 2007).

Voxiva collaborated with the Malaria Vaccine Initiative (MVI) at the Program for Appropriate Technology in Health (PATH) to create the Africa Clinical Trials Portal (ACTP) in 1999. ACTP is a comprehensive, on-line resource for easily accessible information on malaria, HIV/AIDS and TB clinical trials in Africa to facilitate knowledge-sharing and provide resources that will ultimately strengthen research capacity and promote scientific collaboration in Africa. ACTP's main audience will primarily be a host of individuals and institutions (e.g., African governments, principal investigators, researchers, administrators, global and national public health organizations, and donor agencies) involved in clinical trials.^{xiii}

5.3 Common Elements of Selected E-Health PPP's in Africa

From the African E-Health PPP's surveyed, the private sector partners usually provide the technology platform and/or solution, equipment, associated training, and maintenance. The non-profit organizations, global health organizations, and health ministries tend to facilitate program coordination, project management, and technology deployment in specific target communities.

In summary, the challenge for African PPP's in E-Health and e-schools initiatives is commercial sustainability and scalability. Innovative business models must be explored to finance ICT-related PPP's that "move thinking from ownership to access, from investment to 'pay for use,' and from the individual to the community as the customer" (Laroque and Latham 2003). While PPPs may offer opportunities for exploiting the comparative advantages of both the private sector (i.e., access to finance, knowledge of technologies, and managerial efficiency) and the public sector (i.e., social responsibility and environmental awareness), they should not be treated as a panacea (Jamali 2004).

Conclusion and Policy Recommendations

Low per capita incomes, widespread poverty, and weak ICT infrastructure pose major challenges for most African countries' efforts to leverage the opportunities provided by E-Health initiatives. E-Health initiatives will harness ICT for development and bridge the digital divide only when connectivity, content, capacity-building, and policy meet real needs in the context of holistic economic growth strategies. The major areas of investment include the development of infrastructure, human resources, relevant ICT content, and supportive policies and legal frameworks that will help industry expand and protect the welfare of its citizens (Kuruvilla et al. 2004; Kirigia 2005).

E-Health is an arena with perhaps the greatest possibility for expanding access to core services to poor populations in Africa. Even though some nations in Africa appear to have achieved some success in the field of E-Health, one difficulty researchers face in evaluating the E-Health capabilities of nations is that many hospitals are run by religious organizations, as well as by profit-making corporations. Thus, there is a dearth of data on how many health facilities actually have ICT capabilities. This is particularly the case in large countries with robust private sectors such as Kenya, Nigeria and South Africa.

There is a need for specialized forums whereby providers of a particular service, such as ARV-related counselling, can network, exchange notes and share information on their respective experiences. This would enhance the collective knowledge base and enable organizations and individuals to learn from each other and from best practices that have already been identified.

There is inadequate information exchange and the sharing of best practices among service providing agencies and individuals. Most of the information available to date has been oneway and limited in reach. Additionally, there is a large duplication of efforts and insufficient linkages between related players. The Nigerian-AIDS e-forum and HealthNet are good examples of the effectiveness of such forums in an international context, laying precedent for the use of ICT in combating HIV/AIDS. A strong need has been identified to enable NGOs and local government agencies that deal with HIV issues access to individualized technical support on an ongoing basis. This can be done by setting up an ongoing support and referral system that networks them to appropriate resource persons. Specific examples include telephone, TV, video and multimedia.

From the discussion above, we propose the following policy recommendations on e-health in Africa:

- 1. Invest in ICT infrastructure that is necessary to enable E-Health initiatives.
- 2. Build capacity which is critical for ICT integration in health and educational initiatives.
- 3. Liberalize and deregulate the ICT industry in order to make prices for ICT services more competitive.
- 4. Promote financial sustainability in ICT development projects through publicprivate partnerships.
- 5. Strengthen legal and regulatory infrastructure in order to facilitate medical communication on issues such as interstate/province licensure and the credentialing of service providers.
- 6. Forge global partnerships, both South-South and North-South, in order to leverage public health information and expertise.

Notes

- i. "E-Health" is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology.
- ii. Sub-Saharan Africa achieved telephone density of one subscriber per 100 inhabitants in 2000 (ITU 2001).
- According to Professor G. Ollere Ajayi of Nigeria's Federal Ministry of Science and Technology, Internet penetration in Africa in 2001 fell below one percent (Okpaku 2003).
- iv. More work may be needed to verify these claims.
- v. The authors were unable to get more data on this topic.
- vi. A list of E-Health definitions in all peer-review published articles from 1999-2004 is conveniently placed in a table within the following publication: Oh, Hans, Carlos Rizo, Murray Enkin, and Alejandro Jadad. 2005. What Is e-Health (3): A Systematic Review of Published Definitions. *Journal of Medical Internet Research* 7, no. 1, Jan-Mar. Abstract for the publication (Pagliari, Claudia, David Sloan, Peter Gregor, Frank Sullivan, Don Detmer, James P. Kahan, Wija Oortwijn, and Steve MacGillivray. 2005. What Is E-Health (4): A Scoping Exercise to Map the Field. *Journal of Medical Internet Research* 7, No. 1, Jan-Mar.) summarizes the historical evolution of the E-Health concept.

- vii. Applying E-Health as a narrative search term to multiple databases yielded 387 relevant articles, distributed across 154 different journals, most commonly related to information technology and telemedicine, but extending to such areas as law. Definitions of E-Health vary with respect to the functions, stakeholders, contexts and theoretical issues targeted. Most encompass a broad range of medical informatics applications either specified (e.g., decision support, consumer health information) or presented in more general terms (e.g., to manage, arrange or deliver health care). However the majority of these articles emphasize the communicative functions of E-Health and specify the use of networked digital technologies, primarily the Internet, thus differentiating E-Health from the field of medical informatics. While some definitions explicitly target health professionals or patients, most encompass applications for all stakeholder groups. The nature of the scientific and broader literature pertaining to E-Health closely reflects these conceptualizations.
- viii. http://www.amref.org
- ix. This project serves about 120,580 people (population of district) based in one District Hospital and five health centers in the district.
- x. http://www.healthnet.org/idrcreport.html.
- xi. www.straight-talk.or.ug.
- xii. http://www.voxiva.net
- xiii. http://www.africaclinicaltrials.org and http://www.voxiva.net

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Health Equity, Innovation and Intellectual Property Rights in Africa

G. Tumushabe & J. Mugabe

Abstract _____

This chapter focuses on the linkages between innovation, health equity and intellectual property rights in Africa. It identifies the health challenges that the African countries face and discusses how intellectual property protection affects the countries' abilities to harness and use technological innovations to reduce the burden of disease. The paper argues that inequalities in public health in Africa are largely associated with the lack of or limited access to health innovations.

1. Introduction

The last 150 years have witnessed dramatic improvements in health status worldwide, beginning in Europe and other wealthier countries in the late 19th century, becoming generalized around the globe in the 20th century. The most dramatic gains over the past half-century have occurred in poorer countries, substantially closing the 'health gap' that previously separated the northern industrialized and southern agrarian worlds^{*i*}. These health gains are variously related to increasing incomes. This resulted in improved diet, living conditions and improvements in public health measures, such as potable water and sanitation, the diffusion of medical innovations, notably immunization and antibiotics (World Bank 1993).

However, substantial reversals of these positive trends are now evident in Africa. For example, in many African countries and particularly those of sub-Saharan region, life expectancy has fallen considerably in the last two decades. Major pandemics such as tuberculosis, malaria, HIV/AIDS and other infectious diseases now account for nearly 80 percent of the disease burden in the poorest African countries (WHO 2004) and disproportionately affects poorer segments of the populations on the continent. The MDGs Report of 2006 notes that the global HIV/AIDS epidemic remains endemic in Sub-Saharan Africa. With just over 10 percent of the world's populations, the Sub-Saharan Africa sub-region is home to 64 percent of HIV-positive people and to 90 percent of children (under 15) living with the HIV. Further, an estimated 59 percent of HIV-positive adults in Sub-Saharan Africa are women (UN MDGs Report 2006).

Despite the dramatic progress made by the pharmaceutical industry in developing new drugs and diagnostic technologies, the burden of disease in many African countries is increasing. For example, in Malawi, neonatal mortality rate is estimated at 42 per 1000 live births, which is higher than the expected rate for a developing country. This mortality is caused by infections diseases and complications during delivery. Tuberculosis has increased fivefold in the past decade. Of about 30,000 inpatient deaths recorded in 2002, 9 percent were diagnosed as malnutrition, 7 percent as tuberculosis, 3 percent as AIDS, 23 percent as acute respiratory tract infections, 9 percent as diarrhoea, 23 percent as malaria and 1 percent as traumatic condition and gynaecological disorder (Ministry of Health 2003).

In its Health Strategy, the New Economic Partnership for Africa (NEPAD) acknowledges that Africa's disease burden is increasing. It observed that "The HIV/AIDS epidemic poses an unprecedented challenge for Africa, reversing the gains made in life expectancy over the past half century. Life expectancy in the most severely affected countries has been reduced by almost a third, from 60 years to 43 years. An estimated 2.4 million people died from AIDS in 2002 and around 3.5 million infections occurred, 1 million deaths (are) caused by malaria each year and 600 000 deaths due to tuberculosis. Malaria has slowed economic growth by 1.3% per annum at a \$12 billion economic cost. Many countries have a tuberculosis burden exceeding the 300 per 100 000 population benchmark for severe disease, with 1.6 million new active cases occurring annually. Sleeping sickness is resurging, affecting between

300 000 and 500 000 people annually." (NEPAD 2003)

Furthermore, there has been stagnation or otherwise continuing deterioration in health and health related infrastructure caused by many years of economic decline and governmental neglect of facilities on the continent. Consequently, health inequities are widening between African countries and those from other regions of the world.[#] In 2001, infant mortality rate per 1,000 live births was 9 in developed countries and 90 in developing ones. In the same year prevalence of tuberculosis per 100,000 persons was 144 in African countries and only 23 in developed ones (WHO 2004). "In 1990, communicable diseases caused 59% of death and disability among the world's poorest 20%. Raising the baseline rate of communicable disease decline between 1990 and 2020 would increase life-expectancy among the world's poorest 20% about ten times as much as it would the richest 20% (4·1 vs. 0·4 years). However, the poorest 20% would gain only around a quarter to a third as much as the richest 20% from a similar increase in non-communicable diseases (1·4 vs. 5·3 years) As a result, a faster decline in communicable diseases would decrease the poor-rich gap in 2020." (Gwatkin et al. 1999)

In spite of the magnitude of these problems, a large and growing percentage of African countries' population has inadequate access to essential medicines and health care. Some estimates suggest that one half of Africa population lacks access to the most basic medical remedies.^{III} This is because of non-availability of medicines which are accessible elsewhere, particularly in developed countries, and also the failure to develop medicines for major diseases affecting African countries. Research has been preponderantly directed towards treatments for diseases of the developed countries. It has been estimated that between 1975 and 1997, only 13 of the 1223 new chemical entities found to have useful pharmacological properties were for the treatment of diseases prevalent in poor countries (Bystrom and Einarsson 2001).

Under current conditions, a majority of African countries are unlikely to meet health related targets of the Millennium Development Goals (MDGs). Recent assessments show that indeed many of these countries are behind schedule in achieving the MDGs generally.^{*iv*} The extent to which they meet the goals may halt and reverse the spread of HIV/AIDS by 2015, reduce maternal mortality ratio by three-quarters by 2015, and reduce under-five mortality by two-thirds by 2015. If this trend were to continue other health related public health problems will be substantially reduced. However this will depend on how well policy makers are guided by the nature of the major policy issues accounting for the current health inequities.

Indeed, there are scientific and technological solutions to many of the health challenges that confront Africa. The development and application of immunization, antimicrobial chemotherapy, and antiviral agents offer enormous potential to reduce the disease burden on the continent. Advances in genomics, proteomics and cell biology have enhanced the understanding of pathological mechanisms, while DNA technology has been applied to isolate genes for

monogenic diseases. This has made it considerably easy to treat inherited disorders of haemoglobin (sickle cell disease) which affects approximately 2 million persons in many African countries. In addition to these developments, rapid diagnostic methods are being developed to identify pathogens in blood or tissues. Consequently, the policy question to be addressed is whether IPR contributes significantly to inhibit access to these health technologies?

Generally, Africa's tragedy lies in the fact that a large percentage of Africa's people does not have access to and benefits from these scientific advances and related technological innovations. For example, of the more than 1500 new drugs commercialized between 1980 and 2000, less than 15 have been approved specifically for tropical diseases. A large percentage of the African children die of diseases for which vaccines exist. Although one could argue that this is in part due to dysfunctional health systems and is a reflection of widespread poverty, it is also caused by the relatively low or limited capacities of African countries to conduct scientific research and technological innovation. The majority of African countries have not established policies and programmes and organized their R&D institutions to focus on the production and application of new knowledge and innovations to solve major and minor health problems.

2. The Nature of Health Equity Problems in Africa

The concept of health equity^v can be traced from the early 1990s when scholarly references to "equity in health" emerged. Whitehead defined health inequalities as "differences in health that are unnecessary, avoidable, unfair and unjust." (Whitehead 1992) Since then, more rigorous conceptual definitions of health equity have emerged. The summation of the literature on the definition of health equity suggests that this is "the absence of systematic disparities in health (or in the major social determinants of health) between social groups

Figure 1: Sub-Saharan African country <i>per capita</i> expenditures on health, 1997 - 2000				
(compared to recommended expenditure: >\$60/capita)				
Number of countries	Amount of spending			
4	> \$60			
2	\$34 - \$60			
11	\$12 - \$34			
18	< \$12			
13	Data not available or population <1.5 million			

World Bank, World Development Report (2004)

who have different levels of underlying social advantage/disadvantage – that is, different positions in a social hierarchy." According to Braveman and Gruskin (2003), inequalities in health systematically put groups of people who are already socially disadvantaged (for example the poor, female and/or members of a disenfranchised social, ethnic, or religious group) at further disadvantage with respect to their health. (Braveman and Gruskin 2003)

The concept of "health equity" is increasingly being used in international public policy discourse on health to connote reducing inequalities in the global disease burden by improving the health of the world's least well off. Consequently, understanding the relationship between IPR, innovation and health equity in Africa requires a detailed examination of the nature of health equity problems on the continent. This enables us to examine the dominant hypothesis that IPR is the major cause of health inequalities and the major reason why African countries are unable to confront the current burden of disease. A better understanding of the nature of health equity problems in Africa will also enable us to suggest practical ways in which IPR can be used as a development policy instrument to spur innovation in health and create Africa's own pharmaceutical revolution. Generally, health equity problems can be classified into the following:

2.1 Inequality in health innovation R&D investments

Generally, R&D investments in health come from both the public and private sectors. The public sector investments can be directed through priority setting through such public policy commitments like the MDGs, or priority diseases such as global pandemics. However the private sector funding is largely directed by market signals. Health inequality therefore persists in Africa partly because for many decades now, the allocation and distribution of health related R&D and the associated health innovation enterprises have not found the appropriate environment in Africa.

The United Nations Development Programme (UNDP) Human Development Report 2001 shows that countries with leading health crises and challenges are also characterized by low technology achievement index. They have low capacity to adopt and use existing technologies (UNDP 2001). The last 12 countries (all African) on the Human Development Index (HDI) ranking of 2001 are characterized by low expenditure on R&D, high disease burden, and low technology absorptive capacity. For example Rwanda with 20,310 malaria cases out of every 100,000 people, has approximately only 35 scientists and engineers per 100,000 people. On the other hand China with 2 malaria cases out of 100,000 has approximately 450 scientists and engineers per 100,000 people. Further, Uganda with 142 tuberculosis cases per 100,000 people reported in 1998 spent only 0.6 percent of its Gross National Product (GNP) on R&D while Norway with only 8 tuberculosis cases out of every 100,000 in the same year spent 1.7 percent of its GNP on R&D.⁴⁷

It is important to recognize that many African countries either have no properly functioning markets or their markets are largely distorted by a number of structural constraints. In this

regard, it is unlikely that the private sector will be attracted to invest in the markets of these countries. Consequently, African governments must take full responsibility in channeling public investments in health innovation R&D as a means of correcting current market failures.

Consequently, it is argued that market failure is a key determinant to the current inequities in health innovation R&D flows. Yet, in Africa, the extent to which IPR contributes to these market failures is less understood. There are no conclusive empirical studies that can demonstrate a direct link between weak or strong IPR to Foreign Direct Investment (FDI) flows whether in health or in any other sector. What is clear though is that many other factors including the overall investment climate, political uncertainty and political instability, and other structural problems combine to militate against the development of a robust R&D health innovation infrastructure in Africa. Addressing these problems lies squarely in the policy domain of African Governments.

2.2 Orphan Diseases

A number of diseases such as malaria are exclusively tropical diseases having major impacts mainly in African countries. In the health R&D discourse; these are commonly referred to as orphan "diseases". In many cases, it is argued that private markets for pharmaceutical innovation based on IPR under-invest in diseases specific to developing countries and create barriers to affordable access to life-saving pharmaceuticals due to monopoly pricing. Until recently, these diseases have not been a focus of global attention and African countries themselves have not invested adequately in developing treatment and diagnostic technologies targeted at these diseases. A growing number of studies show that not more than 10 percent of global health research efforts are devoted to diseases prevalent in African countries.^{vii}

2.4 Access to essential medicines

Another major health equity issue relates to access to essential medicines by countries and populations affected by the greatest burden of disease in Africa. Where access is generally possible, there are also issues of efficacy of such drugs. Generally, efficacy of drugs depends on a long chain of sometimes interlocking factors, which are: research and development (R&D) of appropriate pharmaceutical agents, production, quality control and assurance, distribution mechanisms, inventory management, diagnosis, prescription, financial accessibility to drug dispensing and pharmacovigilance. The malfunctioning of the different facets of this chain can have devastating impacts on the health status of the population while undermining attempts by Governments to remedy major imbalances in health care.

Access to essential drugs is the primary foundation of many national healthcare programmes around the world. Availability of affordable and accessible essential drugs enable countries confront the current problems of morbidity and mortality by focusing adequate attention to child survival programmes, antenatal care, and control of such pandemics as tuberculosis, malaria and HIV/AIDS. However, access to essential drugs is still inhibited by a number of factors such as: proliferation of counterfeit and substandard products; increasingly fluctuating production of essential drugs often dictated by the market; prohibitive costs; and generally insufficient R&D in new medicines.

To understand the role played by IPR, a closer analysis of the antiretroviral drugs situation provides better insights in this area. From the outset, it is important to recognize that there is hardly any accurate data on the consumption of antiretroviral drugs on the continent. There seems to be a consensus that very few of the approximately 25 million HIV-positive people in Africa have access to antiretroviral drugs.

A 2001 study by Amir Attaran and Lee Gillespie-White found that many of the anti-retroviral drugs were in fact not patented in most African countries. Yet, there were no significant price differentials between the zero patented drugs and the patented drugs nor did consumption of such drugs vary in proportion. Although the authors caution about using their findings as sufficient basis for analyzing the relationship between patents and prices, they provide a good basis for informed policy debate on the tripartite relationship between patents, prices and access to medicine.

However, what is clear is that most African countries are finding major difficulties in ensuring effective, affordable and easy-to-use medicines. In many cases, existing or new drugs are too expensive; production of effective medicine has been discontinued; certain diseases are becoming increasingly resistant to older medicine or very few drugs are being developed to tackle diseases of high priority to Africa.

Generally, some level of consensus exists on several other policy domains that influence health outcomes of different populations: macroeconomic policies, debt and debt reduction, health systems, education, nutrition and food security, development assistance, trade and market access, and the physical environment (Labonte, Schrecker, Sanders and Meeus 2004). These policy domains are interconnected and the health impact of any one policy or set of policies within a given domain is often hard to determine precisely.

The nature of health equity problems in Africa is therefore a complex one that cannot be defined by the structure of the global IPR architecture. This complexity requires that some of the policy prescriptions alone be considered largely as a minimum package and deliberate attempts must be at creating the macro-policy environment within which health policy and policy interventions have to be designed and implemented. Consequently, to be effective, these health policy interventions require good governance and policies that support the creation of legal and social institutions that are conducive to economic and human development.

3. IPR and access to medicine

The relationship between IPR and access to essential drugs has been on the global public

health agenda for over the last 10 years. In particular, the World Health Organization has provided an important platform for this debate. In this context, there have been considerable efforts to define international guidelines for reformulating public health systems in member countries of the United Nations. For its part, the United Nations General Assembly addressed part of this problem in its Resolution 2001/33 which deals with access to drugs for the treatment of pandemic diseases among the populations of developing and least developed countries.^{viii}

There are debates within the WTO largely focusing on models advanced for protecting intellectual property in WTO member States and the management of IPR in accordance with the rules, safeguards and specific expectations contained in the TRIPS Agreement.^{ix} In Resolution 2001/33, the United Nations General Assembly calls upon the member states of the UN to refrain from taking any measures that could limit access to drugs and to the biopharmaceutical technologies used in the prevention and treatment of pandemic diseases and the infections that are most frequently associated with them. In addition, member States are encouraged to "adopt legislation or other measures, in accordance with applicable international law, including international agreements acceded to, to safeguard access to such preventive, curative or palliative pharmaceuticals or medical technologies from any limitations by third parties."

Whatever the nature of the debate, Intellectual Property Rights are regarded as indispensable for protecting the research portfolio of the drug companies and for stimulating discoveries of new treatments of diseases. The inevitable price hikes associated with monopoly protection of patented drugs limiting access to such drugs by marginalized sections of society is what brings drugs patents into focus.

In the pharmaceutical industry like in many other processes involving generation of new technology, IPR creates several deferent types of legal rights that national and international legal regimes are seeking to protect. These include: product patents largely covering the pharmacologically active chemical or formulation; process patents covering a manufacturing process for the same product; use patents covering the use of a drug for a medical indication; and "exclusive marketing rights"- an interim legal status in international patent law that pertains only to the list-developed countries under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO).^x The commonality among these different patent rights is that all of them confer a degree of market exclusivity to the patent holder.

In the light of this market development, the current global debate on IPR protection and health equity raises at least four inter-related questions. The first question is whether newer essential drugs that would address many ailments in Africa are more expensive than they would have been if not under patent protection. Over the last decades, there has been widespread debate that even access to generic drugs is hampered by the existence of patents. Consequently,

the second question is whether IPR actually slows down the introduction and access to generic drugs needed in Africa. The third question is whether more new drugs for neglected diseases, which tend to be part of the bigger problem in Africa are being developed. The fourth question is whether stronger IPR protection can spur the transfer of technologies to African countries.

3.1 IPR and the Cost of Essential Drugs

Pro-access to essential drugs advocates have argued for years that drug patents is one of the major factors hampering access to medicine in Africa. Since 1975, the WHO has pursued access to medicine including its 1978 Alma-Ata Declaration on Primary Health Care^{xi} and its review of this issue through the World Health Assembly and its Executive Board. A number of other United Nations Bodies especially have also focused attention on the impact of IPR on the cost of essential drugs and access to medicine in developing countries.^{xii} In 2000, the UN sub-commission for Protection and Promotion of Human Rights adopted a resolution on "Intellectual Property & Human Rights." It declared that " implementation of the TRIPs Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, and the right to self-determination", and "requests all Governments and national, regional and international economic policy forums to take international human rights obligations and principles fully into account in international economic policy formulation." In a series of Resolutions, the Commission regularly calls upon member states of the United Nations to pursue policies in accordance with international law to promote the availability of pharmaceuticals and medical technologies to treat pandemics such as HIV/AIDS.xiii

Further, multilateral bodies such as the European Union and the G8 have also increasingly become unequivocal in linking IPR and access to essential drugs in developing countries. The European Parliament passed a resolution on access to drugs for HIV/AIDS victims in the Third World (15/03/2001).

Nevertheless, there is growing consensus that although patent protection is an important issue to be addressed in the context of access to medicine including the cost of drugs, it cannot possibly be a major factor in comparison to all other factors. In fact, IPR cannot be considered to be the major reason for the high costs of medicine in many African countries. For example, in the last five years, the cost of ARVs has fallen sharply on account of a number of reasons including: the famous case of the Pharmaceutical Manufacturers' Association v The President of the Republic of South Africa; the decision of the Government of Brazil to threaten to issue compulsory licenses in the event that negotiations for licenses with brand name pharmaceutical companies did not materialize; increasing generous donations of ARVs by pharmaceutical companies often brokered by philanthropic organizations; the intensive advocacy campaign by high profile individuals and NGO coalitions; and the growing technological capacities of different countries to produce generic drugs.

Public health authorities also agree that the slow uptake of anti-retroviral drugs in Africa has been due to several reasons including stigma still associated with HIV/AIDS and ineffective healthcare delivery systems. These factors tend to account for the lack of access to essential drugs such as ARVs especially given the fact that the prices of such drugs have fallen sharply over the years.

3.2 IPR and Health R&D Investment Flows

The conventional argument is that strong IPR protection and in particular patent law regimes can spur technology transfer and increase FDI flows including in the area of health and access to medicine. If this were to happen, it is argued; it would lead to reduction in the cost of medicine and increase access to much needed drugs and other pharmaceutical technologies. However, the anecdotal evidence currently available either points to the contrary or essentially does not validate this conventional argument. First, it is important for Africa to recognize that multi-national pharmaceutical companies in the industrialized countries and the national companies in many developing countries have been able to develop their pharmaceutical industry to present levels because they used the national legislation on patents as policy instrument to develop and strengthen their technological, commercial and economic development. The Paris Convention on intellectual property rights gave freedom to national governments to define and set standards for pharmaceutical patents.

The therapeutic revolution which began in the mid-1940s after World War II enabled drug companies in ten of the most industrialized countries to innovate and introduce new products to the market. But it is important to note that one of the major factors that spurred this therapeutic revolution is that many of these countries refused to grant product patents for pharmaceuticals, until they had reached international competitiveness. In practical terms, these countries clearly validate the argument that a patent free environment where the State takes leadership in organizing the science and technology Research and Development (R&D) enterprise is essential for the technological development of the pharmaceutical industry. For example, Japan, Germany, Sweden, France, Italy and Switzerland - home of some of the most innovative pharmaceutical companies, persistently resisted granting pharmaceutical product patents until their countries had attained considerable levels of development and pharmaceutical R&D (France, Germany, Japan, Switzerland, Italy and Sweden introduced product patents in 1960, 1968, 1976, 1977 and 1978, respectively). Even under the Paris Convention, States retained the sovereign right to enact appropriate national legislation on patents. Most of the developing countries that have so far developed considerable pharmaceutical R&D capacity including Brazil which is a founding member of the Paris Convention protected neither products nor processes in the pharmaceutical industry.ivx

3.3 IPR and the Transfer of Health Technologies

Generally, there are several arrangements that exist to facilitate the flow of technology and

know-how across national borders. These are contractual agreements, licensing, product line agreements, exchange of skilled personnel and know-how contracts. While there are largely no substantive distinctions between these mechanisms, they may be distinguished by a number of factors ranging from the duration of the right to the nature of the obligations incurred by the contracting parties. Licensing for example merely allows the use of the technology; joint venture arrangements typically provide technology required in the undertaking of a joint project; turn-key contracts involve the building of an entire industrial plant or research facility and giving the "key" to local partners.

In spite of this variety of technology transfer mechanisms, it has been observed that technology transfer, in its legal and conceptual articulation, is not achieved by any of these modes (Gana 2005). For example, a study on the implications of the 1996 Industrial Property Code of Brazil on local production and access to medicines revealed *inter alia*, that: of the 1,387 drug patent applications filed since 1996 when the Act was signed into law, only 36 (2.6 percent) were filed by residents of Brazil compared with more than 500 by United States Residents (Bermudez et al. 2006). A similar study of Thailand's 1992 revised patent law, which in all aspects applies the standards of IPR protection as those required by the TRIPS Agreement found that there had been no significant increase in technology transfer or FDI flows, and that spending on pharmaceuticals had increased at a higher rate than overall healthcare spending.

3.5 International Trade, IPR and Health Equity in Africa

The classic economic theory of international trade presupposes that international division of labour ordinarily results in a more rational allocation of the factors of production. This is because, it is often argued, international division of labour allows for specialization which facilitates the acquisition of skills and know-how and the formation of capital. In any case, international division of labour allows for the realization of economies of scale, which would, other factors constant, result in more output produced with less inputs thereby resulting into higher standards of living. In neo-classic economic theory, free trade is the condition for this beneficial process of integration and globalization. In this regard, the intermediate objective of the World Trade Organization is to "liberalize trade" in the framework of "an open, rules based, multilateral trading system" which is dynamic in the sense that new rules can be added through regular multilateral trade negotiations, commonly referred to as "Rounds of Trade Negotiations", while existing rules are enforced through a multilateral and biding dispute settlement mechanism.^{xv}

The current controversy between IPR rules under the multilateral trade rules and public health in Africa essentially stems from the ultimate and fundamental objective of raising standards of living which are inherent in the Marrakech Agreement establishing the WTO. In its opening paragraphs, the WTO Member States take cognizance of the fact that

> "their relations in the field of trade and economic endeavour should be conducted with a view to raise standards of living, ensuring full employment and a large

and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development."

However, beyond these fundamental objectives, the multilateral trade rules have historically recognized that commercial considerations may in certain circumstances have to be subordinated to legitimate and overriding public policy objectives. Indeed, the practice of various international bodies as well as the jurisprudence of the multilateral trading system from the General Agreement on Tariffs and Trade (GATT) and beyond the WTO clearly recognizes this cardinal rule. For example the International Health Regulations of the World Health Organization^{xvi} allow time-limited trade and travel restrictions that may be necessary and essential to prevent the spread of infectious diseases, provided such restrictions cause minimal disruption of international trade flows.^{xvii}

The 1947 General Agreement on Tariffs and Trade (GATT),^{xviii} the Agreement on Technical Barriers to Trade (TBT) and the Agreement on Sanitary and Phytosanitary Standards (SPS) all recognize the right of Member States of the WTO to restrict imports and exports if necessary to protect health of humans, animals and plants. The later two Agreements favour the formulation of international standards and the SPS unequivocally recognizes the food safety standards adopted in the context of the Codex Alimentarius Commission.^{ixx}

The global trading system from the GATT to the WTO has had a long tradition of creating mechanism and flexibilities for public health. However, it is not until the adoption of the TRIPS Agreement and the unfolding of pandemics of global proportions such as HIV/AIDS and malaria at the turn of the century that the debate on IPR and Public health took centre stage in international trade policy discourse. It is important though, to note that protection of intellectual and industrial property has historically been pursued through highly specialized international bodies and agreements such as the World Intellectual Property Organization, the Paris Convention, the Patent Cooperation Treaty (PCT), etc. However, by the end of the Uruguay Round of Trade Negotiations that ended with the adoption of the Final Act embodying the WTO Rules (Marrakech Agreement Establishing the WTO), agreement had been reached to bring issues of IPR into the framework of the WTO. In effect, this meant that from then on, the protection and enforcement of IPR came under the ambit of a legally binding multilateral trading legal regime and its dispute settlement mechanism.

Besides requiring WTO Member States to grant 'effective and adequate protection' of intellectual property rights, the WTO obliges its Members to ensure national and most favoured nation treatment as regards this protection. Further still, the Agreement obliges the member states to adopt procedures that enable IPR holders to ban imports of counterfeit

or pirate products.^{xx} The TRIPS Agreement however provides limited exceptions to the exclusive rights conferred by a patent,^{xxi} by obliging a patent holder to share his invention with others by means of compulsory licensing.^{xxii}

Consequently, in neo-classical international trade and division of labour, strong IPR protection makes absolute economic sense. For countries that have developed strong innovation capacity, they are able to reap huge economic benefits through monopolies and pricing inherent in exclusive marketing rights granted under a patent. Otherwise, in the absence of an organized and functioning national system of innovation, strong IPR protection can stifle local innovation capacity and undermine national public policy efforts to promote public interest issues such as access to medicine and diagnostic technologies. Indeed, it is important to recognize that although the TRIPS negotiations have been driven by this neo-classic argument, the claim that introducing TRIPS compliant legislation would stimulate transfer of technology, encourage FDI, strengthen indigenous R&D and innovation and ensure the early introduction of new products including medicines is not backed by empirical data.

4 Health innovations and access to medicine in Africa:

The relevance of IPR to health innovation and its impact on health equality can vary across countries and sectors since it creates appropriate incentives for stimulating innovations by enabling companies and individuals recoup their R&D investments through IPR guaranteed monopolies. However, it has been argued that for African countries with very limited investments in science and technology and innovations systems that are not properly developed, IPR does not offer the benefits that would ordinarily accrue to those countries. In fact, African countries need to pursue less protective regimes while using IPR as an instrument to stimulate science and technology innovation.

Secondly, it has been demonstrated that the link between IPR and access to medicine is not well supported by empirical evidence. Instead, there are a variety of reasons why poor populations in many African countries are unable to access life-saving medicines and diagnostic technologies. These range from poor health delivery systems to poor healthcare and absence of qualified professionals. IPR therefore can only be partially responsible for the costs of medicine in Africa. In any case, there are generally promising initiatives that suggest new mechanisms facilitating access to new technologies and innovations in the public health sector. A few of these initiatives have been tried by selected African countries which provide examples of what needs to be done to address the problems of health equity in Africa.

4.1 Compulsory licensing

Compulsory licensing is the term given to a legal approach that permits the manufacture and use of generic drugs without the agreement of the patent holder. Compulsory licensing as a tool for public policy in patent legislation has become a common feature of global and national

instruments. Accordingly, compulsory licensing may be granted in cases of national emergency or when a state wants an invention to have public use on non-commercial terms. The effects of compulsory licensing are, to increase competition, supply the market, and in many cases to reduce prices of the affected drugs. Over the last decade, compulsory licensing has been one of the most controversial issues in the debate regarding the interpretation and application of the TRIPS Agreement of the World Trade Organization. The debate which is still ongoing within the TRIPS Council of the World Trade Organization revolves around the circumstances under which and the restrictions that should apply to the application of compulsory licensing as a public policy measure in addressing public health problems of developing countries. Some examples provide insights into this debate.

The first example concerns the grounds under which a compulsory license can be granted under article 31 of the TRIPS Agreement. The United States of America contested the WTO compatibility of Brazil's Industrial Property Law 9279 of May 1996. A mutual settlement between the parties, reached in 2001 suggests that a patent owner can, in derogation of his exclusive rights, be forced to share his invention if the patented product is imported rather than produced domestically in the country granting the compulsory license.xxiii The second case involves a voluntary licensing deal on GlaxoSmithKline (GSK) patents for the ARVs Retrovir, Combivir and Epivir to Aspen Pharmacare in South Africa.xxiv The licensing arrangement enabled Aspen to manufacture and produce the products and sell them to the South African government and other parties in the not-for-profit sector. Under the arrangement, GSK waived their right to royalty fees and allowed a provision that allows a 30% fee on net sales to be paid to NGOs that manage care programmes related to HIV/AIDS in South Africa. The GlaxoSmithKline deal simply illustrates the extent to which a combination of political leadership, corporate commitment and public pressure are required to ensure that intellectual property rights go beyond the narrow confines of the markets and profits to work for public health.

The GlaxoSmithKline South Africa arrangement was recently repeated in Kenya where GSK negotiated with a Kenyan company, Cosmos Limited, to start manufacturing generics of lamidvune (Epivir), zidovudine (Retrovir) and a combination of the two, Combivir. The patents for the three medicines are held by GSK giving it exclusive rights to manufacture and distribute the drugs in Kenya. This licensing arrangement creates opportunities for helping improve access through mass and cheap production while facilitating compliance with patent conditions.

4.2 Parallel importation

Parallel importation is rapidly becoming one of the policy options that countries are using to lower drug prices and increase access for the poor. Parallel importation involves purchasing proprietary drugs from a third party in another country, rather than directly from the manufacturer. The intention is to take advantage of the fact that in many cases, pharmaceutical companies charge significantly lower prices in one country than in another. For instance, in Britain, where parallel importing is common, the listed price for Glaxo Wellcome's Retrovir is £125, but consumers can purchase the same proprietary drug imported from other European countries

for as little as £54.

Prices for the same product can vary widely among countries because of many factors, such as differences in intellectual property rules, differences in local incomes, and the degree of competition among producers. For example, a 1998 study by the Consumer Project on Technology found prices for SmithKline Beechman's version of Amoxil was \$8 in Pakistan, \$14 in Canada, \$16 in Italy, \$22 in New Zealand, \$29 in The Philippines, \$36 in Malaysia, \$40 in Indonesia, and \$60 in Germany. By allowing some form of parallel importation, countries can shop around and get better prices, using market forces to lower national expenditures on a range of goods, including pharmaceuticals.

4.3 Differential Pricing

Differential pricing is another policy strategy that is increasingly being used to address the problem of access to essential medicines especially by the poor countries. Differential pricing refers to drug prices that are within the buying power of consumers in developing or least developed countries. In this context, the 'degree of accessibility' of the consumer to essential drugs is the major defining factor in the pricing policy for such drugs. The ultimate objective of this measure is to ensure access to essential drugs for the majority of those people from the most economically and socially deprived population groups.

4.4 Price Discount Negotiations

Another emerging public policy response to increase access to essential drugs is "price discount" negotiations. Since about 2000 and following on the increasing pressure from access to medicine campaigners, five multinational drug companies and five international agencies^{xxv} began negotiations on price discounts on selected HIV/AIDS drugs. The conditionalities include reinforced and additional protection and enforcement of patents of participating pharmaceutical industries. However, the five drug companies want the UN partners to explicitly renounce the use of the TRIPS flexibility mechanisms, in particular, compulsory licensing and parallel importation that limit the industry's price setting power.

In any event, price discount negotiations are carried out country by country, drug by drug, and company by company only. This approach significantly undermines the African consensus that emerged from Doha where meaningful progress was made because of the joint negotiations adopted by the African Group of Countries. As in the case of TRIPS, important gains made from the multi-lateral system are being undermined by bilateral processes where individual African countries are generally weak negotiators. Indeed, as of February 2001, within a period of 9 months after the negotiations were launched, Rwanda, Senegal and Uganda had successfully negotiated price discounts. The emerging practice on price discount negotiations clearly shows that industry is the winner as it secured long-term protection for its patents even in the presence of key flexibilities including the grace period for developing countries to fully implement the TRIPS Agreement.

4.5 Drug Donation Programmes

Drug donation programme is one of the major public policy responses to health equity issues regarding access to essential drugs. In July 2000, the Group of 8 Industrialized Nations (G8) meeting in Okinawa, Japan, endorsed the international Development targets for HIV/AIDS, tuberculosis, and malaria. This was followed by the European Commission policy framework for tackling these diseases, the April 2001 UN Secretary General Call to create a Global Fund to fight HIV/AIDS, the April 2001 Abuja Summit of the Organization of African Unity, the UN General Assembly Special Session on HIV/AIDS in June 2001 and the July 2001 G8 Summit in Genoa. These efforts culminated into a global endorsement to establish a special global financing facility to help fight the spread of the above mentioned diseases.^{xxvi}

4.6 Global Partnerships in Health Innovation

In the last decade, there has been proliferation of major public-private partnerships aimed at developing and deploying new medicines and vaccines for global health pandemics and neglected diseases. These initiatives such as the Medicines for Malaria Venture (MVV), Drugs for Neglected Diseases Initiative (DNDi), African Poverty Related Infection Oriented Research Initiative (APRIORI) and The Global Health Initiative pull together resources from the public and the private sector to accelerate drug discovery, drug development and deployment. These initiatives are discussed in more detail in Chapter 2.

4.7 Pooled Procurement

Pooled procurement of drugs is an alternative strategy used by mainly countries with small populations to procure critically needed drugs. Although the strategy has not been widely used in practice, it can help countries to pool together limited resources to procure essential drugs in bulk. Pooled procurement strategy has been used in the Caribbean, where seven different countries joined together to purchase drugs. The strategy which started in the 1980s has enabled these countries to reduce prices by around 50%. In addition, this combined operation has allowed the countries involved to develop a single multi-country unit with expertise in drug evaluation and price negotiation. This strategy could be used by groups of African countries to mitigate high prices on account of monopoly guaranteed patents.

5. Conclusions and Policy Recommendations

There is now recognition that scientific and technological capacity is key to modern development. In Africa, this is well reflected in the wide range of national policies as well as continental programmes of action that are being developed in the context of NEPAD. However, it is important to recognize that presently, Africa has yet to produce a critical

mass of skilled workers capable of initiating and sustaining a dynamic development path. On the contrary, Africa's capacity to generate knowledge and participate in the knowledge society has continued to decline. Africa's research and development expenditure amounted at most to \$4.2 billion in 1994 (0.9% of the world total). The share of Sub-Saharan Africa, including South Africa, was only \$2.3 billion (0.5% of the world total). This has exacerbated the asymmetry between rich and poor and the imbalance in the structure of global governance, widening the gap between the "connected" world and "isolated" Africa.^{xxvii}

This asymmetry is clearly evident in the health sector. Through this paper, we have argued that the technological advances in the pharmaceutical industry have led to dramatic improvements in health and overall human development indicators around the world. On the contrary, Africa remains trapped in quadruple burden of: infectious diseases, chronic illnesses, injury and HIV/AIDS. African countries have not developed critical science and innovation capacity to address the health needs of the African people including diseases that are peculiar to Africa and African communities. The majority of African countries have also not been able to access and utilize the wide range of science and technology tools that have been proven to enable nations improve the health conditions of there citizens. A combination of these two failures largely accounts for the degree of health inequalities within Africa and between Africa and the rest of the world.

Our analysis has revealed the following points:

- i) Problem of health inequality is manifested in at least 5 different ways: Allocative and distributive inequality in health innovation R&D investments; variations in investments in orphan diseases R&D; apparent interest in transnational diseases compared to limited interest in global diseases; Access to essential medicines; and differences in the social determinants of health.
- ii) Anecdotal evidences exist linking IPR to these different aspects of health inequity. For example, this study finds no conclusive empirical studies that can demonstrate a direct link between weak or strong IPR to FDI flows whether in health or in any other sector. What is clear though is that many other factors including the overall investment climate, political uncertainty and political instability, and other structural problems combine to militate against the development of a robust R&D health innovation infrastructure in many African countries. In many ways, addressing these kinds of problems lies squarely in the policy domain of African Government and not necessarily on the structure of the current global IPR architecture.
- iii) Current global discourse on the burden of disease in Africa has been driven by the problems of access to essential medicine. Much of the discourse points to the fact that the global IPR architecture is largely to blame for lack of access to essential medicine in most African countries.
- iv) IPR protection is only part of a bigger problem. African countries have put

more faith in changing the global IPR architecture than in developing the necessary national legal, policy and innovation infrastructure to harness the benefits inherent in IPR protection. The current health policies and programmes of many African countries largely focus on primary health care programmes and less on building national capacities in health research and development.

The following policy recommendations can be drawn:

Design indicators to measure progress in health innovation

A review of the current indicators measuring progress in the health sector show that many of these indicators focus on primary health care access issues and the traditional parameters such as distance to health centres, doctor to patient ration, cost of medicine, etc. The direct impacts of IPR can only be well understood by focusing on whether IP facilitates or hinders innovation and innovation capacity before we begin to measure the downstream impacts of any IPR regime. Consequently, there is need to expand existing health indicators to include indicators that focus on measuring and monitoring progress in the areas of health innovation capacity and availability of access to medicine enhancing technologies.

Strengthening tertiary institutions-industry linkage:

The traditional or theoretical argument for strong IP protection is that it stimulates innovation. This may be true for countries that already have strong scientific and innovation capacity. However, for many African countries, there is general consensus among practitioners that national science and technology capacity is limited and innovation capabilities almost non-existent. Yet, to benefit from any IPR regime whether in the context of international law or national jurisdiction, science, technology and innovation capacity is a condition precedent. *To build, sustain and achieve this capacity, African countries must invest in building strategic linkages between tertiary institutions and industry to try and bridge the gap between theory and practice.*

Change the structure of public health financing:

It is important to re-emphasize that the problems of health inequalities experienced in Africa are inherent in the structure of public health financing on the continent. The current structure of public health financing has three dimensions: government funding, donor funding and a hybrid of the two commonly referred to as public-private partnerships. Government funding is largely limited and is rarely invest in science, technology and innovation in any meaningful ways. Donor funding is constrained by donor priorities and interests. Public-private partnerships have their own problems inherent in unequal relationships and associated governance problems. *Consequently, the extent to which public health financing programmes, ranging from education and training, health R&D to public health services delivery, are designed and executed will determine the progress to be made in making IPR work for African countries.*

Take advantage of existing flexibilities within the existing international legal instrument:

One way of addressing this issue is the exploitation of technologies whose patents have expired. It enables institutions to make use of such technologies which have been proven to be effective at very little cost. NEPAD should then require that countries report on how they have taken advantage of these flexibility mechanisms.

Taking advantage of the grace periods provided by TRIPS

NEPAD and other African institutions need to invest in establishing and sustaining a dialogue among African policy makers on the need to take advantage of the TRIPS grace period before it expires.

Notes

- Most of these gains, however, have been concentrated in South East Asia, as well as Latin America where countries have accumulated reasonable pharmaceutical industry capacity to partake in the ongoing pharmaceutical revolution.
 See for example the report by the Rockefeller Foundation and Swedish International.
- See Report of Millennium Project Task Force 5 Working Group on Access to Essential Medicines.
- iv. See for example the Republic of the Gambia (2003), First National Millennium Development Goals Report, and reports from Ghana, Kenya and Tanzania.
- At a general level, "equity" may be defined as social justice or fairness. It is an ethical concept, grounded in principles
 of distributive justice.
- vi. These figures are drawn from UNDP (2001), Human Development Report 2001, Making New Technologies Work for Human Development. United Nations Development Programme, New York.
- vii. See for example Sachs, J. (2001), 'Tropical underdevelopment', Cambridge, MA. NBER Working Paper 8119.
- viii. Cf. Resolution 2001/33 on Access to Medicine in the context of pandemics such as HIV/AIDS.
- ix. For more detailed discussion on this issue, see S. STERCKX, Patents and Access to Drugs in Developing Countries: An Ethical Analysis, in Developing World Bioethics, vol. 4, n.1, 2004. pp 58.; P.J. HAMMER, Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health in Journal of International Economic Law, Vol.5, n.4, 2002, pp 883.
- x. See Trade-Related Aspects of Intellectual Property Rights, Article 70.
- xi. Following a Resolution of the World Health Assembly (WHA28.66) of 1975, the, the Executive Board of the World Health Organization in 1977 introduced the first model list of essential drugs which, through the Declaration, was considered as one of the key elements in improving primary healthcare. The 12th List of Essential Medicines was published by the WHO Expert Committee in 2000. See WHO Technical Report Series # 914. The WHO has continued to consistently review this issue at the subsequent meetings of the World Health Assembly (WHA) and the Executive Board (EB). See for example the 1999 Revised Drug Strategy adopted at the 52nd World Health Assembly and a series of the Assembly's resolutions adopted at its 54th session. cf. "Strengthening Health Systems in Developing Countries" (WHA 54.13); "Scaling up the Responses to HIV/AIDS" (WHA 54.10); and "WHO Medicines Strategy" (WHA 54.11) of 21 May 2001; WHO 2002: "WHO Medicines Strategy: a progress report", Report by the Secretariat. EB111/30 of 13 December 2002.
- xii. For example Resolution 2007/7 of the Sub-Commission on Human Rights of August 17, 2001 invited the High Commissioner for Human Rights to report on issues of access to medicine. See E/CN.4/Sub.2/2001/13; E/CN.4/Sub.2/2001/10 of August 2, 2001; and E/CN.4/Sub.2/2001/L11 dd. 2 of August 16, 2001.
- See Resolutions on access to medication in the context of pandemics such as HIV/AIDS (E/CN.4/RES/2001/33 of 20 April 2001 and Resolution 2002/32 (E/CN.4/RES/2002/32) adopted at the 57th and 58th Session respectively.
- ivx. In the case of India which did not become a member of the Paris Convention, its Patent Act of 1970 provided a seven-year protection for pharmaceutical processes and not protect pharmaceutical products.
- xv. See the Preamble to the Agreement Establishing the WTO 1996. Marrakech.
- xvi. The International Health Regulation of WHO provides the overall legal framework for international efforts to check and prevent the spread of infectious epidemics such as bird flu, cholera, etc.

xvii. See the 1951 International Sanitary Regulations (WHO Regulation No. 2 adopted at the 4th Session of the World Health Assembly).

- xviii. GATT, 1947, Article XX (b).
- ixx. The Commission operating under the auspices of the FAO and WHO is responsibility for the establishment and continuous codification of international rules and standards regarding food safety.
- xx. See Article 51-60, TRIPS Agreement.
- xxi. Ibid, Article 30.
- xxii. Ibid, Article 31.

xxiii. The TRIPS Agreement itself does not specify the grounds on which a compulsory license can be granted.

- xxiv. The licensing arrangements for this deal also involve the patent holders of lamvudine (Shire Pharmaceuticals Group plc) who waived their right to royalty payments on the products produced under these arrangements.
- xxv. Multinational drug companies: Boehringer-Ingelheim, Bristol Meyers, Squibb, Glaxo-Wellcome, Hoffman LaRoche and Merck. International Agencies: WHO, UNAIDS, UNICEF, W.B. and UNDP.

xxvi. For more detail, see http//global fundatm.org.

xxvii. (Economic Commission for Africa 1999b).

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CHAPTER 7

Financing Science and Innovation in Africa: Institutional development and challenges

F. K. Teng-Zeng

Abstract _

This paper examines the investments on science, technology and innovation activities in Africa and makes an appraisal of some of the recent associated policy initiatives. Section 1 introduces the paper and highlights the importance of finance and financial instruments in promoting science and innovation activities. Section 2 looks at the current levels of funding in selected African countries. Section 3 deals with recent African governments' funding initiatives. For example, in the 2006/07 Budget, South Africa's Finance Minister, Trevor Manuel, announced that the South African government intends to increase business investment in R&D. This would mean increasing not only the current R&D expenditure from 100% to 150% but also the depreciation allowance for capital expenditure from the current 40:20:20:20 to 50:30:20. Elsewhere, the Federal Government of Nigeria has announced its intention to create a US \$5 billion (about N675 billion) National Science and Technology Endowment Fund to address the problem of funding that has hampered the country's industrial development. In the light of the importance of research in the health sector and development in most African countries, this section briefly highlights the investment in this sector. Section 4 looks at national agencies or institutions whose activities support the funding of scientific research, human resource development and technological innovation in African countries. Section 5 considers some of the regional and international initiatives whose aim is to boost investments in science and innovation, including programmes under New Partnership for Africa's Development Programme (NEPAD) and its efforts to create an African Investment Facility. Finally, Section 6 draws conclusions and highlights some of the challenges that lie ahead.

1. Introduction

The financial resources committed to supporting science, technology and innovation (STI) activities are important in promoting socio-economic development, transformation and competitiveness of national and regional economies. These resources now continue to receive more and more global attention, although funding is only one of the several key ingredients required to promote and sustain a nation's development. In the current evolving and competitive knowledge economies, adequate funding is critically important. Consequently, the amount of financial resources committed by governments, and increasingly the private sector, in the performance of scientific and technological innovation activities indicate how important the sector has become in the development goals of each country or region.

Several reports consider a growing gap between the developed and developing countries research and development (R&D) expenditure as a reflection of the global haves and havenots. A report in the learned journal titled Nature (published in February 2006) talks about the "Scientific Balance of Power" purely in terms of the current investment levels by 19 individual countries across different regions (Brumfiel 2006). Therefore, governments have a duty to look closely and more accurately at the current data on R&D expenditures and the current policy initiatives with a view to increasing private investments to enhance national development and competitiveness strategies. This is one way to ensure that a country does not fall too far behind its current competitors. For instance, the European Union (EU) is concerned that the collective investments of less than 2% of Europe's gross domestic product (GDP) of its member countries does not favourably compare with over 2.5% of the United States and more than 3% of Japan. This is despite the fact that countries such as Sweden and Finland compare favourably with the two countries above in their R&D expenditures and are ahead of the EU R&D 2010 targets (Frank 2005). It is also one way to ensure that those countries and economies already too far behind strive to close the gap in order to enjoy some of the benefits derived from increasing investments in science and innovation activities. Hence, a major analytical feature of investment in R&D is the percentage of a country or region's GDP devoted to R&D activities, which is often termed the gross expenditure on research and development (GERD).

Generally, R&D investments can be put into two categories:

- Current expenditures that include the wages and salaries of research personnel and the cost of materials; and
- Capital expenditures that include the cost of equipment and facilities (OECD 2003).

Hall (1995) has observed that about 90% of each R&D dollar is spent on 'current' expenses, the remainder representing capital expenditures or fixed assets (Hall 1995 as cited in OECD 2003: 13). However, because infrastructure is so important for knowledge creation and utilisation as well as skills development, special funds must be set aside to maintain and develop R&D infrastructure.

2. Gross Expenditure on R&D in Africa

Any analysis of R&D expenditure indicates that at the turn of the 21st century, STI in Africa lags behind most other regions of the world, and includes some developing regions (Adeboye 1998; Krishna, Waast and Gaillar 1998; Nel and Teng-Zeng 2003; Gaillard et al. 2005; see also UIS 2001; UNESCO *World Science Report 1993*; 1998; 2005). Current comparable data show that Africa as a whole accounted for 0.6% share of world GERD in 2000: SSA 0.4%, Arab states in Africa 0.1% and South Africa 0.3% respectively. Other regional figures are Asia at 30.5%, Oceania at 1.1%, Latin America and the Caribbean at 2.9%, Europe at 27.2% and North America at 37.7% (UIS 2004).

In Africa, only Tunisia has committed more than 1% of its GDP to research and development activities since 2004. Although South Africa is "Africa's science powerhouse" and also accounts for a higher proportion of the continent's GDP^{*i*}, the country spends about 0.95% of its GDP on R&D, that is, about R16.5 billion in 2006/07 (DST 2008a).^{*ii*}

Table 1 below presents a number of selected African countries and their commitment of financial resources to research and development as a percentage of GDP including possible future expenditure targets for the countries or regions. Comparative data on selected countries from outside Africa are included.^{III} As already mentioned, with the exception of Tunisia, there is currently no other African country where national expenditure on R&D activities is more than 1% of its GDP. Only South Africa remains on target to achieve 1% of GDP by 2009 or earlier (DST 2004). However, the contribution towards the funding and performance of R&D in most African countries by the private sector remains very poor. Here, South Africa remains an exception, with the private sector accounting for about 58.3% investments on R&D in 2005/06, up from 55.5% in 2003/04 (CeSTII 2007)

Gross Expenditure on R&D in Africa					
Country / Region	Year	R&D expenditure as % of GDP	R&D expenditure US\$ / NC	Gross national in US\$ (billions) 2003	Future target for R&D expenditures as % of GDP
Algeria	2002	0.70		61.6	1(2008)*
Argentina	2002	0.39		140.1	1 (200)
	2006	0.65			
Australia	2002	1.57		436.5	
Botswana	2005	0.43			1(2008)*
Brazil	2000	0.97		479.5	
	2004	0.91			
Canada	2003	1.84	CAD 22.4b	773.9	
	2005		27		
Chile	2003	0.61	NCP303,001m	68.7	1.2 (2006)
	2004	0.70			1.5 (2010)

Country / Region	Year	R&D expenditure as % of GDP	R&D expenditure US\$ / NC	Gross national in US\$ (billions) 2003	Future target for R&D expenditures as % of GDP
China	2000 2001 2002 2003 2004 2005 2006	0.90 0.95 1.07 1.13 1.23 1.33 1.42	NCY 895.7b 1042.5 1287.6 1539.6 1966.3 2450.0 3003.1	1416.8	1.5 (2005)
Egypt	2003	0.9		93.9	1 (2008)*
Ethiopia	2005	0.34			
Ghana	2000	0.4		6.5	1 (2008)*
India	2002		Rs.	570.8	2 (2008)
	2003 2005	0.8 0.61	18000.16crores 19726.99 21639.58		
Kenya	2004			12.8	1 (2008)*
Republic of Korea	1985 2000 2001 2002 2003 2004	1.00 2.39 2.59 2.53 2.64 2.85	NCWb 138,485 161,105 173,25 190,687 221,853	576.4	3 (2005)
Malaysia	2002 2004	0.69	RM 2.50b 2.84b	96.1	1.5 (2010)
Mauritius	2005	0.47		5.0	1 (2008)*
Morocco	2003	0.79			
Nigeria	2000			47.5	1 (2008)*
Philippines	2003	0.23		87.8	
Senegal	2005	0.05		5.6	1 (2008)*
Singapore	1991 2000 2001 2002 2003 2004 2005 2006	1.01 1.88 2.11 2.15 2.12 2.24 2.36 2.39	NC\$756.80m 3009.52 3232.68 3404.66 3424.47 4061.90 4582.21 5010	90.2	
South Africa	2000 2001 2003 2004 2005 2006	0.64 0.76 0.81 0.87 0.92 0.95	NCR 5712m 7499.6 10082.6 12010.0 14149.2 16520.6	126.0	1 (2008)* and 2(2018)

Country / Region	Year	R&D expenditure as % of GDP	R&D expenditure US\$ / NC	Gross national in US\$ (billions) 2003	Future target for R&D expenditures as % of GDP
Tanzania,	2004	0.01			
United Republic					
Tunisia	2000	0.45	TND 121m	22.2	1.25 (2009)
	2001	0.53	153		
	2002	0.63	188		
	2005	0.73	234		
	2004	1.0	350		
	2005	1,05	395		
Uganda	2003	0.2		6.2	1 (2008)
Regional					
Africa (SSA)	2000	0.3		351	1 (2008)
North Africa &	2000	0.2		744	1 (2008)**
Middle East					
Latin America &	2000	0.6		1,747	
the Caribbean					
SADC	2002				1 (2015)
EU-25	2002	1.93			3 (2010)
OECD	2000	2.3			
World	2000	1.7		34,577trillion	

Notes: -- Data not available; *Proposed target set by NEPAD in November 2003; **Target date excludes non-African countries. NC = National currency

Sources: Framework based on Teng-Zeng (2004). A*STAR Singapore 2005 R&D Survey; DST South Africa National R&D Surveys Various years; MOST, Korea 2005 R&D Activities; Tunisia, MSRTCD (2005); Data in column five adapted from World Bank World Development Indicators 2005; ISQ (2008).

3. Financial Investments and Initiatives

Africa's investments on R&D and innovation activities remain very low in comparison to other regions and at the individual country level. However, there has been encouraging signs of increasing investments due to some governments' commitment to expanding national expenditure on science, technology and innovation activities. Some of these initiatives include new policy documents and funding agencies to strengthen their national systems of innovation. In my view some of these initiatives and the funding allocated, especially those made since 2000, are not often reflected in some recent publications. Although, a number of reasons may account for the non-availability of relevant R&D data, the lack of regular national R&D surveys or the limited-participation in external surveys such the Canadabased UNESCO Institute for Statistics is one of the major factors (See Table 1 above). The NEPAD African Science, Technology and Innovation Indicators Initiative (ASTII Initiative) could not have come at a better time.

In this section of the paper, some of the investments initiatives across four sub-regions are highlighted below, although in no order of priority. In view of the importance of the health sector in this publication, a brief overview of funding on health research in Africa is provided as a sub-section.

3.1 Southern Africa

Botswana

In July 1998, the Botswana Parliament approved its national Science and Technology (S&T) Policy. Although no financial targets were set in the policy document, the Government of Botswana (GoB) has take the important role of S&T for economic growth and development very seriously. To that end, efforts are being made to increase funding and develop the necessary infrastructure, as well as creating a conducive environment. The approval of the ST Policy was followed by the creation of a new Ministry of Communications, Science and Technology (MCST) in September 2002. As part of the 9th National Development Plan (NDP9) presented in November 2002, the new ministry has been allocated a budget estimate of P1.1 billion (US\$194.8 million) to be spread over the NDP9 period (2003/04-2008/09).

In February 2005, the Government also announced that the commissioning of a National Research Science and Technology Plan, which was completed in December 2005. This Plan identifies national research priority areas and provides the direction of investments and therefore the implementation of the national S&T policy. Also, in the February 2006 Budget, the government announced that the Botswana Research, Science and Technology Investment Agency (BRSTIA) would be established in the course of the 2006/7 financial year to promote competitiveness, as well as co-ordinating and monitoring all government R&D funding. Further in November 2005, the Botswana Parliament approved a Bill for the establishment of the Botswana International University of Science and Technology the construction of which has been estimated at P5 billion (GoB 2005; 2006). This project should boost scientific research and training infrastructure in the country. In the context of BRSTIA, a Scientist and Technologist Fund has been created purposely for human capital development. Also, there is an allocation for Tertiary Education Development Fund, which was P235 million (US\$40.2 million) in 2006/07 and P305 million (US\$50.7 million) in 2007/08.

In the 2005/06 fiscal year, MCST was allocated P261 million (of development budget) which increased to P347 million (US\$57.7 million) in 2007/08 and P315.7 million (US\$50.2 million) for the 2008/09 year (excluding the recurrent budget allocations). As part of the MCST development budget, the allocations for Science and Technology Research Institutions for the 2008/9 fiscal years were P25 million (US\$5.7 million) in 2005/06, P32 million (US\$5.2 million) 2007/08 and P59 million (US\$9.3 million) respectively (GoB 2008; Teng-Zeng 2007a). The current estimate for R&D expenditure as a percentage of GDP is 0.43%. The government has undertaken to construct the Botswana Innovation Hub which requires investment in

additional infrastructure to support these activities in important sectors such as information and communication technology and biotechnology.

South Africa

In the post-Apartheid South Africa, there has been a reorganisation and on-going transformation of the research, innovation and training infrastructure for socio-economic development and competitiveness. In August 2002, for instance, South Africa created a new Department of Science and Technology (DST) to bring the activities of the national system of innovation (NSI) into more focus and co-ordination. Part of the government's strategy involves the formulation of different sectoral policy documents that will promote scientific research and industrial innovation. Some of these documents include the National R&D Strategy, Integrated Manufacturing Strategy; Biotechnology Development Strategy, Space Science and Technology, Nanotechnology and the new DST Ten-Year Innovation Plan. All of these initiatives require huge expenditure outlays for implementation.

The government is also committed to doubling its current spending over the next six years in real terms. The national Science Vote (which was R1.7 billion (US\$197.4million) for the 2002/2003 fiscal year provides support to the NSI through the funding of the Higher Education Institutions, Science Councils and other national R&D programmes. The overall R&D expenditure in 2003/4 survey is now estimated at over R10 billion, up from R7 billion (US\$813.1million) for the 2001/2 fiscal year (DST 2003; 2005). The last national R&D survey reported a national R&D expenditure estimate of R16.5 billion in 2006/07 (CeSTII 2007; DST 2007; 2008). Therefore, the national R&D expenditure, expressed as a percentage of GDP, has increased from 0.81% in 2003/04 to 0.9% in 2005/06, and is projected to reach 1% of GDP in the 2008/09 financial year (National Treasury 2007).

During the 2000/01 financial year, the South African National Research Foundation (NRF) -- the main funding agency for higher education -- received 26 applications for multi-user research equipment of a regional or national nature. The applications were to the purchase value of almost R27.7 million (US\$3.6 million), of which R15.4 million (US\$2.0 million) was requested as a grant from the NRF. However, only six out of the 26 applications were partially supported following a peer-review process whose focus was on national and regional priority and the quality of the applications, a process in which the final recommendation was made by a panel of experts. At the same time, available funding for equipment in the National and Regional Equipment Programme decreased again during the year from R4.4 million (US\$714982) in 1999/2000 to R1.8 million (US\$237310) in 2000/2001. This highlights the importance of improving on the state of research infrastructure provision in the educational sector, among competing demands from other sectors in the economy. Because of this need, the NRF has made a provision for state-of-the-art research equipment and infrastructure as a major strategic priority. In the 2003/2004 financial year the Foundation spent R11.7 million on research equipment as compared to R4.5 million (US\$680818) in the previous financial year (NRF 2004: 26).

The National Research Equipment Programme was introduced. NRF finalised a contract with the DST, making available R50 million (US\$7.9 million) in the 2005/06-2007/08 financial years, and a further R110 million (US\$14.6 million) for 2008/09. However, the NRF granted 19 awards estimated at R51.4 million (US\$7.3 million) in the 2006/07 funding cycle. A further R20 million (US\$2.8 million) was made under the National Nanotechnology Equipment Programme in 2006 (DST 2005; NRF 2007:21).

Meanwhile, the Innovation Fund and Technology for Human Resources in Industry Programme (THRIP), both managed by the NRF, make further provision for the purchase of research equipment within their respective categories. For example, THRIP, which is a joint venture between the government of South Africa (through the Department of Trade and Industry-the DTI) and the private sector, has contributed about R108 million (US\$ 12.5 million) (government accounting for R34 million (US\$3.9 million) and industry R63 million (US\$7.2 million) up to 2002.^{//}

Overall, government funding to the DST alone (for research and development) has increased by R1.2 billion (US\$160.1 million) over the MTEF ending 2008/09, thanks largely to funding for core science and technology infrastructure initiatives such as the Centre for High Performance Computing, nanotechnology characterisation centres, astronomy and space science. An interesting development in the South African science system is the establishment of greater bilateral and multilateral links with the international S&T systems – a shift in policy away from its isolated Apartheid past. These linkages have seen an increase in foreign funding towards the country's R&D activities to 6% by 2001/02, from a zero in 1994, and a further increase to 10% in the 2003/04 fiscal year (National Treasury 2006:726-27). Also, in line with the Ten-Year Innovation Plan, it is envisaged that the foreign funding for GERD be increased to 15% by 2018 and to maintain this percentage over a decade (DST 2007).

Meanwhile, in order to promote private investment in R&D activities, Finance Minister Trevor Manuel announced in the 2006/07 Budget that the South African government intends to increase business investment in R&D. This means that the deduction for current R&D expenditure will be increased from 100% to 150%. In addition, the depreciation allowance for capital expenditure will increase from the current 40:20:20:20 to 50:30:20 (National Treasury, Budget Tax Proposals 2006/7, p10). The implementation of the tax incentive policy became effective in November 2006.

Mozambique

Building science, technology and innovation capacity for socio-economic development is receiving co-ordinated efforts and political attention in Mozambique. In July 2003, the Council of Ministers of the government of Mozambique approved a new S&T Policy document in which the government undertook to spend about US\$18.8 million over a five-year period (Teng-Zeng 2004). In 2005, a national Act for the creation of an Innovation Fund was

enacted paving the way for the establishment of a National Research Fund (NRFund). The NRFund is a national, independent institution, established by and operating under a mandate provided by the Minister of Science and Technology (MCT). It will invite proposals for funding, evaluate them, award the funding, and monitor and evaluate the results of the funded proposals, as well as funding on its own initiative those programmes and projects that promote and enhance S&T in the country. Under the present initiative the government is committed to achieving an S&T expenditure level of 0.8% of GDP by 2010 (MCT 2006:82). Currently, the government is developing the mechanisms for funding streams for S&T.

However, an over-dependence on donor sources for research funding is a major weakness to overcome in the medium to long term. Government sources often cover salaries for public universities and research institutes, but much of research funding comes from foreign donor sources and the level of support varies from institute to institute. For instance, in 2002 foreign funds accounted for over 80% of research funding in the Social Sciences and Humanities, 70% in the Health Sciences, 51% in the Engineering and Earth Sciences, 56% in the Agricultural Sciences and 100% in Forestry (MCT 2006:5). It is the considered opinion of this author that this situation cannot remain sustainable in building a vibrant and competitive national research and innovation system over the long term. Generating and mobilising domestic resources for research activities is critical.

Zambia

In its 1996 National Science and Technology Policy, the government of Zambia proposed to spend 3% of GDP on scientific and technological activities, but this never materialised. A Science and Technology Fund was also promised but has never been established due to the lack of funding from the government. Current R&D as percentage of GDP was estimated at 0.005% in 2005 (CREST/DST 2007). However, the Fifth National Development Plan 2006-2010 was adopted in July 2006 and for the first time included a chapter on science and technology to address the country's socio-economic development efforts. In other words, the government promised once again to increase funding for science, technology and innovation activities. The plan allocates 83.2 billion kwacha (± US\$23 million), which represents about 0.3% of the overall development plan budget in the 5-year period (Ngandwe 2006).

Zimbabwe

In January 2005, Zimbabwe announced the establishment of an Innovation and Commercialisation Fund (ICF) with an initial capital outlay of 30 billion Zimbabwean dollars (US\$5 million). The fund is intended to promote innovation by harnessing the country's potential and untapped technological skills (All Zimbabwe 2005). Both the Ministry of Science and Technology and the Scientific and Industrial Research and Development Centre (SIRDC) would jointly assess applications for funding in order to determine the commercial viability of such projects. However, the current political crisis and economic meltdown militates

against the building of a sound research and innovation system. Currently, the hyperinflationary level in the economy makes any promised investments on R&D not very meaningful.

3.2 Western Africa

Ghana

In 2000, Ghana passed legislation establishing Ghana Education Trust Fund (GETFund) that would provide the necessary financial resources to support educational infrastructure development, including universities and polytechnics. While government and other donors may contribute to the fund, the core funding of GETFund is based on 2.5% of the prevailing rate of the national Value Added Tax (VAT) deductions or such percentage not being less than 2.5% of the Value Added Tax rate, which Ghana's Parliament may determine. In 2003, GETFund was allocated 224 billion cedis (US\$26.1million) to carry on with the construction of library blocks, lecture theatres, administration blocks, etc. The Fund was given an additional 28 billion (US\$3.2million) for faculty research and development, and 32 billion (US\$3.7million) to support a student loan scheme (GoG 2003). GETFund's success in supporting physical infrastructure development has led to calls for it to increase the research component of its grant to support the research and innovation activities of higher education institutions. Indeed, the current National Health Insurance Scheme may be based on the success of GETFund.

Also, in 2004 Ghana's Parliament passed the Venture Capital Fund Bill and the Long Term Savings Bill. The Venture Capital fund is intended to address the problem of inadequate capital in the private sector, especially in the Micro, Small and Medium Enterprises (MSMEs). Given the importance of ICT in socio-economic development and transformation the government announced the establishment of Ghana Investment Fund for Telecommunication Service (GIFTEL) (GoG 2005).

In addition, as part of Ghana's Ministry of Education's *Education Strategic Plan* (ESP) 2003-2015 and the Education Sector Project (EdSep), a fund called Teaching and Learning Innovation Fund (TALIF) has been set up for tertiary institutions to improve teaching and learning facilities and programmes as well as helping with postgraduate training. TALIF is financed with credit facility from the International Development Association (IDA) of the World Bank Group and counterpart funds from Ghana's national budget. The level of counterpart country will be 10% of each project's total budget. However, some projects can get support from additional resources in other institutions and agencies. In July 2005, TALIF's results indicate that a total amount of US\$6,361,863.55 was approved for allocations in the second proposal call (Teng-Zeng 2005).

Between 2000 and 2005, the budget estimates allocated to the former Ministry of Environment and Science (MES) more than doubled (from 72.5 billion to 157.7 billion cedis) (US\$10.9

million to US\$17.4 million). Science is now under the Ministry of Education, Science and Sports (MoESS). As one of the key public research establishments, the Council for Scientific and Industrial Research (CSIR) gets much investment outlays, including 7.8 billion cedis (US\$883172) to develop infrastructure for biotechnology research. Also, under the World Bank Micro, Small and Medium Enterprises programme, the Bank approved US\$40 million funding towards the construction of an ICT industrial Park at Tema (Teng-Zeng 2007b).

Recently, presenting the 2007 National Budget Statement in November 2006, the Minister of Finance announced the establishment of an Endowment Fund for Science and Technology Research (STREFund) with an initial allocation of 5.0 billion cedis (currently 500000 new Ghana Cedis (US\$566136).^{vi} The private sector and other institutions are encouraged to contribute to the STREFund to create a regular flow of resources for basic research. The CSIR will co-ordinate this initiative (GoG 2006b). On the 4th of June 2008, the STREFund was launched officially. The report indicates that the fund has been registered as a private company and mechanisms for tax incentives have been provided for all the corporate entities that will contribute to the fund (Ghanaweb 2008).

Nigeria

Recently, Nigeria has doubled its efforts to increase funding for the research and innovation system and assist regional S&T activities by making available US\$5 million as an endowment fund to the African Academy of Sciences based in Nairobi, Kenya. There have been budgetary increases for the Federal Ministry of Science and Technology and Education. In its new S&T Policy, the government proposed the re-establishment of the National Science and Technology Fund (NSTF) into which 20% of the education tax and 50% of tax on foreign technology transfer fees will be committed for the promotion of R&D activities in the country. The overall Federal Government budget for scientific research is said to have increased from 1.5 billion Nigerian Naira (NGN) in 1998 to NGN 5 billion 2004, an increase from US\$11.5 million to US\$38 million (Isoun 2004). There has been increasing investments in sectors including Space Science and Technology and biotechnology.

The Education Tax Fund (ETF) has committed N1.2 billion (US\$9.3 million) to support the provision of ICT and capacity building in Nigerian universities. This has been going on since 2000. Statistics available showed that in 2002 an amount of N600 million (US\$4.8 million) was spent on ICT projects in 244 colleges of medicine, N165.6 million (US\$1.3 million) on the ETF Diginet project at N27.6 million (US\$224500) per geo-political zones, N170 million (US\$1.2 million) on information technology education and N332 on capacity building in 2003 (Omunu 2005).

An important funding instrument in Nigeria is the Petroleum Technology Development Fund (PTDF). It was created by the Federal Military Government Decree 25 in 1973. The decree was amended as the PTDF Act in 1990. However, the PTDF was not in operation until the President Obasanjo Administration set up the PTDF Management Committee in September

2000.

In order to improve research and human resource training, the Nigerian Federal Government approved the introduction of special budgetary provisions known as the Direct Teaching and Laboratory Cost (DTLC) and New Teaching and Research Equipment Grant (TREG) in 2004. A total amount of N2.5 billion (US\$19.4 million) has been released and covers from the first to the third quarters of the 2005 academic year. In addition, the salaries for university lecturers were increased from US\$200 to \$1000 over a period of three to four years in 2004 (Isoun 2004). Further, the salaries for university lecturers and researchers were revised and improved in the first quarter of 2008.

Nevertheless, at a special meeting of the new Committee of Pro-chancellors (CPCs) of Nigerian universities held at the University of Lagos on 3 October 2005, the former Executive Secretary of the National Universities Commission (NUC), Professor Peter Okebukola, indicated that President Obasanjo's administration has in the past five years invested over N195 billion in the 24 federal universities. He is reported as expressing concern that many of the problems still persisted. Therefore, he urged the university authorities to take a deeper look into the management-induced problems of their institutions instead of grumbling about funding.

Finally, in order to create a sustainable funding mechanism for the research and innovation system, the Nigerian government announced its intention to establish a N675 billion (about US \$5 billion) National Science and Technology Endowment Fund to address the problem of funding that has hampered Nigeria's industrial development in 2006. This decision is part of the recommendations that were made following a much more comprehensive review of the national research and innovation system -- a joint initiative between the Federal Government and UNESCO, with funding support from the Japanese Government. In July 2008, a committee to help finalise modalities for the establishment of the Fund was set up.

Senegal

The Government of Senegal (GoS) has identified funding for scientific, technological and innovation activities as a major challenge to socioeconomic development and competitiveness. In 1997 the government accounted for 32% of total research funding in the country (GoS 1997:47; Gaillard 1997). Therefore, to improve the funding of research and innovation, the government, through the Ministry of Scientific Research, formulated a new five-year Strategic Plan (2006-2010). According to the plan, it would spend 2% of GDP on research and development by 2015. This is from its current low base of 0.05%. The estimated budgetary allocation for the Ministry of Scientific Research (MSR) was CFA 2 364 566 000 (US\$4.9 million) for the 2006 fiscal year (MSR 2006).

The key government funding instrument is the Fonds d'Impulsion de la Recherche Scientifique

et Technologique (FIRST) which supports research and training in the national research and innovation system.

However, international funding (both bilateral and multilateral) is still very important for the Senegalese research and innovation. For instance, the UNCTAD 2007 Least Developed Country Report indicates that African LDCs received 82% of total aid for research for LDCs during the period 2003-2005, whilst Asian LDCs received 15%. With a total aid for research of 28% going to LCDs, Senegal alone accounted for 33.5% of STI-related aid disbursement going to African LDCs. According to the report, African LDCs also received more than 70%, i.e. US\$427.3 million, of aid disbursements for advanced and/or specific skills for the period 2003-2005. Similarly, Senegal is reported to be an important recipient of aid, accounting for 11% of aid disbursements for advanced and/or specific skills to LDCs during 2003-2005 (UNCTAD, 2007:168). Senegal is a member of the Islamic Development Bank (IDB), and stands to benefit from the IDB 2005 policy decisions to support at least 10% of member countries annual budgets for science and technology.

3.3 Eastern Africa

Uganda

In September 2001 Uganda formulated a draft national science and technology policy and established a National Innovation Fund in 2002 with an approved budget of Ushs 150 million (US\$867052) for the 2002/03 fiscal year (GoU 2002; UNCST, 2006). Affirming the operation of the Innovation Fund in 2003, the Finance Minister announced that in its first year, the Fund supported eight institutions in the agricultural, health and industrial sectors. In addition, prototypes of power inverters and stabilisers, digital systems and monitors were designed and developed locally (GoU 2003). The government started the construction of the Namanve Industrial and Business Park to increase the manufacturing sector activities for exports in 2004. It also established the Presidential Scientific Innovation Award system to promote innovative activities with seed funding of Shs400 million (US\$231371) in the same year (GoU 2004).

Presenting the 2005/06 budget, Ezra Suruma, Uganda's Minister for Finance and Economic Planning reiterated that the country must accelerate the pace of industrialization through the advancement and application of scientific knowledge and technological innovations. Therefore, to increase and improve agricultural production and services, the sectoral budgetary allocation for agriculture was increased by 29% thus rising from Shs. 115.6 billion (US\$66.8 million) in 2004/05 to Shs. 148.9 billion (US\$82.2 million) in 2005/06 fiscal year. In the same fiscal year, to promote support for targeted value-addition in coffee, banana, gum Arabica and cotton, the government allocated Shs. 7.25 billion (US\$4.0 million) including resources channeled through the capitalization of the Uganda Development Bank (UDB) for such interventions. The Finance Minster also set aside Shs. 2.75 billion for industrial R&D and announced that an Innovation and Industrialisation Fund to support R&D activities

will also be operationalised (GOU 2006). In 2006/07 Budget statement announced in June 2006, the government provided Ush8 billion (\$4.3 million) towards research in banana development, fruit juice processing, and malaria research. This was in addition to a five-year US\$30 million (Ush55.8 billion) project under the Millennium Science Initiative funded by the World Bank to support research, education and training in science and technology (GOU 2006; Okore 2006; Teng-Zeng 2006).

Furthermore, in the 2007/08 budget, the Ugandan government designated fields such as information and communications technologies (ICT), science, technology and industrial development as being key priority areas in research. The government promised to increase public investment in these fields by at least shs60 billion. This includes shs5 billion for the construction of the country's National Data Transmission Back Bone to improve fibre-optic network and wireless capability (GOU 2007).

Tanzania

In July 2003, Tanzanian Minister for Higher Education, Science and Technology (MSTHE), Pius Ng'wandu, announced the government's intention to increase its funding for S&T by US\$16 million, to US\$86 million. A further increase was in the pipeline, leading to the revival of the dormant Tanzania National Fund for the Advancement of Science and Technology (NFAST). The director-general for the Tanzania Commission for Science and Technology, Yadon Kohi, observed that the planned increases in the science budget epitomise the fact that scientific research had now a pride of place in the country's political priorities. The current estimate is that domestic R&D allocation is 0.01% of GDP per year. The 1996 national Science and Technology Policy promised 1% of GDP expenditure on R&D by 2000, but was never realised. The budgetary allocation for MSTHE was TZS42, 552, 700 (US\$33.5m) in 2004/05 (CREST 2007).

According to Mukama and Yongolo (2005:17), donor contribution to R&D expenditure efforts in Tanzania represented about 52%, followed by government with 34%, and with research institutions internally generated funding of 14%. This is over the period between 1995 and 2004.

Rwanda

Recovering from the 1994 genocide, Rwanda has adopted science, technology and innovation as a core part of its economic and social transformation processes. It has formulated and started the implementation of its National Science and Technology Policy in 2005 which has seen the creation of a separate Ministry of Science and Technology under the Presidency. Under the new Science and Innovation policy, the government proposes the establishment of a National Council/Commission for Science, Technology and Innovation (NCSTI) and one of its Working Committees will be the National Research Fund (NRF). The Rwandan government has promised to allocate annually 0.5% of the total budget to the NRF which will be managed by the NCSTI for research and development activities. Resources for R&D will also be generated through participation in both bilateral and multilateral research projects as well as in regional and international technological programmes. The commercialisation of services and research output by S&T institutions is also considered to be an avenue for generating additional funding for the promotion and expansion of scientific and innovation activities (GoR 2005).

Meanwhile in a recent interview with SciDev.Net in February 2007, Romain Murenzi, Rwandan Minister for Science, Technology and Scientific Research, indicated that his ministry is working with the UK's Department for International Development (DFID) towards the establishment of the council for science, technology, and innovation to regulate and fund research activities in the country (Ngandwe 2007).

Furthermore, breathing a new life into increasing investment in science and innovation activities, President Paul Kagame announced at the recent 8th African Union Heads of State and Government Summit in Addis Ababa in January 2007 that the government has started the implementation of the resolution of expending 1% of the country's GDP on science and technology. He stated that in the current fiscal year (2006/2007), the government is spending 1.6% of GDP, and plan to increase it to 3% in the next five years on science, technology and innovation activities. These resources are supporting Rwanda's science and research institutions including teaching in primary and secondary schools and sector-based centres of higher learning and research in the agriculture, health, infrastructure, environment and biodiversity (Kagame 2007).

Kenya

Although Kenya is a major hub for hosting most of Africa's and international research centres, information on the funding of science and innovation activities at national is scanty. In 2004 a Bill was approved in the Kenya Parliament establishing the National Research Fund for public universities which would be allocated only KShs.3 million (US\$396040) in 2003 but that this amount would increase to KShs.15 million (US\$194301) in 2004 (The Nation 16 October 2004). The new research fund would be implemented by the Kenyan Commission for Higher Education. During the debate leading to the establishment of the fund, the Chairman of National Council for Science and Technology of Kenya, Prof George Kingoriah, indicated that research institutes accounted for 0.01% of country's GDP. Instead research institutions budget proposal was KShs.350 million (US\$4.5 million) more than the approved budgetary allocation (Mkawale and Beja 2004). In January 2005, the annual budget for the Kenya Medical Research Institute (KEMRI), a major public research establishment in the country, was estimated at KShs3.0 billion (US\$37.5 million), of which the Kenyan government accounted for 50%, collaborating research partners 45%, the remaining being the institute's internally generated funds (KEMRI 2005).

However, in line with achieving the Goals of Vision 2030, there are plans to conduct a

comprehensive study of the national science systems to increase investments by creating the Endowment Fund for Innovation and Research with initial budgetary allocation of KShs.200 million (US\$3.1 million) in the 2007/2008 budget statement (RoK 2007:16). Meanwhile the Kenyan government established a separate Ministry for Science and Technology in December 2005. In its Strategic Plan for the 2007/8-2011/12 fiscal years, the new ministry has proposed an estimated expenditure of KShs.98,030 million (US\$1.5 billion) in support of science, technology and innovation activities (MOST 2007).

Furthermore, the new Coalition Government in Kenya has announced its intention to create 100 software development enterprises. To that end, it has allocated KShs.300 million (US\$4.7 million) towards industrial innovation and pilot programmes which include fish leather processing, mango processing, mini-leather processing, honey processing, cashew nut and palm wine processing, fruit processing, as well as the rehabilitation and upgrading of technology for development centre in the 2008/09 fiscal year. The Coalition Government is to table proposals for a National Policy for Science, Technology and Innovation and the creation of National Science Foundation and the National Innovation Agency (RoK 2008).

3.4 Northern Africa

Tunisia

Following a presidential decree in 1999, Tunisia has increased its investment of 0.43% of GDP in 1999 to achieve a 1% of GDP investments on R&D GDP in 2004. Tunisia has again committed itself to expend 1.25% of GDP on R&D by 2009 (Ben Ali 2007; MSRTCD 2005; 2006). National R&D expenditure increased from TND 121 million (US\$88.6 million) in 2000 to TND 350 million (US\$294.2 million) in 20004. As part of increasing investment in research and innovation activities, the World Bank approved a US\$76 million loan on 15 June 2006 to support higher education and to help create a knowledge-based society in Tunisia. Under the loan agreement, the Tunisia's Ministry of Higher Education, Scientific Research and Technology will spend the money in the following areas: expanding access to higher education, modernising the higher education system, strengthening the universities' autonomy, and providing grants to improve academic quality and institutional performance (World Bank 2006; Teng-Zeng 2006). The two important instruments for boosting scientific research and innovation are the Premium of Investment for Research and Development (PIRD) and the Valorisation of Research Results (VRR), introduced in 1994 and 1992 respectively (MSRTCD 2006).

Egypt

In 2005, Egypt drafted a 12-year national plan that proposes to substantially increase national investments in R&D activities through a working budget of US\$8.5 billion (Sawahel 2005). The science and innovation system is being revamped with the intention of creating a new granting agency called the Egyptian National Funding Agency which will improve

investments and management of research funds. The current S&T expenditure as percentage of GDP is estimated at 0.2% (Koenig 2007).

3.5 Sectoral Funding in Health Research

It is worthy mentioning that investments in STI activities in Africa vary from sector to sector. However, a greater proportion of the investments remain concentrated in the agricultural, education and health sectors. In addition, the information and telecommunication industrial sector is also receiving special attention in most African countries in recent years largely because the technologies interlink and are pervasive in this sector. In this sub-section, funding for health and health research is briefly discussed.

3.5.1 Health research funding and performance institutions

Generally, the activities involving health research and development are carried out in government departments and agencies, research institutes and centres, universities, medical schools and hospitals, and non-governmental agencies (both profit and not-profit). A recent WHO Africa Regional Office (WHO/AFRO) draft survey of health expenditure report in 37 countries in Africa has identified at least 684 institutions engaged in the funding or performance of health research and development. The 166 institutions provide useful data on research expenditures as shown in Table 2. It is important to note that while the number of research institutions could be higher, some of them may still not have separate budget lines for undertaking research and development activities, hence the disparity between the sampled institutions and those that provided data on health research expenditure.

Table 2: Distribution of Health Research Performing Institutes							
Type of institution	Number of institutions in the sample	Number that provided 2005 health research expenditure data					
		Number of institutions	Number of countries				
Government agencies	212	45	26				
Hospitals	135	19	12				
Independent research institutions	88	36	21				
Medical schools	93	23	9				
Other (NGOs, charitable institutions)	77	32	13				
Other (universities, business firms)	79	11	8				
All	684	166	37				

Source: Adapted from WHO/AFRO (2008)

3.5.2 Health R&D expenditures

Over the years, expenditure for the health sector and research in developing countries has received a number of policy and global attention, with international agencies such as the World Health Organisation (WHO), Council on Health Research for Development (COHRED) and the Global Forum for Health Research (GFHR) playing prominent roles. One of the critical pioneering reports was the Commission on Health Research for Development (CHRD) which recommended, among other things, that:

- developing countries should invest at least 2% of national health expenditure in research and research capacity building
- at least 5% of project or programme aid for health sector from development aid agencies should be earmarked for research and research capacity strengthening" (CHRD 1990)^{vii}.

In addition, the African Union recommends that at least 15% of national budgets should be devoted to the health sector, 2% of which be set aside for research and development. Meeting these investments targets remains a challenge not only for African governments but also for the development partners as well.

In terms of current health research expenditures, a recent draft report was presented in Algeria at the Ministerial Conference on Research for Health in the African Region. The report estimates that the total expenditure for health research in 37 African countries was US\$517.5 million in 2005. This expenditure represented about 12.6% of the global total of US\$4.1 billion and includes internal and external resources on health research expenditure by Low and Middle Income Countries (LMICs) in 2003. Although the combined health research expenditure represented about 1.3% (WHO/ AFRO 2008; GFHR 2006), there are differences at the individual country level. For instance, an analysis of public sector R&D spending in Tanzania showed that health and medical research accounted for 74% of the total expenditure. This is followed by agricultural sciences at 14.6%; engineering sciences and technology at 10.31% and the social sciences with less than 1% percent at 0.39% (MOFEA 2008).

Similarly, the recent South African National R&D Survey indicates that the share of medical and health sciences in the total national R&D expenditure increased slightly from 14.8% in 2005 to 15.1% in 2006. The engineering sciences and natural sciences sub-sectors accounted for 20.9% and 20.3% of total expenditures in 2006 and 2007 respectively (DST 2008).

Overall, very few African countries have managed to commit 15% of their national budgets and 2% of this amount to support health research and development. However, just as most developing countries are yet to attain the investment of 1% of GDP on R&D expenditures, most of them have not achieved the minimum target of 2% of health R&D expenditure.

Furthermore, the CHRD's recommendation is that at least 5% of health sector development aid be set aside for strengthening research capacity in health and development. Considering this recommendation, a recent Global Forum Health Research (GFHR) report indicates that Official Development Assistance (ODA) accounted for 7% of total health funds in Low and Middle Income Countries. This includes the total not-for-profit sector such as private universities, foundations and charities (GFHR 2006). Though encouraging, the report presents an aggregate picture and so does not show the distribution of these resources, especially the actual transfers to health research institutions in the Low and Middle income countries, and, as a matter of continental and regional interest, those research institutions and agencies based in Africa. (More research in this area is required in the future).

4. Science Foundations and Funding Agencies

Based on the above overview of investments on STI activities, I observe in the Table 3 below some of the key funding agencies that support or will support science and innovation activities in selected African countries. Until quite recently, some of these funding agencies or facilities did not exist, while others have been reorganised or resuscitated to improve their performance. The NRF of South Africa, for example, is currently the biggest funding agency in Africa. Launched officially in 1999, it replaced the Foundation for Research Development, established in September 1990, and has funding responsibilities for the natural and physical sciences. In addition, the DST Ten-Year Innovation Plan proposes the establishment of a Technology Innovation Agency which could incorporate the funding activities of the Innovation Fund and the Biotechnology Regional Centres Programmes (DST 2007b).

Most of the funding bodies or mechanisms highlighted in the table are fully supported by national governments or obtain partial contributions from corporate entities through the appropriate legislations. The agencies may also leverage funding from both bilateral and multilateral development assistance bodies. Moreover, the proper functioning and effectiveness of these agencies to implement and manage projects may provide avenues for inter-agency agreements within Africa and externally.

Table 3: Science Foundations/ Funding Bodies in Selected African Countries							
Country	Foundation/Fund	Abbreviation	Year	Main Resource Source			
Algeria	Agence Nationale pour le Développement de la Recherche	ANDRU	Juillet 1995;	Government			
Botswana	Universitaire Botswana Research, Science and Technology Investment Agency	BRSTIA	due in/for 2006/7	Government			

Country	Foundation/Fund	Abbreviation	Year	Main Resource Source
	Ghana Education Trust Fund	GETFUND	2001	Government
Ghana	Endowment Fund for Science and	STREFUND	2008 (2006)	Government
	Technology Research			
	NCST Research Fund			Government
Kenya	Endowment Fund for Science and		2007	
	Innovation Research			
Lesotho	S&T Innovation Trust Fund		Proposed	
	(Foundation)		2003	
Malawi	Fund for the Advancement of	FAST	Proposed	
	Science and Technology		2002	
	Education Trust Fund	ETF		Government
Nigeria	Petroleum Development Fund	PDF		Government
	National Science and Technology	NSTF	Proposed in	
	Fund		2003	
Rwanda	National Research Fund		Proposed 2005	
Senegal	Fonds d'Impulsion de la Recherche	FIRST		Government
	Scientifique et Technologique			
	National Research Foundation	NRF	1998	Government
South	Innovation Fund	IF	1999	
Africa				Government and
	Technology Innovation Agency*	TIA	2007	Business
			proposed	
	Technology for Human Resources	THRIP	1994 (1991)	Government
	in Industry Programme			
Tanzania	National Fund for the Advancement	NFAST		Government
	of Science and Technology			
	National Innovation Fund	NIF	2002	Government
Uganda	Innovation and Industrialisation	lif	2006	Government
	Fund			
Zambia	Science and Technology	STDF	1997	Government
	Development Fund			
Zimbabwe	Innovation Commercialisation Fund	ICF	2005	Government

(--) Date in brackets represents when the first appropriate legislation was passed or initiative proposed. *The Technology Innovation Agency may incorporate the funding activities of the Innovation Fund.

Source: Own compilation

5. Private sector in R&D investments

Despite the increasing interest and recommitment to spend more money on R&D and innovation activities by some African governments and some of the exciting trends observed above, a major challenge that is facing Africa is not only how to get governments to increase

their R&D expenditure, but also how to get the private sector strongly involved in the funding and performance of R&D activities, and the eventual transfer and diffusion of technologies on the continent. Although no reliable data are available, the contribution towards the funding and performance of R&D in most African countries by the private sector remains very poor. Although it is argued that multinational corporations are becoming important players in the R&D field in SSA, particularly in the agricultural sector, the level of investments are still relatively low as compared to the government funding.

The keen interest of the private sector in R&D in SSA (and other developing countries in general), according to Pray and Echeverria, is stimulated by at least three main reasons. First and foremost, current economic policies in general and structural adjustment policies in particular advocate market liberalisation and a less interventionist stand on the part of governments in all economic activities. Secondly, the private sector is assuming a more active role in research, both basic and applied, related to the development of new biotechnology in agriculture and this in turn is expected to have important repercussions for technology development and transfer in developing countries. Thirdly, a more active role for the private sector is closely linked to international pressures to strengthen intellectual property rights protection related to plants or plant genetic resources (Pray and Echeverria 1991; Brenner 1992).

In South Africa, the private sector (or business) currently accounts for 43.8% of investments in R&D. Lately, there have been concerns of decreasing performance of R&D from private companies partly due to outsourcing of R&D activities, but this does not seem to be the case. In most African countries structural adjustment policies did not improve the situation in terms of investing in R&D. In fact, during the 1980s and 1990s, the structural adjustment policies led to de-industrialisation. At the same time the free market approach and economic crisis in Africa led to a drastic dissolution of national research systems that were established and supported from the 1960s and 1970s in a number of countries (Waast and Krishna 2003).

A counter argument to the preceding paragraph is that in the past the low rates of private sector investment and performance of R&D in Africa have been attributed to the following factors: a considerable shortfall in knowledge when it comes to production; enterprises (that are subsidiaries of multinational corporations) carrying out R&D in locations outside Africa; a generally low level of manufacturing activity in the region; the porr output infrastructure for R&D; and, highly trained and qualified R&D personnel being in short supply (Adeboye 1998:168). These issues are still relevant but are not the only reasons. It must be said that most foreign investors still have negative perceptions of the continent. Eliminating such negative perceptions has not been helped by the political turmoil and corruption which are a hallmark of many African countries.

Yet attracting the private sector to invest in Africa may still be difficult. For example, up to the mid-1990s, about one-third of the \$33 billion total investment in agricultural research

worldwide was accounted for by the private sector. However, little of this research takes place in developing countries. Most of it (\$10.8 billion, or 94% of the global total) was undertaken in developed countries. In developing countries, the private sector's share of research is estimated at 5.5%, making the public sector the main source of funding (Pardey and Beintema 2001:11). Nevertheless, these are still some of the policy challenges that have to be addressed by African leaders and their development partners under the NEPAD initiative.

6. Regional funding initiatives

In the past two decades (or more), there have been several attempts at creating regional funding instruments to support STI activities in Africa. However, the early initiatives did not achieve the desired results. With the new initiative being driven under the auspices of AU/NEPAD, some of these regional initiatives (including some individual national efforts for regional S&T development) are discussed below.

6.1 African Foundation for Research and Development

One of the first useful attempts at creating a regional funding mechanism occurred in July 1994 when African leaders established and launched a new body known as the African Foundation for Research and Development (AFRAND). Also known as the Presidential Forum on the Management of Science and technology for Development in Africa, the launching of this foundation followed the meeting of African heads of state and government. The foundation was organized by the board of Trustees of the Research and Development Forum for Science-Led Development in Africa (RANDFORUM) in Maputo, Mozambique, in July 1994, under the chairmanship of President Joachim Alberto Chissano. This new body, which later established its headquarters in Lilongwe, Malawi, was to serve as a research and development fund to finance science and technology programmes in Africa by providing seed venture capital to convert promising research results into technological products and social services. The establishment of AFRAND was hailed as "a milestone in Africa's development because for a long time Africa had lived off other people's technology, or regions' financial resources, and other continents' brainpower" (Okumu 2002).^{viii}

Indeed AFRAND was considered as a unique body that was not intended to be another bureaucratic organisation like many other such bodies in Africa and elsewhere. It was a fund in the sense that it was not meant to support basic research as such; rather its mandate was to principally help in transforming R&D results into key technological products and social services that Africa needs. The African Development Bank was supposedly responsible for banking and investment for AFRAND, assuring prudence and financial competence (Okumu 2002:279). In addition, AFRAND founders wanted to design it in such a way that the organisation was not politicized in order to prevent its the demise, like bodies before

it. AFRAND is a hybrid body in the sense that it was established under an intergovernmental charter to give it a pan-African legal framework; but it would at the same time function as an independent, self-sustaining body with its own autonomous governance and directorate (Okumu 2002). However, the AFRAND initiative was not successful despite the good intention for which it was created. Africa is still in search of an appropriate regional funding mechanism to support research and technological development activities as highlighted below.

6.2 African Science Innovation Facility (ASIF)

The failure to establish AFRAND as a regional funding mechanism has led to renewed efforts to create the African Science and Innovation Fund (ASIF) under the auspices of the NEPAD Science and Technology and the associated Consolidated Plan of Action (NEPAD 2003; 2006). In 2006 the NEPAD-OST commissioned a background study to look into the various funding mechanisms or options available so as to enable NEPAD and the African Union to make an informed decision. Entitled Designing a Model for the African Science and Innovation Facility, the report was produced in October 2006 by Geoff Oldham, John Adeoti and Sandy M. Thomas. The establishment of ASIF was then part of the Extraordinary Conference of the African Ministers Council on Science and Technology (AMCOST agenda items), which was held in Cairo, Egypt from 20-24 November 2006. However, the Plan for the establishment ASIF final decision was deferred at the African Union Heads of State and Government meeting held in Addis Ababa in January 2007. The theme for this meeting was on science, technology and innovation for Africa's development. The highlight of the meeting was: increasing investments in research and innovation activities in Africa. The January 2008 Summit of the African Union decided that the Science and Innovation Fund be merged with the education fund so that a single fund should be established for education, science and technology by 2009. Coordination of efforts for establishing the science and education fund has also been transferred from NEPAD OSD to African Union Commission. It is, however, unlikely that the fund will be established by 2009 considering the drop in impetus as the coordination role changed hands.

6.3 Southern African Co-operation Fund for Scientific Research and Technology Development

The South African Department of Science and Technology and the NRF have developed and launched the Southern African Co-operation Fund for Scientific Research and Technology Development (SARCF) within the context of the 12 NEPAD S&T flagship programmes. The aim is to promote research partnership between South African researchers and their counterparts in the SADC region.

In addition to SARCF, the DST/NRF has launched the African Scholarship for Policy and Innovation Studies (ASPIS) to provide scholarships for non-South Africans to undertake

postgraduate studies in South African institutions. In the short term, the DST has committed to spending R13 million (US\$1.8 million) over a three-year period to support the programme. In the 2006/2007 call for application, the NRF Research and Innovation Support and Advancement (RISA) received over 2000 applications from students across Africa and awarded over 160 scholarships (NRF 2007).

6.4 International funding/donor agencies support

In the current funding landscape, international funding is still very crucial for promoting science, technology and innovation activities in Africa. However, various funding/donor agencies or potential funding agencies continue to express an interest in funding multicountry research programmes across the continent. For instance, at a UN and the European Space Agency sponsored workshop held in Lusaka, Zambia from 26-30 June 2006, and attended by scientists from 17 countries in sub-Saharan Africa, a draft plan of action for applying satellite technology to a wide range of development issues was discussed. Participants were informed that the European Development Fund was ready to fund the plans if African regional economic blocs such as the Southern African Development Community and the Economic Community of West African States were to submit coordinated proposals (Wamboga-Mugirya 2006). A regional or sub-regional functioning funding facility can play a critical role in leveraging such international financial resources for the development of the continent.

6.4.1 Non-governmental Organisations funding support

Besides the bilateral and multilateral agencies' support for African countries, the role being played by international non-governmental organisations, notably Foundations, is becoming crucially important, especially in reviving and sustaining research infrastructure, including developing the human resource. However, little research is available in this important sector in most African countries to highlight Foundations support for the research and innovation systems development at local, national or continental level. For instance, the Partnership for Higher Education in Africa (PHEA) Programme was created and is supported by the Carnegie Corporation of New York, the Ford Foundation, the Rockefeller Foundation and the John D and Catherine T MacArthur Foundation. With an initial investment of US\$150 million over five years in 2000, this exemplifies the growing support from the non-profit organisations. The four foundations supporting PHEA were increased to six with, the inclusion of William and Flora Hewlett and Andrew W Mellon Foundations as contributors, and with an additional funding of US\$200 million over a five-period from September 2005 (the Kresge Foundation joined the six foundations in 2007, bringing the total number to seven). Reports indicate that the Partnership has supported 49 universities in the nine countries of operations. Twenty-two of the universities received major funding for university-wide transformation.* The key programme areas include information and communication technologies, higher education research and analysis, research networks for research and postgraduate training as well as the frontiers of knowledge university leaders forum.

Similarly, the Bill and Melinda Gates Foundation provided \$20million worth of funding to the US National Academy of Sciences in order to develop capacity building programmes with the national science academies in selected African countries. It has also provided funding towards Health and Medical research in Africa which exemplifies the growing interest of the NGO community in the research and innovation systems in Africa.

7. Conclusion and Policy Recommendations

This Chapter has looked at the science, technology and investments activities across the continent although within a cross-section of countries. There has been increasing investments in science and innovation and the creation of funding bodies to support and facilitate these efforts. Due to a lack of appropriate research infrastructure, especially physical ones, current efforts are aimed at building these facilities as the anchor for scientific and technological innovations. However, the 'magical' 1% of GDP expenditure on research and development remains a major challenge for most countries.

At the sectoral levels, investment in health research is increasing in most countries, even though falls short of the 2% of resources in national health budget to be committed to health research (as recommended by the Commission on Health Research for Development in 1990 and adopted by most governments including international agencies such as the WHO).

International funding at the individual country level is still very critical in most countries' research and innovation systems sustainability. At the same time, international funding bodies are also looking at supporting multi-country projects at the regional or sub-regional levels to promote capacity building and development. Indeed regional efforts through the NEPAD Office of Science and Technology and the African Union Commission are being made to leverage international funding for projects. How the NEPAD-OST and AU Commission work with the international development partners to secure the necessary funding for sector programmes remains critical. For instance, the WHO has adopted the recommendations that 5% of health sector development aid should be devoted to research and development. It is important to work with the development partners including non-governmental foundations to leverage the appropriate funding.

Nevertheless, the difficulty most development partners have in meeting the international development assistance funding targets emphasises the point that no international support is a substitute for national and regional efforts. If African countries are to develop and sustain research and innovation systems that address their developmental needs and competitiveness in the globalising knowledge-based economy, national funding instruments should be strengthened and the ASIF initiative should be implemented. AFRAND failure should be a guiding principle.

The fragmented and little coverage on science, technology and innovation activities in terms of regular surveys and dissemination of results, especially on the actual expenditures on R&D remains a serious challenge. It is hoped that the on-going African Science, Technology and Innovation Indicators Initiative will bring a better understanding of the research and innovation systems across the countries on the continent. Fortunately, representatives from most of the countries highlighted in this paper attended the First Science and Technology and Innovation Indicators workshop in March, 2008. However, the Agricultural Science and Technology Indicators and Health Metrics Initiatives are two sectoral programmes already being driven by international agencies. How the NEPAD STI Indicators Team negotiates with these agencies for data-sharing and ownership remains one of the significant determinants of the success or failure of the continental initiative.

In addition, scholarly work in science, technology and innovation studies should be established in higher education institutions with appropriate networks. While there are individuals on the continent who are working in this field, there are few research centres. Where such centres exist (in public research institutes or the private sector), it is suggested that appropriate links be developed with university centres across the continent and internationally.

Notes

- i. In 2003, South Africa accounted for 24.9% (US\$160.8 billion) of the African continent's GDP.
- ii. Note that individual national expenditures or proposed expenditures in most cases are my own conversions using OANDA currency converter into the dollar equivalent.
- iii. Australia and Canada are used for purposes of comparison with South Africa, which is Africa's best performer both in terms of technology application and production capacity.
- iv. However, the Department of Education (DOE) also has a research bloc grants subsidy mechanism whose aim is to support universities and universities of technology which are awarded on the basis of teaching inputs for masters and doctoral students. The grants are awarded for research outputs linked to research publications, as well as for graduated research masters and doctoral students. The DOE also provides research capacity development grants to support previously disadvantaged institutions and some of the newly merged institutions. This funding strategy could be very useful in most African countries seeking to revive and strengthen research in the higher education sector.
- v. To deal with the 2 million percent inflationary pressures the government introduced a Z\$1 billion notes and had to redenominated currency with effect from 1 August 2008. The new exchange rate will be Z\$1=US\$1.
- vi. Ghana introduced a new currency redenomination policy with effect from 1 July 2007 following years of currency devaluation. The new currency exchange rate was GHC1=US\$1, which is still holding firm.
- vii. For the first time this report provided data on global health research and development expenditure estimates based on 1986 expenditure data.
- viii. At the founding of AFRAND, 16 African states were represented by 10 heads of state, 2 Prime ministers, 1 deputy prime minister, and 93 official ministers (Okumu 2002:279).
- ix. Please contact John Mugabe and his colleagues for a formal discussion on this part.
- x. The first phase of the programme supported six countries including Ghana, Mozambique, Nigeria, South Africa, Tanzania and Uganda, with Kenya, Egypt, and Madagascar joining in the second phase.

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