

Bridge over troubled waters

THE RESEARCH-POLICY-IMPLEMENTATION GAP

Europe has butter and tomato mountains. AIDS has research mountains. In the article that follows **Geoffrey Setswe** examines the place of research in the response to HIV. He reviews some of the literature on the role of research and questions whether research findings are being properly integrated into HIV prevention. Although superficially it might appear that most AIDS research is a self-perpetuating activity that has lost its connection with the epidemic it analyses, Setswe concludes that – properly planned and co-ordinated – research remains an important part of our response.

Introduction

The relationship between research, policy development and implementation is worthy of examination. In particular, there is the question of whether HIV/AIDS is being over-researched, and whether research findings are being properly or ethically applied. Furthermore, to what extent are behavioural and clinical research findings being made available to the research subject communities, and is research being conducted in their interests or other interests?

With reference to some of the policies adopted by the Southern African Development Community (SADC), either at regional level or by member states, to what extent are these policies 'evidence-based', rooted in research, or not. It is necessary to consider the barriers to implementation of HIV/AIDS programmes and examine ways of bridging the gap between research, policy and implementation.

There is also the question of whether there is sufficient co-ordination and dissemination of the research that is being initiated by different academic or research bodies within countries and within the region, and whether there is a balance between academic freedom and the need – in the context of a nation-threatening epidemic – to ensure that resources are not wasted through duplication or on research with little use or value.

What is the focus of HIV/AIDS research? Is HIV/AIDS over-researched?

HIV/AIDS research consists of a multitude of activities that focus on basic and clinical science to understand and treat HIV infection and its related conditions; prevention science to track and prevent the spread of HIV; understand the behaviours that put people at risk of HIV infection and develop interventions to change these behaviours; and health services research to address the nexus between scientific research and the application of that research into health care services (Kaiser Family Foundation, 2002).

The HIV/AIDS epidemic is complex, fuelled by biomedical, social, economic and political forces. Solutions can no longer be expected from one group of scientists, laboratory, clinical, social, behavioural or policy experts. HIV/AIDS research spans the spectrum of basic science, clinical research, prevention interventions, policy development, ethics, social science and operations research.

More than 20 years of effort and investment in HIV/AIDS research has resulted in numerous advances including:

- the identification of HIV, the viral agent causing AIDS;
- the development of a test to detect the presence of antibodies to HIV in blood and other tissues;
- a doubling of the average survival time for a person living with HIV/AIDS;
- the development of drugs to treat HIV infection that reduce the impact of the virus on the human body;
- advances in the treatment and prevention of several HIV-related diseases and infections, including pneumocystic pneumonia, cytomegalovirus (CMV) retinitis and toxoplasmosis;
- the identification of barriers to access to care for people with HIV, and disparities in access and outcomes for some populations;
- a reduction in the number of new HIV infections due to successful community and individual level prevention interventions; and
- the discovery that the use of antiretroviral drugs can dramatically reduce the risk of transmission of HIV from a pregnant woman to a foetus (Kaiser Family Foundation, 2002).

There have been major research discoveries, well-crafted policies, nicely-worded commitments, declarations and charters, and innovative programmes to deal with HIV/AIDS. We also know what research is needed to develop policies and which programmes and interventions are effective. However,

- there is still no cure for HIV;
- the potential for the development of an effective vaccine is many years away;
- more than 40 million people are infected. Almost two-thirds of the world's HIV-positive people live in sub-Saharan Africa. More than one in three people aged 15-49 in Botswana and Swaziland is HIV-positive, and more than one in five adults are HIV-positive in Lesotho, Namibia, South Africa and Zimbabwe;
- about 20 million people have died from this epidemic; and
- HIV/AIDS is outstripping bubonic plague as the world's worst epidemic.

Ekambaram (2004) argues that we assume that more HIV research might bring better HIV prevention. We also assume that creating awareness of HIV/AIDS on a larger scale would bring instant change in behaviour, attitudes and practices. Research has proven us wrong – knowledge of HIV/AIDS does not automatically translate into change in behaviours, attitudes and practices. Ekambaram concludes that although there is still room for expansion in our understanding and knowledge of certain aspects of the HIV/AIDS epidemic, there are relatively few real research gaps. AIDS researchers concur that there are few other communicable diseases that compare with the extent to which AIDS has been researched. Put simply, HIV/AIDS is over-researched.

Freudenthal (2001) disagrees with Ekambaram (2004) and argues that, though much is known, there are research gaps, but that research gaps are not the main obstacle to successful HIV/AIDS prevention and mitigation programmes. He agrees that the knowledge of how to prevent HIV transmission exists, but argues that research results are seldom utilised in the implementation of HIV prevention and care programmes. Again, despite all the behavioural studies, many people have not changed behaviours. He describes the following as areas that still need to be researched:

- The need for research to focus on the ways in which dominant norms and youth culture place young people's sexual health at risk, and to also investigate the ways that certain groups of young people resist those norms;
- Research on specific socio-economic contexts and in particular an understanding of gender differences in the socialisation of young people into sexuality. In addition, it is important to investigate young men and women's perceptions of sexuality and gender relations;
- The need to understand how best to influence policy-makers, how best to select, train and supervise peer educators, how to address gender and cultural factors and how to scale up programmes;
- Media studies for developing innovative approaches for reaching more remote rural areas; and
- More research on how to make reproductive health services user-friendlier for young people (Freudenthal, 2001).

CASE STUDY : THE XV INTERNATIONAL AIDS CONFERENCE

The vision of the XV International AIDS Conference in Bangkok, Thailand, was to link community and science to galvanise the world's response to HIV/AIDS through increased commitment, leadership and accountability. The theme of the conference, 'Access for All', reflected the need for all scientists, community workers and leaders from the field, the public and private sectors, to have access to all resources developed after 20 years of living with HIV/AIDS. The organisers explained that this meant access to all people who write policies, give support and offer care (Access for All, 2004).

The organisers received over 10 000 abstracts for review. About 9 000 of them were accepted as papers, posters or citations in the abstract book. Just over 600 papers and/or posters were from South Africa, representing about 6.7 per cent of the abstracts submitted.

Scientists, activists, policy-makers, people living with HIV/AIDS and others working in areas related to the HIV/AIDS epidemic presented abstracts and shared information and data from the biomedical, behavioural and social sciences as well as from the public health-related areas. The five tracks were basic science; clinical research, treatment and care; epidemiology and prevention; social and economic issues; and policy and programme implementation.

The following table provides an indication of the number of papers and posters that were available only on the first day of the conference, the number of sessions on the first day, and how they were allocated.

TABLE 1: DISTRIBUTION OF SESSIONS ON THE FIRST DAY OF THE XV INTERNATIONAL AIDS CONFERENCE

SESSION	NUMBER	PER CENT
Plenaries	4	0.3%
Oral sessions	163	10.9%
Poster presentations	28	1.9%
Skill building workshops	20	1.3%
Poster exhibitions	1 280	85.6%
TOTAL	1 495	100%

The presentation of 9 000 papers in about five days clearly indicates that HIV/AIDS is over-researched. Ekambaram (2004) is correct in the assertion that the amount that has been written and researched on the HIV/AIDS epidemic is out of proportion to society's success in tackling HIV/AIDS. It seems that as the statistics mount so does the research mountain, and the research mountain presented at the XV International AIDS Conference attests to this. It may well be that efforts should be channelled to quality, not quantity research, that will be innovative and collaborative and address specific questions. Furthermore, the mountain of research presented at conferences and published in journals is a drop in the ocean compared to the research that lies in cupboards and is not acted on.

The international AIDS conferences take place once every two years and are characterised by extensive research, policy and public health work presented over a short period of time. This is the major criticism of these conferences. The number of papers and posters presented over the years has increased dramatically, as has the number of attendees and participants. AIDS conferences are one of the largest gatherings of scientists, policy-makers and programme implementers. What is ironic about these gatherings is that it may be the first time that some researchers, policy-makers and implementers meet – in a foreign country. Many policy-makers hear for the first time about research work going on in their own countries at these conferences, and researchers hear for the first time about interesting projects going on in their own countries.

TABLE 2: DISTRIBUTION OF POSTER EXHIBITIONS ON THE FIRST DAY OF THE CONFERENCE

POSTER EXHIBITION SESSION	NUMBER	PER CENT
HIV immunology	77	6.1%
External invaders and new diagnostic tools	284	22.2%
The big picture – numbers and environment	278	21.7%
Well-being and quality of life	237	18.5%
Methodological issues in HIV/AIDS research	94	7.3%
Relationships between policies & programmes	310	24.2%
TOTAL	1 280	100%

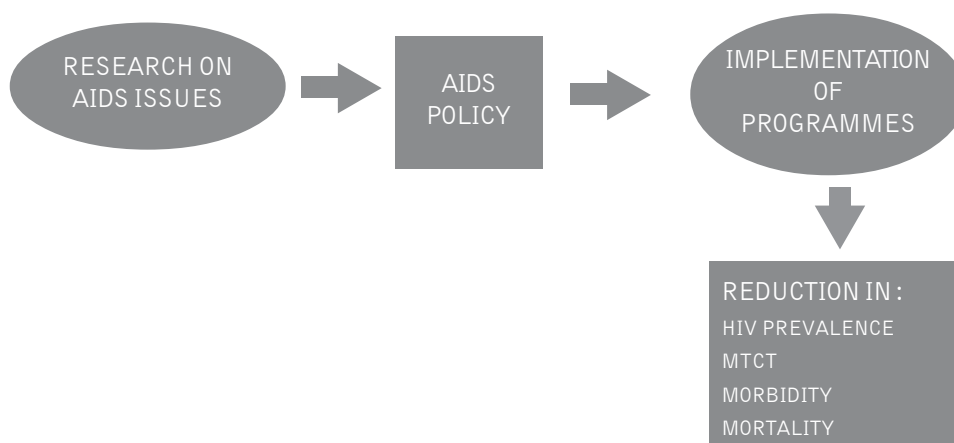
The poster exhibition session on the relationship between policies and programmes had the largest number of posters – 310 or 24.2 per cent – than any of the other five sessions. This implies that there is a lot more work being done to translate policies into programmes. The question is whether this work is innovative and important. Much of the innovative work reflected in Table 1 was allocated to poster sessions instead of the more prestigious plenary and oral sessions, and included important work on the relationship between policies and programmes.

Connections between policy, research and implementation

The relationship between researchers and policy-makers is often assumed and/or misunderstood but rarely analysed (Philpott *et al*, 2002). Researchers believe that if their research were of good quality, rigorous and conclusive, then it would influence policy. For policy-makers, research may seem one of the less relevant and more impenetrable of the many influences, including political pressures, to which they are subjected. They further indicate that much of the literature about the transfer of research findings into policy focuses on examples of the failure of research and researchers to have any significant impact on implementation and practice. It may thus be surprising to some that research which rigorously demonstrates effective and beneficial interventions does not necessarily lead to policy change.

Neilson (2001) conducted a literature review on the influence of research on policy and found that approximately 23 per cent of the approved research projects supported by the International Development Research Centre (IDRC) included in their objectives the expectation that the research they support would influence policy. This is a disappointingly low expectation considering that many researchers made an assertion that influencing policy-makers and/or decision-makers is an intended result or expectation of their research. They want to know if their research has had an impact on people's everyday lives.

FIGURE 1: FRAMEWORK ON RESEARCH-POLICY-IMPLEMENTATION IN HIV/AIDS



One of the stated aims of the track on policy and programme implementation at the XV International AIDS Conference was to highlight progress, lessons learned and evolving challenges in policy development and practice and the implementation of HIV/AIDS programmes. The objectives of this track were to:

- share information on policy evolution and leadership of HIV/AIDS programme implementation at global, regional, national and community levels;
- describe the impact of existing and evolving policies on HIV/AIDS programme implementation;
- share lessons learned and provide examples of effective HIV/AIDS programmes, including innovative efforts to overcome barriers to scaling up and sustaining programmes in a variety of settings; and
- identify gaps in policy development based on the existing information about the AIDS situation and the availability of resources to implement and expand programmes.

Sessions in this track focused on policy and programme implementation issues, including the broad categories of HIV/AIDS prevention, medical, palliative and psycho-social care for HIV/AIDS patients' support and HIV/AIDS impact mitigation and economic alleviation (Access for All, 2004). Figure 1 provides an ideal framework on research-policy-implementation of HIV/AIDS. However, the research presented in the track on policy and programme implementation indicates that the link is not as straightforward as suggested in Figure 1.

If, according to Neilson (2001), so few researchers (23 per cent) expect that their research would influence policy, and if policy-makers think research is less relevant (Philpott, 2002), then how do we expect the objectives of the conference to be attained? Again, if the results of studies emanating from this session are anything to go by, then we should be seeing dramatic reductions in HIV prevalence, mother-to-child transmission of HIV, illness and deaths from opportunistic infections due to HIV/AIDS. The reality is that we are seeing none of that.

Garner *et al* (1998) described initiatives to develop evidence-based care and make the point that researchers, policy-makers, and clinicians have already done much to engender a science-led culture in developing countries. They identified Zimbabwe and South Africa as countries where researchers are working with their governments to test ways of shifting research into policy and practice.

Policy analysis and research utilisation models

This section examines several policy and research utilisation models to determine whether all HIV/AIDS research is utilitarian. The utilitarian perspective embodies the idea that acts should be evaluated according to their consequences.

Research is a clearly defined, technical input into policy-making (Unterhalter *et al*, 2003). Policy is seen as a rational form of problem-solving and organisational control based on clearly specified information and calculations that flow from this. In this approach, researchers input clear 'clean' data, and a rational policy output results. For example, the researchers at the Peri-natal HIV Research Unit provide clear 'clean' data on the efficacy of AZT and Nevirapine in the prevention of mother-to-child transmission (PMTCT) of HIV to the Ministry of Health, and their technical input thus influences the production of rational national policy on PMTCT.

The second approach to policy analysis used by Unterhalter (2003) is sometimes referred to as critical policy analysis. It takes a different view of the ways in which policy emerges and the relationship between policy-makers and researchers. In this approach, policy emerges in particular forms in particular contexts and must be understood in relation to specific configurations of power. AIDS policies are thus not best understood as solutions to clearly specified problems but are themselves instances of political, economic and cultural contestations within the state, and between the state and civil

society. For example, the Treatment Action Campaign's (TAC) contestation against the Ministry of Health for provision of antiretroviral drugs in public health services is a case in point. They also fought pharmaceutical companies in court to reduce the price of antiretroviral drugs.

A third approach considers the need for more refined approaches to thinking about policy. It draws on the ways in which social actors engage with policy, the shifting alliances that form around policy and the regulatory frameworks, which enable certain policy positions to be spoken, while others are silenced (Unterhalter *et al*, 2003). For example, the Medicines Control Council (MCC) announced that Nevirapine (NVP) was no longer recommended for monotherapy before research had been presented at the XV International AIDS Conference in Bangkok. The initial disagreement arose at the national AIDS Conference in Durban in 2003. Although NVP had been registered since April 2001, researchers had challenged the MCC's veiled threat to de-register based on the refusal of the Food and Drug Administration (FDA) to register NVP for monotherapy, and questions around the conduct of the original trial. At a heated session organised by the TAC and its partners at the Bangkok conference, some senior government officials closed ranks with the MCC and Minister of Health and put down the 'fire' that was started by a press release and the Minister's inappropriate and untimely comments.

The National Association for People with AIDS (NAPWA) seems to have been silenced by TAC's more appealing approach to challenging government's HIV/AIDS policies and implementation of programmes at public health services. Historically, TAC was formed with the aim of strengthening NAPWA, not to compete with it. It can be argued that the weakening of NAPWA had more to do with their decision to align themselves with government on policy, as well as organisational mismanagement, rather than TAC's approach.

Hanney *et al* (2003) describe several models of research utilisation, including the classic, purist and knowledge-driven model, which suggests a linear sequence in which research generates knowledge that impels action; and the problem-solving, engineering or policy-driven model which also follows a linear sequence, but begins with the identification of a problem by a customer who requests the researcher to identify and assess alternative solutions.

Reimers and McGinn (1997) describe how they view the linear approach to policy-making in practice, and explain that the underlying assumption of this approach – or

what they term 'utilisation as using pre-cooked conclusions' – produces knowledge that can inform policy choices.

The central question in this approach is, what can the researcher as knowledge producer do to influence the process of policy-making? The perspectives within this approach range from those proposing efforts to increase the effectiveness of dissemination to those that propose advocacy and social marketing as ways to persuade policy-makers. Common to these perspectives is the assumption that knowledge production and utilisation proceed in stages. The first stage, in which knowledge is created, is the domain of the researcher. In the second stage – dissemination or persuasion – the researcher tries through various means to capture the attention of a seemingly passive decision-maker in order to translate the results of research into policy more or less automatically (Reimers *et al*, 1997).

Caplan (1979) championed the 'two communities' theory, which explains the use, or non-use of research as a symptom of the cultural or behavioural gap between researchers and policy-makers. For him, the limited use of research by policy-makers is, in part, due to the fact that researchers and policy-makers have different worldviews. Although the notion of a cultural gap between researchers and policy-makers has been given a great deal of positive attention, the weakness of early explanations such as this lies in the fact that it is based on a simple dichotomy of 'use' versus 'non-use'. The 'two communities' theory is further weakened by its assumption that the use of research feeds into the policy-making process in a direct, or linear, manner. Caplan's theory is supported by, for example, the non-use of condoms in prisons. Researchers and prison authorities have different views about distribution of condoms to prisoners. Again, the distribution of condoms without support of the authorities or government for this initiative may affect their use by prisoners.

Later explanations based on the writings of Weiss (1977), Webber (1991), Sabatier & Jenkins-Smith (1993) and others include the idea that the research-policy link is not a direct one, particularly in relation to data and information sources. These writings support the claim that research is only one of many sources of information for policy-makers, and that it is not a simple dichotomy between 'use' and 'non-use' but rather that knowledge/research utilisation is built on a gradual shift in conceptual thinking over time. Locally, this is depicted by a clash between medical models showing efficacy of ARVs and economic paradigms that influence government decisions on resource allocation.

Weiss (1977) spoke about the 'enlightenment function' of research while Hanney *et al* (2003) described the enlightenment model, which posits that research is more likely to be used through the gradual 'sedimentation' of insight, theories, concepts and perspectives. This model has the advantage of extending the range of ways in which research is utilised.

The social interaction model is a set of interactions between researchers and users rather than a linear move from research to decisions. It ensures they are exposed to each other's worlds and needs (Hanney *et al*, 2003). This probably deals with the different worldviews raised by the 'two communities' theory of Caplan (1979).

In the tactical model described by Hanney *et al* (2003), research is used when there is pressure for action to be taken on an issue, and policy-makers respond by announcing that they have commissioned a research study on the matter. While this can sometimes be seen as a cynical delaying tactic, there are other occasions where the commissioning of research provides the political system with a valuable breathing space, thus reducing the chances of irrational policy-making. For example, the South African government used research as a delaying tactic by commissioning research on the costing of antiretroviral drugs in October 2003, before a decision was taken on their introduction in August 2004.

Ryan Coetzee, of the opposition Democratic Alliance (DA), challenged the human resources strategy of the Ministry of Health by indicating that 31 per cent or 52 574 posts were vacant. But the department used the tactical model by denying that the vacancies were as many as the DA suggested and announced that they had commissioned research to determine the scale of unfilled vacancies and would make an announcement on this matter in due course (Jack, 2004).

Are research-findings being properly or ethically applied?

International research ethical guidelines, including those of the Council for International Organisations of Medical Sciences (CIOMS), emphasise the need for proposed research to undergo ethical and scientific review in both the initiating and host countries. This is to avoid exploitation of patients in the host country and be responsive to the needs of vulnerable communities. Many communities in Southern Africa fit into the UNAIDS definition of vulnerability because they have limited economic development, inadequate

protection of human rights and discrimination on the basis of HIV antibody status, inadequate community/cultural experience with or understanding of scientific research, limited availability of health care and treatment options and limited ability of individuals in the community to provide informed consent. These communities are vulnerable to ethical abuses by researchers.

Makgoba (2000) provided a strong example of the ethics of AIDS research in a developing country at the XIII International AIDS conference where he cited an example of a research project which did not benefit the community – the biological warfare programme under the leadership of Dr Wouter Basson to develop substances that would either render most blacks infertile or selectively poison or maim black people, was certainly not aimed at benefiting the community. There is also the example of the Tuskegee Syphilis Experiment in which officials of the Public Health Service (PHS) in the United States were conducting a study on the effects of untreated syphilis on black men in Alabama. The study ran from 1932 and was terminated around 1972 and participants were not offered treatment even when it was available from the 1940s (Jones, 1993). The study was devised without ethical review, there was no protocol, and its only purpose was to see 'the natural course' of syphilis in African-American men; the people who were studied did not benefit.

Before the approval of the roll-out plans for ARVs in some Southern African countries, participation in drug trials was the only way of gaining access to antiretroviral therapy. Drug trials were sometimes conducted solely because they facilitated access of drugs for some patients, although this often provided very positive benefits to the individual.

Informed consent may be difficult to achieve, especially when engaging people from disadvantaged and vulnerable communities where literacy and education opportunities are inadequate and where there are language barriers. These barriers are often used as an excuse to subject vulnerable people to unethical research (Makgoba, 2000).

People living with HIV/AIDS and community-based organisations that serve them have played an essential role in research. Community-based trial groups provided some of the early tests of AIDS drugs. Internationally, AIDS activism has led to dramatic changes in public and private responses to AIDS, including speeding up the drug review and approval process at the MCC, increasing participation of women and disadvantaged people in clinical trials, and greater accountability among research institutions. People with HIV are now incorporated into the research and drug development process and

provide valuable input into the design of clinical studies, the implementation of research programmes and the setting of research priorities.

Because women and disadvantaged South Africans represent a significant proportion of people living with HIV/AIDS, new AIDS cases, and new HIV infections, their involvement in HIV/AIDS research is critical. Yet, in the earlier years of the epidemic, women and disadvantaged people often were left out of many research trials and protocols, resulting in a lack of clinical data about the impact of HIV and HIV-related treatments on these groups.

Success stories in the implementation of HIV/AIDS policies

Firstly, the Mwanza trial on the treatment of sexually transmitted infections (STIs) in Tanzania is presented as a success story in developing an effective relationship between research and policy. Secondly, Botswana is presented as a model for implementing HIV/AIDS policy on antiretroviral drugs in the public health system.

CASE STUDY

CASE STUDY : POLICY ANALYSIS OF THE MWANZA TRIAL

The Mwanza trial has been described as a success story in developing an effective relationship between research and policy. The London School of Hygiene and Tropical Medicine, the African Medical and Research Foundation (AMREF) and various government institutions in Tanzania conducted this randomised controlled trial (RCT) from 1991-1994 in Mwanza. The trial demonstrated the effectiveness of improved treatment services for sexually transmitted infections (STIs) in preventing HIV infection, improved case management of STIs in rural health units and the reduction of HIV incidence by about 40 per cent in the general population. Philpott *et al.* (2002) explored in detail the interaction between a group of researchers and policy-makers involved in the research policy interaction and their perception of that process. There were three key findings as to how and why the trial had such a significant policy impact:

- the policy environment was favourable;
- the researchers and policy-makers formed strategic alliances for policy shift;
- it was possible to present the data in an easily understandable form.

The authors outline the lessons learned from this case study as follows:

- From an early stage, researchers should be aware of the policy environment, historical context and other enhancing factors, and use these as forces to drive policy change, if trial results demonstrate the effectiveness of an intervention.
- Researchers should try to build strategic alliances with those likely to have an academic, geographical, political or development interest in the policy implications of the research, to discuss initial ideas, develop proposals and disseminate results.
- Presentation of easily digestible data from the Mwanza trial certainly helped to influence policy world-wide. This demonstrates that results presented simply and clearly, and understood by those with a non-research background, can have major impact.
- Key study results should be translated into points easily digested by policy-makers, while trying to avoid the pitfalls of oversimplification.

Botswana's roll-out of antiretroviral drugs to its population is another success story in Southern Africa. An opinion piece in the Kaizer Daily HIV/AIDS Report of August 6, 2004 stated that Botswana was on the verge of treating all HIV-positive people in need of antiretroviral drugs.

Some of the lessons learned from the Mwanza case study seem to also apply to the Botswana success story. Firstly, researchers who assessed the need for a nationwide ARV programme were aware of the policy environment, historical context of the Botswana and other enhancing factors. Secondly, the ARV programme in Botswana developed from strategic alliances with partners such as the Harvard AIDS Institute, pharmaceutical industry and others who had academic, geographical, political and developmental interest in the policy implications of the ARV programme. They were all co-ordinated by African Comprehensive HIV/AIDS Partnerships (ACHAP).¹ Thirdly, the National AIDS Coordinating Agency (NACA) presented easily digestible data on the implementation of the ARV policy.

¹ A partnership of the Government of Botswana, Merck & Co., Inc./The Merck Company Foundation and the Bill & Melinda Gates Foundation.

It should be conceded that the decision of the Botswana government to implement an ARV programme might have more to do with political and economic calculations by the government than a desire to act on knowledge established by research. However, the programme enabled the government to develop appropriate ARV policies and implement them.

Barriers to implementation of HIV/AIDS policies in Southern Africa

Despite what we know from research and best practices like Mwanza and Botswana, there are also social, political and economic barriers to the translation of research into successful programmes. In 2004, the Human Sciences Research Council published the findings of an audit it conducted into HIV/AIDS policies of key countries in Southern Africa and described the following barriers to implementation of policies and strategic plans.

Although the roll-out of ARVs in Botswana is considered a success story, the Human Sciences Research Council audit of 2004 identified several barriers to the implementation of its HIV/AIDS policies. The lack of proper monitoring and evaluation, absence of trained professionals in the area of HIV/AIDS, poor access to financial resources, inadequate commitment of some service providers, ignorance of policies among communities, as well as excessive governmental bureaucracy, low utilisation of existing services, such as prevention of mother-to-child-transmission (PMTCT), voluntary counselling and testing (VCT), home-based care (HBC) and orphan care programmes, and heavy workloads among people in service areas other than HIV/AIDS contributes negatively to the implementation of HIV/AIDS policies in Botswana.

In Lesotho, lack of financial resources and skilled human resources, government bureaucracy, poor organisation of agencies, a lack of support at decision-making levels of government, institutional rivalry and duplication of efforts among various NGOs and other implementing agencies were identified as barriers to implementation of HIV/AIDS policies (HSRC, 2004).

Lack of participation in policy development at local level, inadequate awareness of the national AIDS policy, limited funds for implementing programmes, inadequate human resources management skills, negative cultural and traditional norms and objectives that were perceived as too ambitious have been identified as barriers to implementation of HIV/AIDS policies in Mozambique and Swaziland (HSRC, 2004).

In South Africa, inadequate human resources, poor infrastructure and lack of awareness, lack of confidentiality because most hospitals and clinics could not provide special rooms for VCT, stigma leading to low numbers of people requesting testing, and lack of awareness of HIV/AIDS policy and strategic plans, have all acted as barriers to the implementation of HIV/AIDS policies (HSRC, 2004).

Hatendi (2001) conducted a survey to ascertain levels of awareness about the Zimbabwe national policy on HIV/AIDS and progress in the implementation of policy initiatives. She found that policy awareness and availability was generally limited, and level of awareness varied amongst NGOs. Policy advocacy, dissemination and distribution strategies were weak. Civil society capacity to engage in HIV/AIDS programming was limited and as a result only the traditional players (health-related NGOs) were implementing the policy in a fragmented and unco-ordinated manner. She also identified the 'top-down' approach to policy formulation and strategic planning for policy implementation with limited consultation, participation and involvement of key civil society stakeholders in the national policy implementation. Civil society ownership of the policy was low, with unclear roles and responsibilities for NGOs in the implementation process. Her findings also reflected low participation by NGOs in the District AIDS Action Committees because of limited NGO knowledge and poor participation in district policy implementation.

Barriers to implementation of policies and strategic plans in Zimbabwe include a belief among the NGOs that the agenda was determined by donors, rather than by the strategic AIDS plan; very low awareness at grassroots level of the national policy on HIV/AIDS; and an absence of a legal framework as constituted by an act of Parliament, which would make the policies binding. There is also high staff turnover and brain drain of those who had represented the various organisations during the policy development process, resulting in loss of institutional memory (HSRC, 2004).

Dissemination, co-ordination and bridging the gap between research, policy and implementation

Wolffers, Adjei and Van der Drift (1998) suggest that the easiest route of dissemination of research findings to end users seems to be from researchers to authorities. They warn that authorities often want research that confirms their own achievements. However, there is sometimes political interference when research findings are undesirable. The South African Department of Health (DoH) refuted the publication of the results of a

study on causes of mortality conducted by the Medical Research Council, on the grounds that the report contained information on HIV/AIDS that was inaccurate, sensational and misleading. They further claimed that the report would mislead the public and create unrealistic expectations. Although the research had been peer reviewed, the cabinet was unwilling to release the report.

The DoH guidelines warn that the researchers should not communicate the results of clinical trials to the public without first subjecting the study to peer review and to the normal rigorous scientific scrutiny needed for therapeutic and vaccine trials. They further warn that phase I and II trials should be published in scientifically refereed journals or presented to scientific forums where the results can be openly viewed and scrutinised. These results should not be released to the mass media before peer review because they may be misinterpreted, misunderstood, sensationalised and result in serious public misunderstanding (DoH, 2000). The Traditional Health Practitioners' Bill, which was approved by the South African parliament in September, will ensure that traditional medicine and its practitioners are integrated into the country's healthcare system. This implies that research work conducted by traditional medical practitioners will be subjected to some kind of scientific scrutiny. The law clearly states that unregistered traditional practitioners will not be allowed to diagnose or treat HIV/AIDS or any other terminal disease, or else they will be found guilty of an offence and liable for a fine or imprisonment of up to 12 months (Traditional Medicines Bill, 2004). While many traditional practices are effective, the continued existence of unsafe practice draws attention to the need for training, research and policy development.

The guidelines further warn that important findings, which need to be urgently released, should be done via the 'fast-track' system employed by most reputable scientific journals. Most medical journals have now developed this system to fast-track review and publish important research findings (DoH, 2000). My view is that in all these guidelines and systems of communicating results, people who are being researched are never prioritised. It is the scientific journals and the media which come first. The results are usually presented in convoluted, scientific jargon that an ordinary citizen may find difficult to understand.

In 2004 the antenatal sero-prevalence survey for HIV, conducted among pregnant women in October 2003, was only released in late September. This was exactly 10 months down the line! The results of the antenatal survey conducted in October 2002, which gathered HIV information from 16 500 pregnant women at 396 state antenatal clinics throughout the country, were also only released in the middle of September

2003. This was almost a year after collection of data and only three weeks before the next survey was due to be conducted. The delay in releasing the data, which in the past was made public in March or April every year, has been another cause of tension between the government and the country's AIDS activists. Although the government said that statisticians took a long time to manipulate the data and caused the delay, some have argued that the reason for the delay in reporting the statistics was political.

There is also confusion in South Africa regarding the prevalence of HIV. There are three different results estimating the prevalence. The UNAIDS (2004) report estimated that there were 5.3 million people living with HIV while the Nelson Mandela/HSRC study of HIV/AIDS sero-prevalence estimated that there were 4.7 million people living with HIV (Shisana & Simbayi, 2002). Statistics SA figures released in 2004 indicated that South Africa had about 1.5 million fewer HIV-positive people than UNAIDS (2004) reported earlier the same month, estimating 3.8 million people living with HIV. According to Heston Phillips, executive manager of demographic analysis for Statistics SA, the agency's figures were 'in line' with estimates of other local agencies such as the Actuarial Society of South Africa, which lowered its estimate of the number of people living with HIV/AIDS in the country from 5.26 million in 2000 to 3.7 million in 2002 after altering its statistical methodology. Statistics SA said that the lower estimate is the result of differences in assumptions about HIV's spread, adding that the figures do not support critics who say the pandemic has been exaggerated (Kaizer HIV/AIDS Daily Report, 2004).

Different surveys and different methodologies are bound to give marginally different results. In view of this there should be some system to allow researchers and the Health Department to collectively analyse results and ensure that the public has consistent and appropriate information. The guidelines from the Department of Health further say that research which has direct public health implications, such as vaccine trials, requires wide consultation. This should include discussions with the South African Department of Health and the Medical Research Council so that implementation of study results can be addressed at an early stage (DoH, 2000). It is important in the era of vaccine trials that there is proper and ongoing consultation with communities, and the South African AIDS Initiative (SAAVI) has developed a unit to deal with community consultations on issues relating to vaccine research.

The DoH (2000) guidelines pay lip service to the involvement of people living with HIV/AIDS in the consultation process from the very early stages of the research process. The TAC, NAPWA and the SA Medical Association might probably tell a different story

about this consultation process. The guidelines, however, identify vulnerable populations that require special consideration such as women, prisoners and children.

Schneider and Stein (1998) presented a paper on factors influencing the implementation of AIDS policy in South Africa at the 12th World AIDS Conference in Geneva. They found that despite the presence of adequate financial resources, an active NGO sector, and clear national consensus on the content of an AIDS programme, there were major constraints to AIDS policy implementation. They concluded that an AIDS plan and the mobilisation of resources are necessary but not sufficient conditions for AIDS policy implementation. They proposed a wider approach to building implementation capacity, which pays greater attention to process-oriented dimensions such as leadership, vision building and participation.

The HIV/AIDS policy research and development system could be described as a collaborative relationship between different stakeholders, with the same goal on the basis of partnership or using common resources on a continuing basis to achieve a common research agenda. The concept of a national AIDS research policy system has to be seen as an integral tool for national health systems development. Its integration, management and programme needs have to be planned very carefully. The Medical Research Council and Wits University developed programmes to co-ordinate AIDS research through the 'Lead programme on AIDS research' and the AIDS Research Institute, respectively. Co-ordination bridges the gap between the different areas.

The key elements in translating HIV/AIDS research policy into action include the development of a research system (policy) requiring intensive discussion, review of the legal bases, identification of stakeholders, building linkages, development of instruments for strengthening networks, development of a sustainable capacity-building mechanism, tapping of financial resources, and development of a system of decentralisation. The network of AIDS research and development systems includes universities, HIV/AIDS research and development centres, hospitals and provincial and district health offices, and has an important role in policy implementation. The linking mechanisms between these focal points can be explained in the context of users, decision-makers, scientific communities, industries and the community at large.

Freudenthal (2001) identified the key challenge as establishing strong linkages between research, policy and implementation. Research proposals should include plans for dissemination of research results to policy-makers and policy-makers, in turn, must

show commitment and willingness to listen to researchers and use research results in the preparation of policy guidelines and design of projects and programmes.

Before the Southern Africa Development Community (SADC) summit in Mauritius in August this year, Executive Secretary Prega Ramsamy said that SADC has developed a five-year plan to streamline regional efforts to fight HIV/AIDS in the region. The plan includes efforts to co-ordinate prevention, treatment and capacity-building policies and integrate SADC policies and programmes into all HIV/AIDS efforts. In addition, the plan calls for bringing all regional policies on mother-to-child HIV transmission in line with SADC policies. SADC also plans to streamline antiretroviral drug policies and enhance the sharing of technical information and resources on HIV/AIDS among member countries (Kaizer Daily HIV/AIDS Report, 2004).

This statement recognises that regional efforts in Southern Africa are not streamlined to integrate policies into HIV/AIDS prevention and treatment efforts. Although the statement does not refer to integration of research into policy and implementation efforts, one can assume that the latter is a challenge at country level. The South African Ministry of Health admitted that there is a need to co-ordinate research efforts between government and other stakeholders at a recent meeting with researchers to discuss whether to continue using Nevirapine monotherapy in light of reports about resistance to it.

The role of research institutions in the formulation and translation of HIV/AIDS research policy into action has evolved over the years. The primary responsibility for formulation and translation of national HIV/AIDS research policy into action lies with the Ministries of Health. In Southern Africa, the Ministries of Health have been trying to fulfil this function through health or AIDS policy institutes/centres, with support from non-governmental and other AIDS agencies.

Research on different aspects of the HIV/AIDS epidemic is done by the AIDS research entities or units at universities such as the Peri-natal HIV Research Unit, AIDS Law Project, Centre for Health Policy, Centre for Policy Studies, Rural AIDS Development Action Research, Reproductive Health Research Unit, HIVSA, Clinical HIV Research Unit and the AIDS Virus Research Unit of the National Institute of Communicable Diseases. The national AIDS Committees in Southern Africa get advice on HIV/AIDS research matters from sub-committees or technical task teams on research, monitoring and evaluation, or similar names, which are made up of experts in HIV/AIDS research from higher education institutions.

Conclusion

More than 23 years into the epidemic, numerous advances have been made in HIV/AIDS research. The relationship between policy, research and implementation of HIV/AIDS programmes represents a bridge over troubled waters – research and policies is the bridge and implementation the troubled waters. Research constitutes a bridge because we have lots of it and policies are solid, with many of them well-crafted. While we have a great deal of research and well-crafted policies to sustain the HIV/AIDS bridge, implementation of these policies remains a great challenge.

Although there is still room for expansion in our understanding and knowledge of certain aspects of the HIV/AIDS epidemic, there are relatively few real research gaps, but such gaps are not the main obstacle to successful HIV/AIDS prevention and mitigation programmes. The fact is that research results are seldom utilised in the implementation of HIV prevention and care programmes.

The question as to whether HIV is over-researched is in some respects the wrong question. It is over-researched, but there are still important research needs. What is required is a better co-ordination of research, better monitoring and selection of research, as well as more attention paid to implementation.

References

- Access for All. 2004. Final program. *International AIDS Conference*, Bangkok, 11-16 July. Available at <http://www.aids2004.org>
- Caplan, N. 1979. The two-communities theory and knowledge utilization. In *American Behavioral Scientist*, 22 (3): 459-470
- Cohen D. 1998. Socio-economic causes and consequences of the HIV epidemic in southern Africa: A case study of Namibia. In *HIV and Development Programme Issues Paper No. 31*. Accessed at <http://www.undp.org/hiv/publications/issues/english/issue31e.htm>
- Department of Health. 2000. *Ethical considerations for HIV/AIDS clinical and epidemiological research*. Pretoria: HIV/AIDS/STD Directorate
- Freudenthal, S. 2001. *A review of social science research on HIV/AIDS*. Accessed at http://www.somanet.org/youthproject_files/SAREC%20%20AIDS%20report.htm
- Garner, P., Kale, K., Dickson, R., Dans, T. & Salinas, R. 1998. Getting research findings into practice: Implementing research findings in developing countries. In *British Medical Journal*, 22 August; 317:531-535
- Hanney, S. R., Gonzalez-Block, M. A., Buxton, M. J. & Kogan, M. 2003. The utilisation of health research in policy-making: concepts, examples and methods of assessment. In *Health Research Policy and Systems*, 1: 2. Accessed at <http://www.health-policy-systems.com/content/pdf/1478-4505-1-2.pdf>

- Hatendi, F. L. S. 2001. Zimbabwe national HIV/AIDS policy. In *The communication initiative*. Accessed at <http://www.comminit.com/strategicthinking/st2001/thinking-473.html>
- Human Sciences Research Council. 2004. *An audit of HIV/AIDS policies in Botswana, Lesotho, Mozambique, South Africa, Swaziland and Zimbabwe*. Pretoria: Human Sciences Research Council
- Jack, E. 2004. DA: Health a massive disaster. News24.com of 24/08/2004. Accessed at http://www.news24.com/News24/South_Africa/Politics/0,6119,2-7-12_1578064,00.html
- Jones, J. H. 1993. *Bad blood: The Tuskegee syphilis experiment*. New York: The Free Press
- Kaizer Daily HIV/AIDS Report. 2004. *Southern African Development Community discusses new regional strategy for fighting HIV/AIDS at meeting*. August 17. Accessed at www.kaizernetwork.org
- Makgoba, M. W. 2000. Ethics of AIDS research in a developing country – balancing power in disguise. Address given by Dr Makgoba at a plenary session of AIDS 2000. *XIII International AIDS conference*, Durban, South Africa
- Neilson, S. 2001. Knowledge utilization and public policy processes: A literature review. *IDRC-supported research and its influence on public policy*, December. Accessed at http://www.idrc.ca/evaluation/litreview_e.html
- Philpott, A., Maher, D. & Grosskurth, H. 2002. Translating HIV/AIDS research findings into policy: lessons from a case study of 'the Mwanza trial'. In *Health Policy and Planning*; 17(2), 196-201
- Reimers, F. & McGinn, N. 1997. *Informed dialogue: Using research to shape education policy around the world*. Connecticut and London: Praeger
- Report on the meeting of the Scientific Working Group (SWG) on formulation of National Health Research Policies and Strategies. 1999. Jakarta, Indonesia, 6-8 December. Available at <http://w3.whosea.org/book11/bs1f.htm>
- Sabatier, P. & Hank, J. (eds.). 1993. *Policy change and learning: An advocacy coalition approach*. Boulder: Westview Press
- Schneider, H. & Stein, J. 1998. *No content without process: factors influencing the implementation of AIDS policy in South Africa*. 12th World AIDS Conference. Geneva, Switzerland, June 28-July 3. Accessed at <http://www.caps.ucsf.edu/overviewabst.html>
- The Kaizer Family Foundation. 2002. *Capitol Hill Briefing Series on HIV/AIDS*. Pretoria: Department of Health – Traditional Medicines Bill
- UNAIDS. 2004. Report of the Global AIDS Epidemic. In *4th Global report*. Geneva: UNAIDS
- United Nations. 2001. *Declaration of commitment on HIV/AIDS*. Resolution adopted by the General Assembly. Twenty-sixth special session, 2 August
- Unterhalter, E., Ross, J. & Alam, M. 2003. A fragile dialogue? Research and primary education policy formation in Bangladesh 1971-2001. In *Compare*, Vol. 33, No. 1. Available at <http://www.cec-worldwide.com/Download/a%20fragile%20dialogue.pdf>
- Webber, D. J. 1991. The distribution and use of policy knowledge in the policy process. In *Knowledge & Policy*, 4 (4): 6-36
- Weiss, C. 1977. Research for Policy's Sake: The Enlightenment Function of Social Science Research. In *Policy Analysis*, 3 (4): 531-545
- Wolffers, I., Adjei, S. & Van der Drift, R. 1998. Health research in the tropics. In *Lancet* 351: 1652-54
- Young, J. 2001. Bridging research and policy – from workshops to an international programme. In ODI, 6, 13th September. Accessed at <http://www.gdnet.org/pdf/BridgingYoung.pdf>

Antiretroviral treatment for beginners

A person who is HIV-positive will require antiretroviral treatment at the stage when his or her infection has progressed to an advanced stage of disease. This point in the progression of the disease is signalled by the onset of a major opportunistic infection or when the CD4 count drops to below 200 cells per millilitre of blood. At this stage of progress of the disease only antiretroviral drugs that inhibit the replication of the virus can arrest further progression of the infection and prevent death.

Antiretroviral drugs effectively act to reduce or prevent the replication of the HIV virus, thereby reducing the viral load and allowing the immune system to reconstitute itself as the key defence against infections. There are now numerous antiretroviral drugs registered for use in South Africa, in both branded and generic versions.

The use of only one of these drugs (monotherapy) will provide some benefit for a short while only but does not suppress viral replication. This is only for a limited time as the virus soon mutates and develops resistance to a single drug and renders it ineffectual. Two drugs (dual therapy) will work better and for a longer time but will still be insufficient to prevent the development of resistance.

Mono- and dual therapy have a very important role in the prevention of transmission from mother to child during pregnancy and labour (this application is described below in the section on PMTCT) as the application is for a short time until the end of the pregnancy and is aimed at saving the baby, but not treating the mother. The long-term treatment of AIDS, however, requires three drugs used simultaneously.

When at least three antiretroviral drugs are used together they work very well to decrease the viral load to a very low level (undetectable). Scientists and clinicians have established that triple combination therapy (three drugs) or HAART (highly active antiretroviral therapy) completely prevents viral replication as well as the development of resistance (mutations) as the interruption of viral replication is comprehensive.

Successful viral suppression occurs within a few months and allows for a return to a good quality of life for the patient.

As the HIV is constantly replicating and dying, it might be expected that after a certain period of time of non-replication, the virus would be eliminated from the body. Unfortunately, the virus hibernates in certain tissues where it may remain dormant for many years and recommence replication once the antiretroviral drugs are no longer in use. As a result, antiretroviral drugs cannot be stopped at any time as this will allow the re-emergence of the virus even after successful treatment has taken place for many years.

The first line of treatment is the most important and provides the patient with the best chance of recovery; this is why it is so important that treatment succeeds at the first attempt. Good adherence to a simple first line regimen such as 3TC, D4T and Nevirapine or Efavirenz can work really well for patient and clinician and there are few reasons why a patient should not continue with such a combination for many years.

If a patient develops resistance to one or more first line drugs because of poor adherence, the patient may be changed to a second line of three antiretroviral drugs. A second line regimen will not contain any of the drugs used in the first line combination.

If a patient develops side effects to one of his/her first line drugs, this individual drug can be substituted, while still allowing the possibility of a second regimen if there should be drug resistance to the first regimen.

Second line treatment is less effective than first line treatment. A patient's best chance of good care and treatment is therefore when the first line treatment is successful. Second line treatment, while being effective may be less so, as the virus may have developed resistance to the class of drugs. For instance, patients who develop resistance to zidovudine (AZT) in their first line treatment may have some resistance to stavudine (d4T) as these two drugs are from the same class of antiretrovirals.

If the second line of drugs fails then the patient may be put on a third line or salvage regimen. This is highly individualised treatment and drugs are used trying as best as possible to avoid those drugs used in the first and second line of treatment. Salvage regimens are expensive (compared to first and second line treatment) and their clinical benefit is considered to be limited. Treatment with a third line regimen is highly specialised treatment requiring referral of the patient to a higher-level facility. Effective third line therapy will be more effective once there are new antiretroviral drugs available. It may be considered as a future option when new laboratory technologies and new drugs become available.

Once second line treatment fails, patients may continue to derive some benefit from treatment as the resistant virus has been shown to be less biologically fit than the 'wild-type' virus that would re-emerge in the absence of treatment.

From a cost and equity point of view, the greater the number of patients who go on salvage regimens, the fewer will be the total number of patients who will be put onto treatment. This will be the case in most middle-income country settings. A trade-off is always going to be made between the beneficial effect of the treatment and the number of people who have access to the treatment.

Against this backdrop, there is now consensus that first and second line treatment should be offered in developing country settings. First line treatment only will probably provide insufficient individual benefit. Funds saved from not providing a third line regimen will be better spent on increasing the number of patients on first and second line treatment.

This crucial point of departure for an antiretroviral treatment programme allows the public sector to have a shortened list of essential antiretroviral drugs, avoiding all the most expensive drugs available on the market. These drugs are already registered and widely used in South Africa, and are listed below.

SHORTENED LIST OF ESSENTIAL ANTIRETROVIRAL DRUGS RECOMMENDED FOR PUBLIC SECTOR USE

CLASS	ANTIRETROVIRAL DRUG	GENERIC AVAILABLE
(NRTIs)	Zidovudine (AZT)	Yes
	Lamivudine (3TC)	Yes
	Didanosine (DDI)	Yes
	Stavudine (D4T)	Yes
(NNRTIs)	Efavirenz	Yes
	Nevirapine (NVP)	Yes
PIs	Lopinavir/Ritonavir	No

Extracted from Abdullah, F. 2003. *The Cost of Antiretroviral Treatment (HAART): Submission to National Health/Finance Technical Task Team*. Department of Health, Cape Town: 1-43 (unpublished).