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# 5 – Overcoming resistance: Big Men and the scale-up of antiretroviral therapy provision

### *Introduction*

The rapid emergence across the globe of large-scale antiretroviral therapy (ART) programmes for people living with AIDS has been nothing short of a revolution. In the space of just four years, the number of people in low- and middle-income countries receiving this life-saving treatment increased fivefold, from 240,000 in 2001 to 1.3 million at the end of 2005 (WHO, 2006a). With a further 5.5 million people in need, the momentum continues, and a global target of universal access has now been set for 2010 (WHO, 2006b). Such a trend would have been unthinkable until the turn of the Millennium; but where AIDS was once effectively a sentence of death for people in Africa, it has become – for many, if not for all – a chronic, manageable condition. Regardless of whether the universal access target is actually met, antiretroviral drugs (ARVs) have become a permanent and central feature of the global AIDS control landscape.

How did this revolution come about? What were the processes and influences that contributed, and to what extent did research play a role? Why were some people so concerned about large-scale ART programmes, and what problems have already been faced that might act as a prelude for the future? These are the questions addressed in this chapter, which charts the evolution of ART provision up to and including 2005, at all three levels – locally, in Masaka; in Uganda as a whole; and also globally. The chapter moves through the three levels as it moves across time, thereby demonstrating the inter-connected and inter-dependent nature of the entire phenomenon.

One of the themes that emerges is the resistance that was faced by those seeking to expand ART provision. There were many different reasons for this resistance, and these varied between levels. But the rapid scale-up of ART provision globally and in Uganda during the early 2000s ultimately took place because of the collective determination of 'advocacy coalitions' to force through their will in spite of the opposition they faced. Advocacy coalitions are groups of "*people from a variety of positions… who share a particular belief system – that is, a set of basic values, casual assumptions, and problem perceptions – and who show a non-trivial degree of co-ordinated activity over time*" (Sabatier, 1993:25). In this case, the coalitions were led by

individuals working in the political and financial spheres at each level. They are described here as 'Big Men' – there were very few women involved at the most senior levels – and they were determined to put in place what they believed to be an essential humanitarian response to the catastrophic African AIDS epidemic.

The discussion in this chapter focuses on ART provision for HIV-positive adults, and is not concerned with use of the drugs for the prevention of mother-to-child HIV transmission (PMTCT).

***Towards ART provision in Uganda (1987 – 2001)***

The treatment of AIDS in Uganda did not start with antiretroviral therapy. The world's first antiretroviral drug – zidovudine or AZT – was approved by the US Food and Drug Administration for use against HIV in March 1987; and at a cost of around US$10,000 per year, it was effectively accessible only for patients in wealthy western countries. Ugandans living with AIDS at this time had to rely on more basic approaches to treatment, which focused on the treatment of the diverse opportunistic infections (OIs) brought about by HIV-related immunosuppression. At its best, this method could provide some relief, but care in Uganda during the 1980s was still very basic. In the words of an experienced counsellor, "*people don't die so miserably nowadays. They used to have such terrible diarrhoea so that you wondered if the HIV even destroyed their intestines. And the skin was so bad, peeling off. You could enter a room with an AIDS patient, and it was smelling terribly. But now treatment and counselling have improved things so much*" [Interview, November 30 2004]. The treatment of OIs was difficult and rarely effective over the longer term, and patients would suffer from one infection after another until they eventually and inevitably succumbed.

Two groundbreaking institutions emerged in Masaka during the late 1980s, to provide care for people living with AIDS: Kitovu hospital's mobile care unit, and The AIDS Support Organisation (TASO). Kitovu Mobile was established to complement the services of the 220-bed Kitovu mission hospital. During some periods, over 90% of patients admitted to the medical wards were suffering from AIDS-related conditions (Kitovu, 1993:4), and this drained already-limited resources from other important areas. Something entirely separate was necessary to deal exclusively with AIDS patients, but setting up the new unit was not easy. "*It was very difficult to get staff to work for me*," founder and former Director Sister Ursula Sharpe explained. "*And if a patient died, we were ostracised. But if they lived for a while, then people came and*

*said, here's my brother, take care of him too. I made a decision to go only to the most inaccessible places where people had no health care, and we would only deal with AIDS. If we'd not stuck to that, then we'd always have been dealing with malaria instead. There were lots of obstacles: some of the witchdoctors opposed us because we were taking away business from them. And it was impossible to get a nurse to talk about HIV prevention, because immediately they did, then people said 'they're looking for sex'"* [Interview, October 4 2004]. In spite of the difficulties, a total of 9,800 individual patients had been seen by Kitovu Mobile staff in the six years up to 1993, by when 3,100 were known to have died (Kitovu, 1994:3).

The second institution, TASO, also took a community-based approach to care, through the provision of counselling, information, medical and nursing care, as well as material assistance for people with AIDS and their families (Kalibala and Kaleeba, 1989). TASO's main message was for clients to 'live positively', both in terms of trying to lead a healthy lifestyle but also by maintaining a positive mental and emotional outlook. The first TASO branch opened in Kampala in 1987, with the second opening in the old measles ward of Masaka's government hospital in November 1988. Four years after its founding, the organisation was serving 6,000 people out of the two branches (Kaleeba et al., 1991). It was not, however, always easy to attract patients. A counsellor who worked in the Masaka office in the late 1980s spoke of the problem of patients presenting too late. Many of their clients in the early days came only "*once the witchdoctor had exhausted their pocket, and then they referred them to us. For example, they would say they have cured the diarrhoea, but the patient now needs the hospital so that the scars in the stomach can be healed by the western medicine. So we decided to go out into the community and get people to come in before they wasted all their money on the witchdoctors*" [Interview, November 30 2004].

In broad terms, therefore, the framework in Masaka for treating people with AIDS at this time was limited to 'witchdoctors', and Kitovu Mobile or TASO[57]. No doubt, the health workers would have given a great deal to be able to provide their patients with the only ARV then available – AZT – had it been affordable. By contrast to the treatment of OIs as explained above, ARVs attack HIV directly by inhibiting viral replication, thereby reducing its destructive impact on the immune system. ARVs do not provide a cure, but this approach to treatment is nonetheless far more likely to bring about a longer-term reprieve from disease than mere management of OIs. With

[57] See Whyte (1992) for a detailed discussion from the period of the nature of the professional and 'folk' health care sectors in rural Eastern Uganda.

regard to AZT, however, it was quickly recognized that HIV's extraordinary rate of replication permitted it to overwhelm the drug's line of attack by evolving resistance to it. As a Ugandan Ministry of Health information paper explained in 1989, "*Life expectancy can be increased for one year to two years*," but the patient would eventually die anyway (MoH, 1989:10).

Given AZT's cost and its relative lack of effectiveness, there was a great deal of scepticism about whether or not ARVs would ever be viable in Uganda. A former volunteer expatriate who worked in Masaka from 1988 to 1990 had thought it would be "*a thousand years*" before anything like that came to Uganda [Interview, 18 May 2004]. Peter Mugyenyi, Uganda's first ART-providing pioneer, concurred, describing at the Uganda Medical Association's annual conference in December 2004, how '*expert opinion*' in the mid-late 1990s had held that an advanced version of ART – triple therapy – would prove to be '*impossible*' to use in Africa. Laboratory breakthroughs had led in 1996 to the introduction of triple therapy, a treatment approach that includes a cocktail of three different classes of ARVs[58]. By attacking viral replication simultaneously in three different ways, triple therapy significantly slows down the development of drug resistance. Also known as Highly Active AntiRetroviral Therapy (HAART), triple therapy remains the standard treatment for AIDS to this day.

There may have been consensus among many public health experts that ART in Africa would prove to be not viable, but Dr Mugyenyi had in fact been providing the drugs in various formulations since 1991, at the Joint Clinical Research Centre (JCRC) in Kampala, a specialist AIDS treatment centre that he had founded with the Ministries of Defense, Health and Education. At this stage, ART remained accessible only to the privileged few Ugandans who could pay, and also to those lucky patients who found themselves eligible for participation in research projects.

Peter Mugyenyi explained the reasons for this in an email written in early 2005. "*There were absolutely no donors willing to consider any support for ART until just recently. We initially provided for those who could afford the cost, and took steps to increase access by persuading employers and private sponsors to support treatment for the poor. From 1992 we had regular and incremental importation of drugs as demand and access increased. By 1996*

[58] The three most commonly used classes of ARVs are: (i) nucleoside reverse transcriptase inhibitors (NRTIs), (ii) non-nucleoside reverse transcriptase inhibitors (NNR-TIs) and (iii) protease inhibitors. They all work by inhibiting the activities of particular enzymes that are necessary for viral replication.

*when HAART became available we were treating over 1,000 patients with the same drugs as were then being used in USA.*

"*Being in a research centre helped a great deal. Simply put, without a research set up we probably would have found it much more difficult to succeed. In research we worked with international experts who, though they never participated in any aspect of provision of ART or establishment of the program, assisted me initially in identifying sources of the drugs and helped in initial importation. Then we took over completely and regularly carried out drugs cost intelligence to access cheaper sources. The drugs initially flowed in without much problems because, as a research centre we could get in unlicensed drugs*" [Email, January 3 2005].

Through this work, Mugenyi and his colleagues proved the 'experts' wrong: ARV provision was feasible in Uganda. But since JCRC was providing the drugs at a significant cost to most of their patients, the great majority of Ugandans who needed them could not afford them. With around 1,000 patients on therapy in 1996, JCRC was meeting 1% or less of total national demand[59].

Prices may have remained high, but at least the treatment now available – HAART – was relatively effective. On this basis, and with the viability of provision in Uganda established at JCRC, the Ugandan government took an important step towards expanding access to ART. On November 5 1997, the Minister of Health, Crispus Kiyonga, announced that Uganda would participate in a four-country pilot project run by UNAIDS, called the Drug Access Initiative (DAI). "*Uganda and other poor countries have argued that we should be assisted so that these drugs can reach those in need*," the Minister said. "*The pilot phase will be aimed at developing new strategies for removing obstacles to improved HIV/AIDS-related health care*" (New Vision, 1997c).

The DAI would constitute the "*first experiences of organized ARV delivery in Africa*" (Katzenstein et al., 2003: S2), with the stated objective of "*setting up the necessary infrastructure and systems to increase access to HIV-related drugs*[60] *on a small but sustainable scale*" (Katzenstein et al., 2003: S1). Five centres were accredited in Uganda to act as providers when the project was launched in August 1998, all of which were in Kampala; and even though the drugs were subsidised and prices continued to fall,

[59] Around 930,000 Ugandans were estimated to be living with HIV in 1997 (UNAIDS, 1998:65), of whom somewhere between 10% and 20% (93,000 – 186,000 people) would have been severely immuno-suppressed and therefore clinically eligible for ART.
[60] These included (i) antibiotics for treating STDs, (ii) drugs for OIs, and (iii) ARVs.

patients still had to pay a large monthly sum. Triple therapy had cost 1.7 million shillings per month (about US$1,000) when it first appeared on the market in 1996, a cost that had fallen to 900,000/= (about US$500) by 1999 (Monitor, 2001).

The needs of all Uganda's AIDS patients would never be met under such conditions – equitable provision to the general population remained a distant dream – but it still represented considerable progress. As the Uganda AIDS Commission commented, "*Even a journey of a thousand miles must start with one step*", (UAC, 1997:14). And indeed, by 2001 – when the DAI pilot project was transformed by UNAIDS into a wider 'Accelerated Access Initiative' – Uganda had ten ARV providing centres in operation, and drug costs to patients had fallen yet further: Depending on the regimen a patient was prescribed, monthly charges now ranged from 155,000 Uganda shillings (about US$90) to 870,000 Uganda shillings (about US$500) (IPPPH, 2003:34). The establishment of this preferential pricing system, and the associated move towards a sustainable programme, was one of the DAI's major accomplishments.

The DAI was not, however, an unqualified success. Although its evaluation concluded that the "*pilot programme successfully expanded access to antiretroviral drugs in Uganda*" (Weidle et al., 2002:34), clinical and laboratory data presented for 476 of the 912 patients who took part in the project showed a number of problems with this model of provision. These were concerned primarily with the cost of the drugs. Clinical outcomes were compromised for the 49% of patients who could not afford the full triple therapy of three complementary ARVs, opting instead for a cheaper and less effective regimen with just two drugs. Furthermore, 33% of those who did not manage to adhere to their regimens as prescribed cited financial constraints as the reason. They were simply unable to pay for the drugs. The result of the difficulties faced in maintaining optimal adherence to an effective regimen was that resistance developed to at least one of the ARVs in 65% of the patients (Weidle et al., 2002:38). A method would have to be found to provide the drugs at no cost to patients; otherwise, ART in Uganda would remain no more than an expensive delay on their inexorable path to the grave.

In spite of these problems, the DAI had a significant impact on the international policy landscape, by highlighting what could be achieved as well as the difficulties that would inevitably be faced by such programmes (IPPPH, 2003:36). The situation internationally was also profoundly affected by the decision early in 2001, of India's

leading drug company, Cipla, to produce cut-price 'generic' versions of the expensive 'branded' ARVs. As a generic drug, no patent payment would be due to the company that originally developed it, which meant that instead of costing US$350 per month, triple therapy could now cost as little as US$350 per *year* (Guardian, 2001).

Suddenly, large-scale ARV provision became a realistic goal even for poor African countries, and, by June 2002, 80 countries had expressed interest in participating in the DAI's successor project, the Accelerated Access Initiative. Thirty-nine of these had already developed plans of action; 22 countries had entered negotiations with pharmaceutical companies; and 19 had successful UN-brokered supply agreements for ARVs (IPPPH, 2003: 76). In other words, the work of the DAI along with the fall in drug prices contributed to a huge increase in demand for ARVs throughout the developing world. ARV provision was now demonstrably feasible in Africa, and, with donor assistance, it was realistic to begin to think of national programmes that were both sustainable and equitable.

But the authorities in Uganda remained unconvinced specifically about the sustainability of any large-scale ART operation, and were consequently very reluctant to permit the importation of generic ARVs when they came onto the market. It took the politically astute maneuverings of JCRC's Peter Mugenyi to force the issue. "*The problem arose [in 2001],*" he explained, "*when the demand for ART became huge and we faced a moral dilemma. So many poor patients were then besieging JCRC in desperate need of the life saving drugs! I do not know about the others, but to me it was just unbearable. I could not just stand by and do nothing about the appalling situation, as almost all the patient's came to see me personally. I and only I took the decision to import generics. I couldn't even risk involving others as it would have been most unwise. I knew very well that the drugs would be impounded and that I was breaking the NDA*[61] *statute. Indeed, I planned to precipitate a crisis so that the catastrophe and tragedy of patients could come in acute focus and be addressed. I was also aware that this could land me in jail and was prepared for that, if only it could help speed up access and save some lives. I am not a confrontational person and very much hate to go against the law but I felt I had no alternative and reasonably there was none. When the drugs arrived at the airport without import licence or any kind of prior authorisation, they were, consistent with my expectation, impounded. A crisis was precipitated, and NDA wanted me punitively punished, but what followed is now well*

[61] NDA = National Drug Authority

*known. In brief, thousands, now in excess of 20,000, are alive because of this move!*" [Email, January 3 2005].

A journalist at the New Vision newspaper explained further how Mugyenyi worked to change the NDA's provisional import license into a more enduring legal arrangement. "*Mugenyi was playing games with the NDA and the government. He said I've imported the drugs, they cost little, but you [the government] have impounded them and people continue to die. Finally the government let the drugs through, and Mugenyi phoned me and said they have let them through. This was supposed to be a one-off, but then he said these people need to continue taking the drugs, so he imported another consignment. And that is how he broke the ground for ARVs to come into Uganda*" [Interview, November 10 2004].

It was therefore the financial advantages of importing generic ARVs that inspired a determined Peter Mugenyi to challenge the political and legal status quo, and that subsequently set the scene for the large scale provision of ART in Uganda.

***Doubts about global ART scale-up***

Even after securing permission to import generic ARVs, few Ugandans could afford the US$350 annual cost of the drugs, and certainly the government did not have the financial capacity to provide any sort of subsidy for them. However, a spark of international interest was emerging, stimulated partially by the Clinton administration's description of AIDS as a threat to US national security and to global stability (Independent, 2000); and partially by the fall in price of ARVs which, for the first time, created conditions whereby the global humanitarian disaster of AIDS might be comprehensively addressed. Moves were therefore afoot to establish major funding agencies for ART provision in developing countries. Where the activists at the Geneva (1998) and Durban (2000) International AIDS Conferences had been saying 'this *must* be done' – and, as described at the start of this book, were supported in their call by the likes of Nelson Mandela – the mantra was now 'it *can* be done'. An unstoppable momentum was building to scale-up ART provision throughout the developing world.

Given the longstanding role of the International AIDS Conferences in highlighting the dominant issues of the day, it was fitting that the next Conference, held in July 2002 in Barcelona, should have been the venue at which an ambitious goal for global

ART scale-up was presented. Dr Gro Harlem Brundtland, WHO Director-General, announced in a keynote address that "*We are aiming for three million people world-wide to be able to access ARVs by 2005*" (WHO, 2002) – a vision that became known as '3 by 5' when it was formally launched in September 2003 by her successor, Dr Lee Jong-wook. Given the recognition that ART was now potentially feasible in developing countries, '3 by 5' was intended to create global leadership and a political framework within which countries and donors would seek to scale-up provision, and to turn the potential into a reality.

The two major donors that effectively legitimised this powerful political act were the Global Fund to Fight AIDS, Tuberculosis and Malaria; and the US President's Emergency Plan for AIDS Relief (PEPFAR). Inspired by a call in May 2001 from UN Secretary General, Kofi Annan, the Global Fund had started work in January 2002. Annan's idea was for a "*war chest*" of $7bn-10bn to be spent annually on a global campaign against AIDS. Ensuring that care and treatment is within reach of all was, he said, a "*personal priority*" for him (Ferriman, 2001:1082). Subsequently, in January 2003 came George W Bush's announcement of PEPFAR, as described in Chapter 4. PEPFAR legislation required that 55% of the fund's US$15 billion – or US$8.25 billion – would be spent on treating people with AIDS between 2003 and 2008, of which 75%, or nearly US$6.2 billion, would be spent on the purchase and distribution of ARVs (Avert, 2006). Thus, within the space of two years, a political and financial framework had been established for the global scale-up of ART provision, and there remained no obstacle to any developing country applying for and accessing the necessary funds for national scale-up.

But by no means everyone thought that this move towards rapid treatment scale-up in the developing world was a good idea. I attended a conference held in Ottawa by the International Society for Sexually Transmitted Diseases Research in July 2003, a biannual scientific meeting to discuss biomedical, behavioural and social aspects of STDs, including HIV. The meeting took place at a key moment in the history of ART scale-up, just before '3 by 5' was formally launched, but just after the establishment of the major funding bodies such as PEPFAR and the Global Fund. ART scale-up was therefore very much on the meeting's agenda.

One of the keynote speeches was given by Mark Wainberg, a Canadian molecular biologist and former President of the International AIDS Society, the group that organises the International AIDS Conferences. He argued passionately that there was

"*no reason*" not to scale up ART provision, and "*no justification*" for saying that ARV scale-up in Africa will lead to drug resistant virus. The danger of wide-scale resistance developing to ARVs was one of the arguments made by those urging caution in relation to scale-up, as explained later in this chapter. But Wainberg's rationale was that African patients are highly motivated to adhere to their drug regimens – perhaps more so than many Western patients – since the implications of the death of the family breadwinner are inevitably that much more critical in a society that lives close to the margins of survival. "*There is no longer anyone else to whom the buck can be passed, but the politicians*," he asserted (Wainberg, 2003).

I spoke with a number of conference delegates – all with longstanding experience of AIDS research in Africa – about Wainberg's speech, and met with universal scepticism about his view. A Professor of Epidemiology and International Health told me that he "*strongly disagreed*" with his comments about adherence in Africa for ARVs not being a problem, and that he had been "*playing to the gallery.*" If this had been one of the International AIDS Conferences, the Professor said, Wainberg would have been applauded by the activists – but not in this scientific setting [Interview, July 29 2003]. A Professor of Medical Microbiology agreed, explaining that, "*Mark has never lived or worked in Africa. He's a very concerned kind of person, an extremely smart guy, an eloquent speaker, but I don't think he understands the reality of Africa or of AIDS*" [Interview, 29 July 2003].

A senior clinical scientist argued similarly: "*This man was head of the IAS*[62]*! I don't know, his perceptions of what it's really going to be like getting ARVs into developing countries, he's so far off the map. But he's obviously been to a lot of these International AIDS Conferences where you can make emotional statements like that about ARVs, and everyone gets up and cheers. And he kept pausing, and playing up to the crowd, but everyone was rolling their eyes*!" [Interview, 30 July 2003].

Why were these experienced western scientists so sceptical about the humanitarian position being upheld by Wainberg and the other advocates of ART scale-up? Three major points emerged during discussions with my respondents at the Ottawa conference and elsewhere, each of which has potentially enormous public health implications. The points included (i) the risk that the growing focus on ART would dilute or supersede HIV prevention activities; (ii) the risk that resistant virus would be generated through sub-optimal adherence to ARV drug regimens, thereby

[62] IAS = International AIDS Society

rendering treatment ineffective; and (iii) doubts over ART programme sustainability. But to each of these concerns, the ART advocates had a response.

**i) *The risk to HIV prevention***

Concerns about the possible negative impact of treatment on prevention had been voiced long before wide-scale ART became a feasible option for Africa. As far back as 1991, there had been arguments suggesting that since ARVs will help people with AIDS to live longer, patients will have more time and opportunity to spread the disease, thus undermining prevention efforts (WorldAIDS, 1991:4). Former WHO Director General Hiroshi Nakajima subsequently warned in May 1997 – shortly after HAART had emerged as an effective treatment for AIDS – that "*The wave of optimism that has enveloped the international AIDS community in relation to the new therapies must not lead policy makers to abandon their commitment to essential long-term activities such as prevention programmes*" (New Vision, 1997d). A Lancet article had also argued that HIV prevention was as much as 28 times more cost-effective than treatment, and that funding HAART at the expense of prevention would result in "*greater loss of life*" (Marseille et al., 2002:1851).

There were also concerns about an increase in risk compensation, the concept described in Chapter 4 that applies to people engaging in higher risk activities when related aspects of those activities are made safer – such as using a condom while having sex with a casual partner, or driving faster when wearing a seat belt. An official from the European Commission explained how "*In the gay community, prevention just went out the window as soon as the drugs came in: now you could have sex without condoms again, and, 'Yee-hah!' That's why it's so dangerous. HIV/AIDS needs prevention in spite of the drugs*" [Interview, 28 August 2003][63]. The problem is further exacerbated by the fact that "*As HIV-infected people on antiretroviral therapy become healthier, they are likely to become more sexually active, potentially creating additional opportunities for HIV transmission to occur*" (Gayle and Lange, 2004:6)[64].

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[63] See, for example, Dukers et al. (2001) for a description of this phenomenon in Amsterdam

[64] While extended life inevitably brings about 'additional opportunities' for transmission, it is important to note that since ART reduces viral load, it also reduces an individual's infectiousness *per partner exposure*. Thus an HIV-positive person who is taking ART is very unlikely to transmit HIV in any given sex act. But the argument here suggests that their extended life may well include a large number of these lower risk sex acts, thus making them more likely *overall* to transmit HIV. By contrast, had they died swiftly of AIDS and in the absence of ART, they would have been quite infectious per putative sex act, but they probably would have been feeling quite poorly, and thus would likely have remained relatively celibate. In addition, their period of elevated infectiousness (i.e before their

A way around this for the ART advocates was to promote treatment and prevention within the context of each other. An infectious disease doctor explained the philosophy: "W*hat I am sure of, maybe because I've been working at primary care level, is that no matter how well you do your prevention effort, people will only generally speaking bind to that if there is some hope of proper treatment. Prevention and cure, prevention and care, go hand in hand. But with HIV, we had a lot of care, pastoral care, faith-based organisations and so on; but there was no treatment, so there was no hope. And I think that if you're 15 years old, you're not thinking about if I get infected I'll get care, but somehow collectively in the population the fact that there is care, accessible care, affordable care that will be sustained, perhaps that may influence some change, some prevention. Let's say the message around prevention will become more legitimate if there is a strong message about care. I think that's why we need both*" [Interview, 17 September 2003].

In a similar vein, a policy advisor for Oxfam saw the current interest in ART as a unique moment in the history of AIDS that must be seized, not just for prevention and treatment, but as part of an even wider package. "*I think that at the moment we've got a fantastic opportunity, and my concern is that let's hold it now before crying for it when it goes. You know, let's hold it now and make it work now. This opportunity is not going to happen again. This is one opportunity, we have never had anything like that on health. Never, ever. So let's grab that opportunity and make it work. Not just for treatment, but for the whole dealing with HIV, for the orphans, for prevention, for everything else. For people to die in dignity. For people to have some food who are HIV positive. For a whole comprehensive package. So what I am saying is that, let's grab the opportunity and use it*" [Interview, 18 September 2003].

A spectrum of thinking existed, therefore, from those who argued for prevention 'in spite of' the drugs; to those who suggested that treatment legitimised prevention activities; to those who argued for taking the opportunity brought about by the increased funding to create a comprehensive package for tackling all aspects of AIDS. Advocates for scale-up contended that weighing prevention against treatment was a '*sterile debate*' based around a '*false dichotomy*' (Garnett, 2003). In spite of the certainty with which this position was put forward, it was a *value*-based opinion as opposed to an *evidence*-based fact. But the view that prevention and treatment are intimately

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premature death) would have been short. Thus they would have been unlikely *overall* to transmit the virus.

linked to each other, and that, in the age of ART, you cannot have one without the other, nonetheless became increasingly established.

**ii)** ***The risk of generating drug-resistant virus***

The very rapid rate of HIV replication imposes great demands on a patient taking ART. If they are to avoid the development of drug-resistant virus, a patient must take at least 95% of their medication on time, every day, for the rest of their life (Paterson et al., 2000). Otherwise they face the prospect of not only treatment failure, characterised by multiple opportunistic infections and eventually death, but also the possibility of transmitting drug-resistant virus to other people, rendering them, too, unresponsive to treatment (Laing and Hodgkin, 2006). Thus, ART programmes must ensure both that health systems function effectively so as to ensure a continual supply of drugs, in perpetuity; and also that everything is done to help individual patients to take their drugs as prescribed, for life. Furthermore, national ART policies must be established in order to counter the danger of unregulated drug provision, which has been recognised as a risk factor for the development of resistant virus (Harries et al., 2001)

Evidence focusing on individual-level experiences (as opposed to health system issues) was used by advocates such as Mark Wainberg in Ottawa to argue that adherence levels would be high in Africa. In the words of a London-based Professor of International Health, "*There's increasing evidence in the literature that actually African-based patients are better compliers than Europeans and Americans who are taking ARVs. There are anecdotes that are getting quite wide coverage now of people who sick up their tablets, and they just wash them and swallow them down again, because they are so motivated to keep HIV at bay*" [Interview, 16 September 2003].

This issue was nonetheless a major concern for a number of my respondents. A Professor of Communicable Diseases in London was concerned not about individual level adherence, but about the state of the larger health system: "*There was an article in The Lancet this week saying Africans are very good at taking their treatment. Well, I'm sure they are, when they're made available. But how are you going to logistically do that in a health service that can't provide anti-malarials?*" [Interview, 17 September 2003]. In this regard, the inherent weakness of Uganda's health system was well illustrated in late 2004, when the national referral hospital at Mulago completely ran out of oxygen supplies for patients undergoing surgery (Monitor, 2004). If such basic provisions as

anti-malarials and oxygen cannot reliably be made available, the argument ran, what hope could there be for ensuring supplies of some of the world's most sophisticated pharmaceuticals, along with all their associated paraphernalia?

The worries were not only felt by western scientists. A London-based Ugandan told me how "*I was one of the people when it started who was quietly advocating for no treatment in Africa. My feeling then was that we cannot afford it. The people would get a pill here and a pill there, and then we would start getting the problems of resistance, which is exactly what is going on now. And then we start fighting a different virus altogether, which you cannot afford to do. So I was one of those who was saying please don't take treatment to Africa. Because we won't be able to control it. But anyway, it's one of those things that you quietly thought about, but you couldn't say it*" [Interview, 16 September 2003].

Sub-optimal adherence is potentially the Achilles' Heel of the entire global ART programme. As explained above, ARV-resistant virus can emerge even in highly controlled treatment environments (Weidle et al., 2002:38), a fact that only fuels the fears of people like the doctor in Masaka who told me that "*In five years, I think we'll probably be worse off than we are now*" [Interview, 8 September 2004].

### iii) *Doubts over ART programme sustainability*

Finances may have become available from 2002, through the Global Fund and PEPFAR to support a large scale-up of ART throughout Africa, and further cuts in the price of generic ARVs were brought about by a successful legal campaign against two major pharmaceutical producers, mounted by South Africa's Treatment Action Campaign (Guardian, 2003); but the promises of financial support to procure these cheaper drugs were not open-ended. The Global Fund itself relies on continuous fundraising efforts, and PEPFAR was initially guaranteed to run for only five years, until 2008[65]. While the moves towards equitable provision were therefore progressing very well, serious questions were being raised about the extent to which this would be sustainable over the longer term. And, ironically, the problem of sustainability would be exacerbated by the very success of the programme, as people who once would have died would now live. Consequently, the numbers of people in need of treatment would grow endlessly as new patients continued to come 'on line' while the old ones lived on. An article in The Lancet put it succinctly: "*Unless annual HIV*

[65] In May 2007, President Bush announced that the US plans to spend a further $30 billion over five years in Africa and elsewhere to combat HIV and AIDS.

*incidence falls sharply from its current level of five million, treatment programmes will be unable to keep pace with the number of people in need, and will become financially unsustainable*" (Gayle and Lange, 2004:6).

A European Commission official cautioned that longer-term thinking is required in order to avoid the serious social and medical consequences that would inevitably arise if funds are not continually forthcoming for decades ahead. "*It will grow until it's unsustainable*," he explained. "*People will say 'this is costing too much, we already have X,000 people on treatment, the economy cannot support this anymore.' And then you're going to have to start saying no to people: 'sorry, we can't treat you, somebody has to die before you can get treated.' And that's an interesting scenario that people will have to think about. But how to protect against that is to ask how much can you afford in 20 years time. Don't put people on treatment today that you can't afford to have on treatment in 20 years time. Everybody has to think like that*" [Interview, 23 August 2003].

This very practical, financial mentality was of course not shared by those in the 'humanitarian' camp, for whom equitability should be the aim at all costs, and for whom a belief that things would somehow work themselves out in the future was the basis for urgent action today. In the words of a delegate at a WHO conference on ART operational research that I attended in Kampala in December 2004: "*We need to think about sustainability but that shouldn't make us not act. You have to just start because you don't have an alternative – it's an emergency. Don't worry about funding at this stage, because the funds will be forthcoming. We need to put the fire out now, not worry about whether there will be another fire tomorrow*."

Almost nobody was arguing that ART should be withheld from Africa altogether; rather, the issue at stake was the speed at which scale-up should take place. The cautious scientists called for the greatest care and deliberation now in order to avoid more serious problems further down the road; while the humanitarian activists called for urgent action now, and for an improvised, ad hoc approach to dealing with whatever unknowable problems might arise in the future. In the event, the humanitarian view won out, the die are cast, and whatever longer-term difficulties that may arise will now have to be faced.

Few people have known HIV for as long as Wilson Carswell, the Scottish surgeon whose prescience at the start of the Ugandan epidemic foreshadowed much of what subsequently emerged; and he is not optimistic about the outcome. "*My money's on*

*HIV*," he told me candidly. "*HIV beats WHO any day. It's like Manchester United versus Carlisle. I mean, even if you're from Carlisle, you're not going to bet on them, are you*?" [Interview, 13 May 2004].

***Engines of change: the 'Big Men' of international politics and finance***

In the end, '3 by 5' did not achieve its stated aim of having 3 million people on treatment by the end of 2005 – there were around 1.3 million people receiving ART by that date (WHO, 2006c). However, '3 by 5' did succeed insofar as it created a political climate in which governments and civil society were supported to put as many people on treatment as possible, and through which considerable financial and human resources were mobilised. It also became a concrete and apparently unstoppable "*step towards the goal of making universal access of HIV/AIDS prevention and treatment accessible for all who need them as a human right*" (WHO, 2006c). Why and how did this happen?

Humanitarian imperative played a central role in establishing a global discourse around the issue, and the fall in prices along with the demonstrated feasibility of small-scale provision served to bring this imperative clearly into the light of day. But nothing would have happened from there had not two factors come together: international political will, and funding. Politics and finance tend to be the domain of what could be described as 'Big Men' – powerful men at the summit of their respective, highly influential professions[66]. Muraskin (1996) details how such individuals from the pharmaceutical industry and various UN and funding agencies worked – sometimes in harmony and sometimes in conflict – throughout the 1980s to develop the Children's Vaccine Initiative (CVI). This was a more technical process than ART scale-up has been, in that it involved the funding and development of heat-resistant vaccines that would not require a cold chain. With the equivalent technical issues already resolved with ART – triple therapy had been in use since 1996 – the debates around providing the drugs in developing countries were both far more public and far more political. Nonetheless, a similar principle applies to ART as

[66] It is important to note that use of the term Big Men here does not in any way suggest that women have played no role in ART scale-up. However, apart from former WHO Director General Dr Gro Harlem Bruntland (who first touted the idea of '3 by5'), there have in fact been remarkably few women involved in the process at the most senior levels. This is mainly because the worlds of politics and finance tend to be male-dominated, and is not in any way an indication that women have not also been engaged and involved in the issue. Within the advocacy sphere, for example, women such as Ellen 't Hoen of Médecins Sans Frontières have made a very significant impact.

it did to the CVI: Big Men decided that the time had come to take action, and action was therefore taken.

Two examples of such Big Men are given here to illustrate how powerful men over-rode the ART doubters, imposed their will, and effectively became the engines of change for global scale-up. It should be stressed that there is no intention in any way to denigrate either of these two men through what is presented. This applies especially to WHO Director-General Lee Jong-wook, who died suddenly in May 2006. The purpose of including these examples is simply to illustrate how powerful men can work to bring about the things that they want to see done.

As suggested above, an international political framework was provided by '3 by 5'. The rhetoric around the initiative was intended to act as an inspiration and to offer leadership, with WHO's Dr Lee stating that "*To deliver antiretroviral treatment to the millions who need it, we must change the way we think and change the way we act*"; and UNAIDS Executive Director Peter Piot adding that this was "*a massive challenge, but one we cannot afford to miss*" (WHO/UNAIDS, 2003:1). However, many people were highly sceptical about whether '3 by 5' was a viable target. A co-organizer of a conference I attended in Florence in January 2004, on securing treatment and care for people living with HIV in low-income countries asked how many of the 100 delegates present at one session thought that the '3 by 5' target would actually be met; only two people put up their hands. This had nothing to do with the scientific reasons given above – people simply did not believe that it was logistically possible.

Discussions at WHO headquarters in Geneva in February and April 2004 suggested that many insiders felt similarly. One respondent explained that when Dr Lee was interviewed for the job of WHO Director General, he had not even mentioned '3 by 5' or ARVs as a priority issue; but once in the job, he had been persuaded by his close advisors to take it up as a major concern of his administration. The public rationale was, my respondent said, that "*This is a disease that needs serious attention, and we must address it – whether we succeed or whether we fail. And if we fail, we shame the world*."

However, there were also internal reasons for pushing WHO to take on '3 by 5', he said, since it "*could serve to unite people within WHO*" around an important humanitarian initiative. That said, there was nonetheless considerable resistance within the organisation, partly for the scientific and programmatic reasons given in the section above, but also because of something much more mundane: funding. "*The*

*mechanisms in the Global Fund aren't in place yet,*" my respondent explained, "*and there's not enough flexible money in WHO. A couple of hundred million dollars, if spent right, could really get this started well, but it's not available, and the result is that people in WHO see '3 by 5' as a threat, since it may cut into their funding. Therefore it has in fact divided people in the organisation. It's a question of robbing Peter to pay Paul*" [Interview, 18 February 2004].

Such was the lack of support for the project that, as another staff member explained, a two-day retreat had been organised for all WHO personnel involved in '3 by 5'. There, Dr Lee had addressed his staff, telling them in no uncertain terms that "*If you don't believe in '3 by 5', you don't belong in this organisation*". He was effectively forcing his will onto his workforce, and apparently creating some resentment in the process. One female employee spoke with exasperation of working with such '*alpha males* '[Interview, 19 February 2004], while another was more forthright, describing Lee as a '*dictator*' [Interview, 18 February 2004]. At the time of my interviews in Geneva, WHO staff were being dispatched to countries all across the globe to provide technical assistance to Ministries of Health as they completed their applications to the Global Fund. "*I spent this morning,*" one respondent told me, "*going to various people and asking if they're free and willing to travel next week – not that they have a choice, because if the DG*[67] *says it, you have to do it and drop everything else*" [Interview, 18 February 2004].

Even if '3 by 5' was seen as flawed by many people, and even though it created some internal friction within WHO, the political framework it provided did create a unified global target. As such, it worked together with changes in the financial framework that had already begun to create the momentum that led to global scale-up. The key move in the financial sphere, as explained above, was the decision by Cipla drug company to produce cheap generic drugs. This stimulated an enormous increase in the money that was made available by donors: cheaper drugs are very attractive from a donor's point of view, since they provide more patients treated for their dollar. As the Oxfam policy advisor explained, "*Look at what happened when the prices came down. Three or four years ago, I remember the time when we were talking about ARVs, and people were saying – I mean, even us here in Oxfam – 'My God! How do I talk about ARVs?' People just scream and say that these people have no food, have no sanitation, no water, what the hell are you talking about? But now it has changed. And I think Dr.*

[67] DG = WHO Director-General

*Hamied in India*[68] *has made history, by his cutting down the price, jumping from $10,000 to $300 [per patient per year]. That just made everyone say, 'ah, right, okay, we can't say no now, we have to think about it.' That really made a big difference*" [Interview, 18 September 2003].

One of the people who made the call for increased funding for ARVs based on these cut-price generic drugs was economist Jeffrey Sachs. Formerly Special Advisor to UN Secretary General Kofi Annan, he has an extensive track record of advising economies in crisis; and my Oxfam respondent explained how he had participated in the process of scaling up ART. "*You can influence them [the donors],*" she told me, "*by knowing which part of academia is listened to; and you know that economists are gods, that's how it is. It was only when Jeffrey Sachs came into it – I mean, you like Jeffrey Sachs or you don't like him, my God, his ego is beyond any belief! – but what he did, which is excellent, is he got these [economic] figures on the agenda*" [Interview, 18 September 2003]. Sachs' work in this regard included the first systematic calculation and projection of the money that would likely be needed by 2007 and 2015 for HIV prevention, care (e.g. of OIs), and treatment with ART (Sachs, 2001:163).

A colleague of Professor Sachs in New York explained how he works: "*For Jeff, [scaling up ART] is all about money. He's aware of all the complexities, but he doesn't have a lot of patience for them. For him, it's basically just about getting the donors to cough up. And the thing that makes our life a bit complicated now is that he's enormously pro '3 by 5'. I think that's partly because of his personality, his temperament, because this is something that he can push for. It* is *about money, it* is *about getting something done, it* is *top down – which, by the way, is what Jeff likes – and it doesn't get you sucked into some complicated vortex of human behaviour*." [Interview, 24 February 2004]. In essence, therefore, Sachs did the sums, put the numbers on the table, and pushed – hard and loud – for someone to provide the cash.

Dr Lee and Professor Sachs were just two of a number of other financial and political Big Men who forcefully imposed their will and over-rode the doubts of their colleagues and subordinates. Muraskin (1996) describes how the Children's Vaccine Initiative was "*a tale of strong-willed individuals who worked within the confines of larger social, economic and political structures but who, nevertheless, 'made history' by their actions*" (Muraskin, 1996:1718). A similar phenomenon was observed here; but to

[68] Dr Yusuf Hamied is Chairman of Cipla, the Indian drug company that pioneered the production of cheap, generic ARVs.

Muraskin's observation it could be added that the Big Men who brought about ART scale-up were in that rare position of being able actually to change the social, economic and political structures that determined what would be done. In other words, rather than having agency merely to act within the structures of their professional world, they had agency to change those structures, thereby creating an entirely new framework within which individuals at all levels would subsequently be obliged to act.

***What was the role of research?***

The main engines for global ART scale-up were therefore political and financial. Given this, to what extent did research also play a role? It could be argued that the broad failure of efforts to demonstrate the effectiveness of HIV prevention interventions (as discussed in Chapter 4) created an environment which permitted ART to come to the fore. ART provides visible results, a satisfying alternative to the ongoing and rather exhausting uncertainty about HIV prevention. "*Failures do not matter*," a public health doctor in London explained. "*Failures, we drop. We don't ask why did that fail, what can we learn from that? But with treatment, we see people improving. We don't need a randomised controlled trial. You just give them the tablets*" [Interview, 17 September 2003]. In this sense, therefore, research played a role in ART scale-up not through what it did, but what it had *not* done – or, perhaps even, *could* not do.

These limits inherent in some of the more traditional approaches to AIDS research have by now been quite widely recognised, and consequently there has been a shift in the type of work being conducted by many groups. For example, through its fundamental orientation towards improving programmatic approaches and processes, Operational Research (OR) – defined as "*the science of better*" by the Institute for Operations Research and the Management Sciences – has become increasingly relevant for large scale ART provision. A WHO background document explains that "*Operational research is a central element in the 'learning by doing' approach to scaling up treatment and prevention. This notion recognizes that incomplete evidence should not constrain scale-up, provided that efforts are made to actively monitor what is happening in countries, learn from comparisons of different programs and policies, and inform decisions*" (WHO, 2006d).

The Drug Access Initiative discussed above, for example, made some critical points – based on OR-approaches – which, according to an official from the Uganda AIDS

Commission, were "*very helpful*" in terms of defining ART policy in the country [Interview, 9 December 2004]. This groundbreaking project established the fact that ART could feasibly be provided in developing countries, and the major scientific paper that emerged from it positively assessed patients' responses and survival rates (Weidle et al., 2002). Nonetheless, the work was conducted under highly controlled conditions, serious problems were identified over and above the encouraging headline results – such as high levels of drug resistance among project participants – and, as such, it did not provide a blueprint for the way global scale-up should be conducted.

Perhaps more influential in terms of global advocacy was a study describing a successful ART project run by Médecins Sans Frontières (MSF) in Khayelitsha township near Cape Town, South Africa. ARVs were first prescribed there in May 2001, a step that was "*motivated by both humanitarian and public health principles*", and with the objective explicitly "*to demonstrate that the use of antiretroviral therapy at primary health care level was feasible, affordable and replicable*" (Kasper et al., 2003:20). In other words, this was a project conducted for the purposes of advocacy, and to that end, operational data were collected in order to demonstrate a point that MSF wanted to make. Data from the first 180 patients to be placed on treatment were presented in the Khayelitsha publication, demonstrating a significant increase in CD4 cell counts[69] and concomitant falls in the rate of opportunistic infections such as TB, and also death. The main conclusion of the paper was that "*Antiretroviral therapy can be safely and effectively used in resource-poor settings, and the time has come to scale-up from pilot projects to widespread access*" (Kasper et al., 2003:21). This point was taken up as a rallying cry for MSF and other ARV advocates. In the words of Ellen 't Hoen, MSF's Paris-based director of the group's Access to Essential Medicines campaign, "*These people are doing very well. A very important message is to show that the drugs can be very effective even in very poor settings*" (Guardian, 2002).

I put this to a Professor of Communicable Diseases who had previously told me of his scepticism towards ART scale-up. Surely the Khayelitsha study proves that it can be done? "*Yeah, 180 patients,*" he replied. "*But what's the good of that? That's all very well, but when they scale that up to a couple of million people… The trouble is, if you say these things, if you voice any of these concerns, you're immediately accused of being a racist,*

[69] CD4 cell counts are used as markers for determining a patient's level of immunosuppression. Most healthy people have CD4 counts of around 1000; ART is usually initiated when the count drops to 200, since this is the level at which people often start to fall sick.

*or that you're saying Africans are stupid and all this. So it's difficult to say. And especially in this atmosphere when it's not science, it's politics that's driving the agenda. This is the trouble, the science has gone out of the window*" [Interview, 17 September 2003].

Politics was therefore driving the agenda for programmatic work on the ground, and this in turn was driving the agenda for research. It is perhaps inevitable that a major paradigm shift such as that associated with ART brings about changes both in the practice of health care but also, quite fundamentally, in the way research is conducted. Operational ART research in Africa during the 1990s and very early 2000s was largely carried out by activists seeking to prove an advocacy point: that ART provision was feasible. With that point established, and with ART consequently and increasingly part of the treatment landscape, it then became hard to conduct any sort of research on AIDS without taking ART into account. Thus a form of reciprocity was established between the research and its topic: Operational research contributed to ART scale-up by showing that it was feasible, which in turn fundamentally changed the face of AIDS research.

***Scale-up in Uganda***

While the arguments over the possible risks and benefits of ART scale-up raged at international level, the first tranche of Global Fund money – US$36 million – arrived in Uganda in mid-2003 (Global Fund, 2003), and the in-country process rapidly got underway. As AIDS Control Programme (ACP) Manager Dr Elizabeth Madraa explained, "*Ministers were not always in favour of buying these expensive drugs. But with this Global Fund cash alongside a further US$3 million we got from the World Bank, it looks like we now have the money to do it if we plan carefully*" (New Vision, 2003a). The Ministry of Health subsequently announced that it intended to place 60,000 people on ART by the end of 2005, as the country's contribution to '3 by 5'.

Meanwhile, in June 2003, the government published its ART policy (MoH, 2003). It had been produced quickly, before national rollout even began, a fact that stands in stark contrast to the very slow progress made with the country's HIV prevention policy, as explained in Chapter 4. The document had been the product of input from a number of actors, including the Ministry of Health, donors, and those groups who were already engaged in provision. Key concepts throughout its development were partnership and collaboration between stakeholders.

The policy's core values revolved around "*equity and universal access*" (MoH, 2003:7-8). The money and the means had become available, and the government would simply have to trust that it would continue – even if it was well understood that neither of the two major donors, PEPFAR and the Global Fund, had made any guarantee of providing long-term funding. In this regard, the new policy implicitly recognised the need for extensive donor support – the country's overall health care funding was estimated at just US$13 per year for all diseases, of which US$8 was provided by the patients themselves, and US$5 by the government (MoH, 2003:5). Thus, even with the enormous reductions in price of ARVs noted above, they were still completely out of the reach of most of the 100,000 or so Ugandans who needed them. Provision would have to be free to the provider if true equity was to be established, and this would be expensive: A comprehensive service includes not just the drugs, but also counselling, testing, clinical diagnoses, treatment for the OIs that inevitably arise, food supplementation, and community-based alternatives to institutional care and support.

A phased rollout was planned, starting with the regional referral hospitals; then moving out to the district referral hospitals; and subsequently down to 'Health Centre IV' level – simple sub-district clinics run by medical assistants. Peter Mugenyi – who, in addition to running JCRC, is also chairman of the technical committee overseeing ARV rollout in Uganda – explained at the Uganda Medical Association's annual conference in Kampala in December 2004 how improvisation and creativity were sometimes necessary in order to expand treatment opportunities for patients. He gave an example of how a British research group had wanted to conduct an ARV study at JCRC with 1,000 new patients, and had complained to him that there was insufficient space at the facility. That was correct at the time, Mugyenyi agreed, but he asked the visitors to return the following week: "*Then we'll have space*," he told them. And indeed, when they came back, JCRC had raised a large tent in the grounds, big enough to deal with 1,000 outpatients. The research group acceded, the study started, and another 1,000 Ugandans started on ART. "*We must not be setting up sub-standard services*," he told the meeting, "*but I don't allow infrastructure to be a constraint*" (Mugyenyi, 2004).

Figure 2 shows the rate at which Uganda's scale-up process actually took place – thanks to such creative approaches – and it demonstrates remarkably steady progress towards the policy target of equity and universal access. This was both because the drugs were increasingly available throughout the country, and because

they were being provided free to an ever-increasing number of people. In December 2003, 20% of all ART patients nationwide were receiving free treatment, while by December 2004, this had risen to 35% (Namagala, 2004). Even so, the fact that only one-third of the country's ART patients were receiving free treatment showed that further progress was needed in this area if universal access was to be achieved.

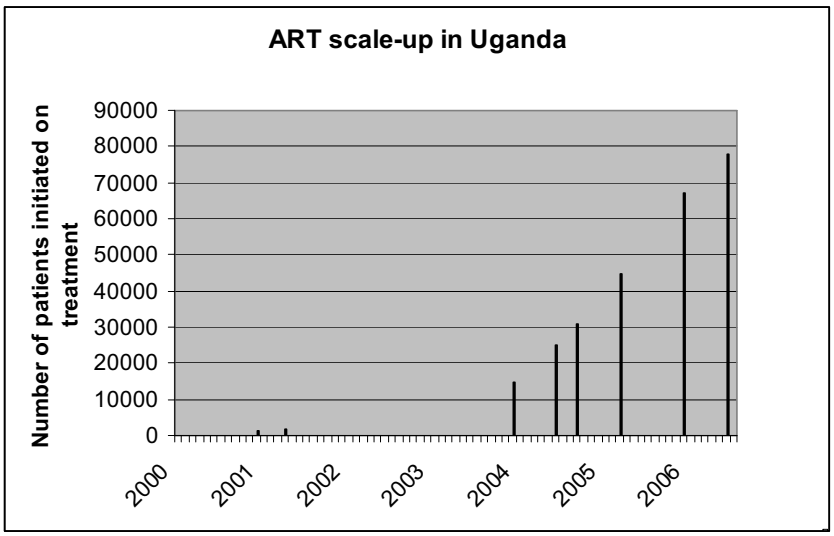


**Figure 2: ART scale-up in Uganda, 2000-2006**
[Sources: Whyte et al., (2003); IPPPH (2003); Uganda Medical Association annual conference, December 2004; The East African (2005); The Monitor, 2006]

Uganda became one of a small handful of countries not only to meet, but to exceed its '3 by 5' target: Instead of the expected 60,000 patients on ART, 67,000 Ugandans were registered as ARV patients by December 2005. According to Dr Elizabeth Namagala, senior medical officer for the ACP, "*It was easy to increase the number of patients on ART once we managed to get sufficient support*" (East African, 2005). Indeed, one Ugandan doctor explained to me that with so much money suddenly coming into the country, "*Now it's a question of too much money. Everyone is wanting to fund us. For the first time I was in a place where they were fighting, not for the money, but for the patients*" [Interview, 11 September 2004].

However, while these figures are extremely impressive, the rapid scale-up of ART stretched an already over-burdened health service yet further, and placed enormous pressure on medical staff. One doctor in Kampala equated the increase in patient numbers at her facility to a '*silent tsunami*' [Interview, April 7 2005]; and the word

'*overwhelmed*' was being heard with ever-increasing frequency in relation to ART provision in Uganda. This had implications for the long-term sustainability of the programme, not least because as AIDS-related mortality rates fell, ever-increasing numbers of patients would require ART. And if medical staff were to find themselves struggling to provide all these patients with adequate adherence counselling, the possible development of drug-resistant viral strains would be greatly increased.

Another problem was that the rapid scale-up of ART provision was accomplished at least in part by giving providers a great deal of freedom in determining how best to provide the drugs to their patients. Many different modes of delivery and care therefore evolved, with each major provider[70] following different operating procedures. Some provided the drugs and laboratory services for free, while others charged; some used generic drugs while others used only the more expensive branded drugs; some worked only out of the clinic while others provided community outreach. And, just to complicate matters further, some providing centres worked with two or more different funding organisations. This means both that doctors in the same clinic might work under different bureaucratic requirements, and also that two people living under the same roof could be attending the same clinic on the same days, but taking completely different ARV regimens. These could have different timing and nutritional requirements, which would only exacerbate the challenge they already faced in maintaining optimal drug adherence rates.

The confusion was not only felt at the level of individuals and clinicians. At a WHO-sponsored meeting that I attended in Kampala in December 2004, to design a five-country ART operational research programme, the lack of a clear picture of what was going on in the country was clearly expressed by the Ugandan team. The data that were available tended to come from the supply side, with a primary focus simply on the number of people who had been enrolled into ART programmes. No systematically collected data existed on how the various programmes were functioning, what problems the medics were facing, nor on the patients' experiences. Consequently, the team proposed a nationwide situation analysis as a prerequisite before any further operational research could be conducted. As their funding proposal explained, "*No systematic attempt has yet been made to document exactly who is*

[70] The various ARV providers in Uganda in late 2004 included the Ministry of Health; JCRC; various NGOs such as MSF, GTZ, TASO and Mildmay; the Uganda Business Coalition and Uganda Cares; private-for-profit providers; and a number of research programmes.

*doing what and how, and consequently the Ministry of Health does not have the information required in order to plan and execute a fully sustainable and effective ART programme for the country*" (MoH, 2005:7).

In other words, just months into the country's national rollout programme, not even the ACP authorities themselves had a clear picture of what was going on. Developments on the ground had far outstripped the knowledge-base, and research was now required in order to ensure that the national ART policy target of equity and universal access could be achieved and maintained over the long term. History was, in a sense, repeating itself: just as HIV prevention activities had been conducted on a wide scale for many years without any clear evidence of effectiveness – as detailed in Chapter 4 – ART rollout had been instigated on the basis of an urgent need to act rather than on a firm foundation of evidence. Furthermore, there was not even at that stage a comprehensive national plan for monitoring and evaluation.

This was the inevitable result of Uganda's rapid scale-up, but, as JCRC director Peter Mugyenyi explained, it had been necessary for humanitarian principles to take precedence over everything else: "*Action had to be taken expeditiously as in all emergencies that cost human lives, irrespective of some possible errors. In such a disastrous situation it is more important to act quickly than to perfect the science and have lengthy plans to avoid any inadvertent mistakes. A scientifically meticulous response is not always possible or desirable in cases of emergency!*" [Email, 12 January 2005].

***Uganda Cares – the birth of an ART provider***

The final section of this chapter brings us back to the local level in Masaka, and to a case study of an innovative ART provider that promised not only equity but also guaranteed sustainability: Uganda Cares. The birth of Uganda Cares illustrates how similar processes to those described at the international level with regard to '3 by 5' also took place at the national and local levels. The story at its essence involved a humanitarian drive that was facilitated by powerful political and financial backing; that faced resistance from a variety of actors; and that finally emerged through the determined work of a diverse group of highly driven individuals.

Many paths – from international, national and local levels – came together to bring Uganda Cares to Masaka. Internationally, the primary actors were associated with the Los Angeles-based AIDS Healthcare Foundation (AHF), the largest single

provider of AIDS care and support in the USA, with expenditure in 2004 amounting to US$92 million (AHF, 2005). Inspired by the 2000 International AIDS Conference in Durban, AHF Director Michael Weinstein and his colleague Henry Chang established a subsidiary organisation called Global Immunity, based in Amsterdam, with the objective of providing free ART in the developing world. With a long and varied history of AIDS work behind him – including stints in Dr David Ho's cutting edge HIV lab in New York[71], community-based activities in the US gay community, and later with Dupont pharmaceuticals in Uganda and Nigeria – Chang was asked to take on the role of Global Immunity's Executive Director. He already knew some of the important actors in Uganda's health services from his time with Dupont, and was familiar with the country's success in combating AIDS, as well as its openness to foreign assistance. His personal experience of Uganda therefore put the country at the top of the list of possible sites for Global Immunity to start work. How, then, did Uganda Cares come to Masaka, the site of Global Immunity's very first clinic?

The connection to Masaka came through the chairman of the district, Vincent Sempijja. In 2001, Sempijja had been invited to speak about the impact of AIDS in Masaka at a conference in Los Angeles, where a chain of meetings led him by chance to the President of AHF, Michael Weinstein, whose offices were nearby.

"*Michael gave me a full day,*" Sempijja told me, "*first with some staff, and later on just the two of us, and he wanted to know what was going on in this country. He had some brief knowledge of Uganda – he knew about the President, how he had come out to talk about AIDS, and even to tell the whole world that his country was facing a whole problem when other countries were denying. All the political leadership to the grassroots, from top to bottom, it was an agreed policy that we must inform our people and in fact tell the whole world. That is how I came into contact with Michael*" [Interview, 1 December 2004]. Sempijja's visit to LA was serendipitous for both sides, since it provided AHF with a powerful local-level individual who could facilitate the fulfilment of their vision in Uganda, and it provided Sempijja with the priceless political prize of bringing the country's first free ART provision to his district.

With this starting point, a meeting on "HIV/AIDS care and support" was held by AHF/Global Immunity in Entebbe in September 2001, attended by 300 participants

[71] In the early-mid 1990s, David Ho's research focus was the dynamic nature of HIV replication in infected people, which contributed to his groundbreaking work in the development of one of the three main classes of ARVs, protease inhibitors. He was named Time magazine's Man of the Year in 1996.

from 20 countries. As well as bringing together interested parties from all over the region, Global Immunity announced their intention to provide 10,000 Ugandans with ART, specifically the poorest of the poor, those who would not otherwise be able to access the drugs. The organisation was to be called 'Uganda Cares', a name inspired by that year's World AIDS Day slogan: "*I care… do you*?"

One of the major innovations of Uganda Cares was a promise to fund treatment not for just for the few years of a funding cycle, but for life, thereby becoming the very first group in Uganda, perhaps in Africa, to seek to guarantee both equitable and sustainable treatment. Henry Chang explained at the conference that the first Uganda Cares centre would be opened in the grounds of Masaka Hospital in less than three months, on World AIDS Day, December 1. "*Our concern is that very many people are dying because they cannot access HIV/AIDS drugs*", he explained. "*We should strive to provide life-saving mechanisms now and the Ministry of Health and my organisation will soon finalise the financial details of this joint venture*" (New Vision, 2001).

This, therefore, was the public proclamation, which suggested that the deal was effectively done, and that come December 1, Uganda Cares would open the doors to its clinic in Masaka. However, a great deal of negotiation – including overcoming some considerable opposition to the idea – still remained to be done. President Museveni had opened the Entebbe conference, and Weinstein and Chang took the opportunity to arrange to meet with him the next day to discuss their programme proposal. But when they arrived at State House, "*We were surprised to see that there were a number of other groups also present*," Chang told me [Interview, 25 October 2004]. These other groups included WHO, UNAIDS, and USAID, as well as senior officials from the Ministry of Health. The President was "*very enthusiastic*" about AHF's proposal to start a free ARV programme, Chang explained, and it was clear that Museveni felt this was a sufficiently important issue to require representation and discussion between all the central stakeholders. As a senior Ministry official who was also present explained, "*The President's view was that the government has a policy of partnership, in order to rally support. So he was happy to accept it*" [Interview, 9 November 2004].

The enthusiasm towards the project was not, however, shared by everyone in the room. In the presence of Museveni, a representative from the Uganda AIDS Commission warned that "*Even if the President has said this will happen, you mustn't expect automatically that it will*." And a UNAIDS official was even more

straightforward in her criticism, saying simply that "*You will fail in your enterprise*" [Interview, 25 October 2004]. Such doubts were also shared by people who were not at the State House meeting, including an AIDS social scientist who told me that the promise of free ARVs made the fledgling Uganda Cares an "*object of derision*" [Interview, 19 October 2004].

Why was there so much resistance to the idea of providing life-saving drugs to dying people? As a Ministry official explained, "*People at programming level – knowing about prices, system requirements, health infrastructures, the need to have laboratory equipment in place – these people said they were too ambitious. So I can understand why they were wary*" [Interview, 9 November 2004]. I put this point to a Uganda AIDS Commission executive, and asked if the scepticism was due to worries about the likely success of the project. "*No*," he replied. "*It was simply a question of losing power*" [Interview, 9 December 2004].

Thus the resistance among the major actors – both Ugandan and international – appeared to be derived both from a sense that their turf was being invaded, and also from very practical concerns about the viability of such an ambitious project. In relation to the latter, it is undeniable that neither Global Immunity nor AHF had any institutional experience of Africa at all. However, it could equally be argued that it was precisely the unfettered idealism and hope that came with this inexperience that permitted them effectively to break the rules of what could be done, and to overcome the conservatism that was the natural domain of the long-term actors. Weinstein and Chang had an idea, they visited Uganda, met the President, offered their plan, and it was accepted. As Chang explained, "*The way we moved into Uganda was a great example of how political will can make something happen. Global Immunity circumvented the standard protocol for changing policy, and went straight to the President*" [Interview, 25 October 2004].

But even with the promise of substantial and indefinite funding from abroad, with President Museveni's unequivocal national-level political support, and with a district chairman willing to provide the necessary local infrastructure, Uganda Cares' birth pains were far from over. As one of the medics involved at the start explained to me, "*We had a tug of war to start it. Even the Ministry was not supporting us. They said 'the drugs are so expensive, there's no way you can do it free of charge, it's not sustainable'. But we had people who wanted to support us, so we said if we can treat 100 people, why shouldn't we do that? We said we can allocate a building for the work – one of the private wards – and*

*storage space. But the Ministry resisted, and it didn't auger well. It took the intervention of State House before we could get accredited. The Ministry said we didn't have the capacity. So we said, 'who is supposed to provide the capacity? YOU!' Anyway, we had the people to do the work*" [Interview, 6 September 2004]. He was talking about events in 2001 and 2002, but Ministerial resistance had not been entirely diffused even at the time of my field work in late 2004. As a Kampala-based public health doctor told me: "*As things stand now, Uganda Cares hasn't really gone to the core of the Ministry. To Director or Commissioner levels. They think this thing is not feasible, but rather that we have to do it for political reasons*" [Interview, 29 October 2004].

Nonetheless, the top-level political support from President Museveni forced the issue through, and the Uganda Cares clinic was opened in Masaka by First Lady Janet Museveni in February 2002, just five months after Chang's initial announcement at the Entebbe meeting. As Vincent Sempijja told me, "*Global Immunity is really very fast. We have worked with many, but they were really very fast*." Scale-up during the first year was, however, slow, as the team developed their protocols and operating procedures. They were, after all, pioneers in providing free treatment to a general population in Africa, and, furthermore, they were developing a comprehensive ART programme before the country even had an approved national ART policy. The first draft of the 'Antiretroviral Policy for Uganda' was not available until June 2003 (MoH, 2003a), with the first edition of the 'National Antiretroviral Treatment and Care Guidelines for Adults and Children' following in August 2003 (MoH, 2003b). In other words, Uganda Cares was effectively operating within a policy vacuum for nearly 18 months. One of the results of this was that some of their earlier patients started with what eventually became the nationally-designated second-line treatment. Once the guidelines were published, there was debate among Uganda Cares medical staff about whether or not to 'downgrade' these patients back to the new official first-line treatment. In order to reduce the risk of their developing resistant virus, the decision was made to keep them on second-line treatment.

After 12 months, 11 Uganda Cares patients had died – mostly because they started treatment too late – but 100 remained on the books, of whom 80 were adults and 20 were children. Clinical improvements had been remarkable, with average CD4 counts increasing from 51 to 310 after one year of treatment, average weight gains of 11.3 kg over six months, and – critically – average patient adherence levels exceeding 95%, meaning that that the spectre of resistant virus would be held at bay (IPPPH, 2003:30).

Another important aspect of the early period of operations was overcoming resistance from other local service providers. I asked District Chairman Vincent Sempijja how they had tried to work around the doubts expressed by some of their local peers. "*At that time*," he explained, "*people had already done a lot of work – the donors and the NGOs. But what they were doing was counselling, educating the patients on how to live positively with AIDS, and then also treating the opportunistic infections, the fevers and the coughs. And also educating the masses, and looking after the sick by giving them some little food. That is what the NGOs were doing, and they had already gone very far. Now somebody comes and says we need to look at treating. It was different to what was happening. So these people looked at it, they were sceptical about it. And others were looking at it and, to be frank, they were not happy. They were envious. They thought maybe it was going to interfere. Despite what they were doing being very good, it was work, it was employment for them. I think you understand what I'm saying. Somebody coming to treat these people with ARVs is going to cause the other processes to become outdated or even stopped. And if you bring somebody who is going to treat people, he is going to get a lot of recognition.*

"*So that was there, and I saw it. I saw it very early, and Weinstein and Chang saw it also, and they suggested we had to use these NGOs who had been doing all this work, and use them on this one. How do you get the patients? Do you just announce on the radio? No, there are already these bodies who have been working with these patients in these other fields. They know them. Why don't we bring them onto a coordination committee, get those patients from them, get those who have already reached that level for treatment, let them recommend them*? *And we really need to continue with preventive measures, because if you can prevent the deadly disease from entering your body, the better. And we need to continue counselling, and educating the masses how to look after their relatives.*

"*There was a lot of work to be done, but these people had that fear which we really tried to solve by bringing everybody on board, by explaining that these kind of preventive methods are very important, even more than before, so let's work together. So harmony came back, and we used the best method really. We got people without bias, and that is how we succeeded*" [Interview, 1 December 2004].

Thus, at local level, an attempt was made to address this resistance by establishing partnerships with the organisations already working in the field. To this end, all Uganda Cares clients are referred by another local service provider, who has

previously been providing them with medical, psychological and/or nutritional support. Since most patients are therefore being served by more than one provider, co-operation between doctors from the different groups is ongoing with regard to individual patients. I observed this while accompanying a palliative care doctor from Kitovu Mobile Care Unit as she travelled round the district, and several times she spoke of the need to check certain details of individual cases with one of the Uganda Cares doctors. Through this regular contact and co-operation, the doubts that I understood from various sources had existed at the start of Uganda Cares operations were dissipated. Instead, the organisation has become an established and recognised part of the local AIDS service provision community.

With the basic programmatic procedures in place, and the potential clinical success of the project established, Global Immunity increased the funding levels so as to facilitate a scaling-up of activities. As of July 2004, Uganda Cares in Masaka was treating 802 clients; and the numbers continued to grow towards the estimated 8,000 people in the district who, according to the District Director of Health Services, were in immediate need of treatment.

The work of Uganda Cares has therefore born fruit in Masaka, but it has also spawned free ART centres elsewhere in Uganda as well as further afield, thus meeting one of the organisation's stated objectives: "*To develop a replicable and scalable model of HIV/AIDS clinical care appropriate to the safe and effective provision of ARVs in resource-constrained settings*" (IPPPH, 2003). The Minister of Health, Mike Mukula, called Uganda Cares a "*proven initiative*" in September 2003 (New Vision, 2003b) – irrespective of the continuing doubts of some of his Ministerial staff – and personally participated in organising for the second Uganda Cares clinic to be opened in his own home district, Soroti, in November of that year. As one of my respondents explained, "*Captain Mukula said even my people are suffering, so that is why Soroti was second. In the third world, it depends really on personal input. Because we don't have enough, it depends on who is there first, it depends on who really shows interest and hard work*." Subsequently, clinics were also opened in Rakai, Mbale and Mpigi.

Elsewhere in Africa, the Uganda Cares 'Masaka model' has been adopted by clinics in Swaziland, Eritrea, Sudan and South Africa; and while I was conducting field work, a WHO team visited Masaka to provide training on this officially recognised 'best practice' to doctors from Zambia, Kenya, Ethiopia, Tanzania and Zimbabwe.

Meanwhile, Global Immunity itself has branched out into nine other developing countries.

A senior Masaka doctor summarised how Uganda Cares had stimulated a change in thinking at national policy level. "*We were the first in the country to give treatment for free, and for the general community. And now, in 2004, we are there, and WHO has said we are one of the best practices. And I think this is what made the Ministry wake up. This was the start of the movement to provide free ART in the country. If we had agreed with the Ministry, we would not be having free treatment now all over Uganda*" [Interview, 6 September 2004]. This view was endorsed by a public health official in Kampala who said simply, "*Uganda Cares played a very big role – they made the Ministry to run!*" [Interview, 27 October 2004].

***Discussion***

Analysis of the material presented in this chapter shows that while the scale of events with respect to the evolution of antiretroviral therapy policy and practice may have differed between global, national and local levels, there were a number of striking similarities in the essential processes at each level. Three areas are discussed in this concluding section in order to demonstrate these similarities, as well as to highlight some of the particular differences between the levels. The three areas are: (i) the importance of key individuals, or 'Big Men', as engines of change; (ii) research and the use of evidence; and (iii) resistance to ART scale-up and how it was overcome. Through this discussion, the interconnected nature of events, as well as the importance and power of networking within and between levels, is also underscored.

With respect to the first area of similarity, the drive for ART scale-up at each level was driven primarily by the decisions of key individuals in positions of political and financial power. These individuals have been characterised here as Big Men, men in the worlds of politics and finance with both the power and the will to fundamentally change the structures in which they work. As Muraskin (1996) points out, social science often views people as having agency to act within the confines of the social, cultural and economic structures that they live in, but here it was the other way round. By working within powerful 'advocacy coalitions' (Sabatier, 1993) – groups of like-minded people working towards a common policy goal at each of the three levels – elite groups of Big Men collectively and irreversibly changed those structures.

At international level, the Big Men included – among many others, and presented here in no particular order – Dr Hamied, CEO of Cipla pharmaceutical company; Dr Lee Jong-wook, former Director General of WHO; and financial guru Professor Jeffrey Sachs. These men, as well as the other major players at the international level, would all have known *of* each other, but would not necessarily have known each other personally; and certainly they would not all have met together more than a handful of times to discuss global ART scale-up. In this sense, the international advocacy coalition was looser than those at national and local levels, where personal and professional ties among many of the major actors have tended to be closer – if for no other reason than geographical proximity. Nonetheless, the objective that the international Big Men collectively worked towards – mass treatment of people living with AIDS in developing countries – was clear and based on what they saw as an unambiguous humanitarian imperative, and this greatly facilitated their collective cooperation.

At national level in Uganda, the Big Men came from the political rather than the financial sphere, since funding for ART programmes has always been entirely donor driven. Thus Ugandan financiers have not played a significant role. These political actors included President Museveni; Crispus Kiyonga, the former Minister of Health, who facilitated the Drug Access Initiative; and – if politics can be defined as the art of getting people to do what you want them to do – Peter Mugyenyi of the Joint Clinical Research Centre. In Masaka, the key political actors were local – most notably District Chairman Vincent Sempijja – although it should not be forgotten that Uganda Cares would never have flourished without strong national level support, directly from President Museveni. For similar reasons to those given at national level, the most important financial actors at local level – Michael Weinstein and Henry Chang of AHF/Global Immunity – came from the international level.

This illustrates the dependency of national and local level political actors on financial support from the international level. But it should not be forgotten that the international financiers also needed the political support of national and local level politicians in order for them to meet their own objectives. These may all have been Big Men, capable of changing large social and economic structures, but they were all also people who were dependent on other people. International Big Men need local Big Men to cooperate with them if they are to meet their objectives – and vice versa. Even Big Men cannot operate effectively by themselves. Furthermore, their various

breakthrough decisions could not have been made without the supportive ideological context that had been established by the army of activists working in the international AIDS advocacy coalitions.

With respect to the second area of similarity – research and the use of evidence – the first point to note is, perhaps rather obviously, that there would have been no scale-up of ART provision at all if the drugs had not been developed in the first place. ARVs were the product of a major breakthrough in clinical AIDS research, which in this sense was therefore the ultimate prerequisite for any sort of policy or programmatic development at any of the three levels.

The role of research as an actor in the scale-up of ART did not end once the drugs existed and their clinical efficacy had been established. The many people who doubted that large-scale ARV provision was feasible in Africa were countered by a small group of scientists who actively set out to demonstrate that it could be done. To this end, operational studies of small pilot projects – such as the Drug Access Initiative in Uganda (Weidle et al., 2002), the Khayelitsha project in Cape Town (Kasper et al., 2003), and the first year of Uganda Cares operations in Masaka (IPPPH, 2003)[72] – played a critical role in 'proving' the naysayers wrong by demonstrating clinical success among their patients, and thereby providing important evidence for use by advocates and the Big Men.

A four-step process of research can be described, which applies equally at each of the three levels: (i) The researchers involved in the various programmes had a pre-existing ideological position that favoured large-scale ART provision; (ii) They implemented an ART programme, partly for the patients in their clinics but also in order to show to a wider audience that their ideological position was grounded and workable; (iii) The clinical successes that they demonstrated justified the arguments of activists, politicians and financiers who wanted to scale up ART provision; (iv) On this basis, political, financial and logistical support for ART scale-up emerged, facilitating the process to begin. The evidence was therefore produced with an explicit agenda: it was to be presented as an advocacy tool which would provide the justification for action. As such, it contributed significantly not only to legitimising the scale-up of ART programmes, but also to establishing international, national and local level ART policies. With the AIDS treatment landscape fundamentally and

[72] Depending on one's geographical perspective, each of these three pilot projects could be seen as working at either international, national or local level.

permanently changed as a result, it also subsequently changed the nature of AIDS research itself.

Having argued that evidence contributed to bringing about ART scale-up at each of the three levels, however, it would be misleading to suggest that the development of large-scale ART programmes was 'evidence-based'. The pilot studies noted above focused almost exclusively on clinical outcomes for small-scale provision, and there was no substantive basis for arguing that the successes would necessarily be repeated across the board when tens, or even hundreds of thousands of people were being treated. As with much of the HIV prevention work described in Chapter 4, ART scale-up was conducted primarily out of an urgent need to act, rather than on a firm evidence base. The evidence that was used helped to kick-start scale-up, but could not, by its very nature, make any definitive claims about the likely success of large-scale provision.

The third area for discussion concerns resistance to ART scale-up, as well as the process of overcoming it. Resistance was faced at each of the three levels, but the reasons for it differed from one level to the next. Internationally, the loudest complainants tended to be scientists who were concerned about the potential public health ramifications of a scale-up process that lacked a stable foundation. By contrast, the worries at national level in Uganda, and locally in Masaka, were both practical and political. Practically, there was unease about sustainability, the capacity of health systems to deliver such an ambitious programme, as well as the possible effects on other aspects of the health system of having some of the best doctors moving exclusively into ARV provision. Politically, there were turf issues, with some people fearing the loss of power, authority, and financing in other areas of AIDS control in which hitherto they had been important actors.

Overcoming the resistance to scale-up – or, in some cases, pushing it through regardless of the resistance encountered – took a different course at each of the levels. Internationally, it is notable that the doubters tended to be non-African public health scientists and clinicians with significant hands-on experience of health care in Africa[73]. In spite of their important knowledge and experience, however, these

[73] This is not to suggest that all public health scientists opposed rapid ART scale-up – there are many issues in international public health on which there is no collectively agreed view. Indeed, as explained above, it was public health and clinical scientists who provided the evidence from small-scale pilot projects which in many respects justified the arguments of the activists, politicians and financiers pushing for scale-up.

people are not, as a group, powerful decision makers. Those whose very job it is to make decisions, and who pushed ART scale-up through – the Big Men – had, in stark contrast to the public health scientists, lived their professional lives far away from the day-to-day reality of health care provision in Africa. Regardless of this fact, they imposed their will and over-rode the concerns of their worried subordinates. The scientists' long-term public health concerns of what might or might not eventually happen as a result of rapid ART scale-up were far less politically exciting to the Big Men than the tangible and immediate outcome of treating and saving dying patients by the thousand – today.

In Uganda, the government resisted ART scale-up in large part because of concerns about sustainability: What would happen to the tens of thousands of people who would be receiving treatment if funding suddenly dried up? These worries were effectively made redundant by Peter Mugyenyi's illegal importation of cheap generic drugs into the country. This forced the government into a politically uncomfortable corner, from which they had little choice but to authorise the procedure, in spite of its being against the instincts of many senior officials in the Ministry of Health. Mugyenyi's actions demonstrate how the determination of one well-placed individual – either because of, or in spite of breaking the law – can overcome firm resistance and bring about major policy changes at national level.

Locally in Masaka, the field of play was far smaller, and it was possible for the Uganda Cares leadership to act in a more consultative fashion than could be accomplished at either the national or international levels. By bringing other NGO providers in as partners, and by ensuring that the work and livelihoods of those working with these NGOs would not be threatened, Uganda Cares gave them an active stake in the project. Through this, the resistance that had been felt was dissipated, and they have now become important partners in the provision process.