

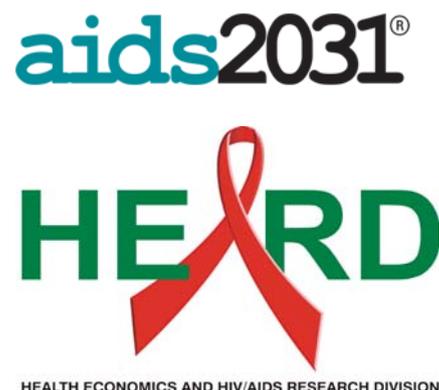
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GOVERNMENT LEADERSHIP AND ARV PROVISION IN DEVELOPING COUNTRIES

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Government Leadership and ARV Provision in Developing Countries

Abstract

Despite unprecedented international mobilisation to support universal provision of highly active antiretroviral therapy (HAART), national governments continue to play the key role in determining access to treatment. Whereas some AIDS-affected countries have performed as well or better than expected given their level of development, institutional characteristics and demographic challenges (e.g. Thailand and Brazil), others (notably South Africa) have not. This paper argues that government leadership affects the 'economics' of antiretroviral (ARV) drug delivery in developing countries in profound ways. Access to HAART for citizens depends crucially on the commitment on the part of their national governments to negotiate with pharmaceutical companies over patented ARV prices, on their policy towards compulsory licensing, and on their commitment to public-health approaches to delivering HAART. Civil society has an important role to play in encouraging governments to become, and remain, committed to taking action to ensure sustainable and widespread access to HAART.

1. International coverage of highly active antiretroviral therapy

The economics of providing highly active antiretroviral treatment (HAART) in developing countries is profoundly shaped by political factors. Most obviously, the key component of costs – drug prices – have been affected by a range of extra-market forces including: pressure from AIDS activists and non-governmental organisations (NGOs) on pharmaceutical companies for reduced prices; popular protest against, and lobbying within, the World Trade Organisation (WTO) for a more flexible approach to protecting intellectual property on essential medicines; successful international and domestic protests against the USA's promotion of the interests of pharmaceutical companies in its trade policy; and international initiatives (notably by the Clinton Foundation) to facilitate bulk discounts on ARVs for poor countries. These interventions, together with the growth of generic pharmaceutical manufacturing capacity in developing countries, facilitated the dramatic reduction in first line (i.e. starting) ARV treatment regimens from about US\$10,000 to US\$350 per patient per year during the early 2000s, to less than \$100 in low-income countries by 2008 (Coriat *et al*, 2003; Lucchini *et al*, 2003; Piot, 2006; Schwardlander *et al*, 2006; Shadlen, 2007; Smith and Siplon, 2006; T'Hoen, 2003, WHO, 2008: 32; MSF, 2008). This sharp fall in prices helped facilitate the global rollout of HAART in developing countries.

By the end of 2007, about 3 million people were estimated to be on HAART, yet less than a third of those needing HAART actually received it and there was wide variation globally in coverage (WHO, 2008). This is a function of practical constraints such as the scale of the HIV epidemic, the distribution of HAART patients between urban and rural areas, country-level economic and institutional capacity to rollout HAART, and the availability of support from external funding sources such as the Global Fund and the US President's Emergency Plan for AIDS Relief (PEPFAR). Cross-country econometric analysis suggests that these factors account for about half of the variation in HAART coverage (Natrass, 2008). The remaining difference can be attributed, in large part, to country-specific policies and characteristics including political will on the part of national governments to roll out HAART. Thailand and Brazil, both well known for their proactive leadership on AIDS, achieve far higher levels of HAART coverage than predicted given their economic, demographic and institutional characteristics – whereas South Africa, which is infamous for its suspicious stance towards ARVs, has a far lower HAART coverage than it should, given its characteristics (*ibid*).

This paper outlines the economic dimensions of delivering HAART in developing countries, showing how national policy is relevant at every point. Particular attention is paid to the contrasting experiences of Brazil and South Africa – two middle-income countries at similar levels of development that adopted very different approaches to rolling out HAART.

2. Direct costs of a HAART rollout

The key component of the cost of a HAART rollout is the price of ARVs, especially those protected by patents. Early efforts by Brazil and Thailand to provide ARVs (mainly AZT) to AIDS-sick people collapsed in the face of high prices and macroeconomic collapse (Brazil in the early 1990s and Thailand after the Asia crisis of 1997). Indeed, the World Bank castigated both countries for even attempting such costly programs (Mauchline, 2008). This concentrated the minds of governments in both countries, and both started to produce generic versions of AZT shortly afterwards (Brazil in 1993 and Thailand in 1997) – neither with the permission of the patent holder.

As the capacity to produce generic ARVs grew (especially in India) multinational pharmaceutical companies responded by offering discounts on their branded products and negotiating voluntary licenses with governments and producers in developing countries (MSF, 2008: 5-6). This process was assisted by international efforts, such as the Drug Access Initiative and the Clinton Foundation, to negotiate bulk ARV orders for developing countries. This, together with a natural desire on the part of pharmaceutical companies to maximise profits through price discrimination, resulted in a highly segregated global market for ARV in which low prices are offered to ‘category 1’ countries (usually low-income and African countries)¹ and higher, but still discounted, prices to ‘category 2 (middle-income) countries (MSF, 2008: 71-6).²

The effect of this price discrimination is most noticeable for the newer drugs. In 2006, the WHO recommended that countries move away from the conventional Stavudine (d4T) based first line regimens to AZT- or Tenofovir-based regimens. This doubled the generic price for first line treatment from \$87 per patient per year to \$153 (for AZT-based regimens) and \$426 (for Tenofovir-based regimens). For those wanting to buy the branded ARVs, the price increase was

¹ Bristol Myers Squibb, however, excludes Southern African countries from its category one.

² Not all companies do this. For example, Roche insists on a one price policy for its fusion inhibitor Enfuvirtide, which at a price of \$25,000 per patient per year, puts this salvage therapy out of reach of almost all people in developing countries (MSF, 2008: 7-8).

much higher with the Tenofovir-based regimen costing \$613 for category 1 countries and to \$1,033 for category 2 countries (MSF, 2008: 10). Most 2nd line drug regimens (i.e. for patients who fail on their first line regimes) have fewer generic equivalents, and so their prices are also substantially above the older first line regimens (WHO, 2008: 32) – see also Figure 3. As more people move onto second line therapies average ARV treatment program costs rise sharply. Evidence from Brazil and South Africa indicates that between 20% and 25% of ARV patients need to be on (significantly more costly) second line regimens after five years of ARV therapy (Leisegang, 2008; Simão, 2008; MSF, 2008: 9).

Unsurprisingly, some middle-income countries (notably Brazil and Thailand) are resisting their category 2 classifications by pharmaceutical companies and are instead engaging aggressively in price bargaining, and increasingly, in breaking patents.

Pharmaceutical patents are controversial because the resulting high prices incentivise firms to invest in the research and development of new drugs, yet can put essential medicines out of reach of millions of poor people (Resnik, 2005; Shuklenk and Ashcroft, 2005; Simão, 2008). Those developing countries with the domestic capacity to ‘reverse-engineer’ patented drugs (notably Brazil and India) were initially able to side-step patent protection by simply not offering patents and allowing domestic firms to produce generic copies. However, with the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), all but the very poorest countries were required, by 2005, to offer patent protection on new drugs if they wanted to retain membership of the WTO (although the very poorest – with the exception of India – were given until 2016 to enforce the patents). Brazil became TRIPS compliant in 1997 and India in 2005 (although both included provisions in their intellectual property regimes that allowed for the issuing of compulsory licenses). Drug companies immediately started patenting ARVs in these countries.³

Partly in recognition of the potentially serious humanitarian costs of strict protection of intellectual property rights, substantial flexibility was built into TRIPS – and this has become greater over time. Following protests by treatment activists and widespread pressure from the international community, the WTO’s 2001 Doha Declaration clarified that TRIPS will not stand in the way of ensuring access to medicines for all (T’Hoen, 2003). This means that if countries include public health provisions in their patent laws (e.g. they regard high prices of essential medicines as a violation of public interest and a form of patent abuse) then they are permitted to issue ‘compulsory licenses’ to domestic firms

³ Three of the newer drugs – Etravirine (an NNRTI), Maraviroc (an entry inhibitor) and Raltegravir (an integrase inhibitor) – have already been patented in India (MSF, 2008: 8).

to produce or import generic equivalents – with or without the agreement of patent holders. India’s intellectual property regime makes full use of TRIPS-related flexibilities, has clear rules for compulsory licensing and holds patent applications to a high standard regarding innovation by requiring that only those demonstrating a major ‘inventive step’ be granted a patent (Ram, 2006: 198). Brazil also makes use of TRIPS flexibilities and includes a provision (which the US objected to unsuccessfully) that compulsory licenses could be offered on patented drugs which were imported into the country rather than produced in Brazil. Like India, Brazil requires that patents only be awarded for truly innovative products. This has been used aggressively – for example, in September 2008 Brazil rejected a patent application by Gilead for Tenofovir on the grounds that the active ingredient had been known since the mid 1980s. This demonstrates that the new global intellectual property regime need not necessarily undermine access to ARVs – however, what it has done is required committed and sustained action on the part of governments to ensure this.

Brazil and Thailand have both used the threat of issuing compulsory licenses to extract significant price reductions from the large pharmaceutical companies (notably Roche, Abbott and Merck) (Shadlen, 2007; Ford *et al*, 2007; Levi and Vitória, 2002). The space for pharmaceutical companies to engage in tiered pricing systems appears to be narrowing as a consequence. In 2006 Abbott was prepared to reduce the price of Lopinavir/ritonavir (Kaletra) to US\$500 per patient per year for poor African countries – but was only prepared to offer it to the Thai government for US\$2,967. After protests from activists, it reduced the price for middle-income countries to US\$2,000. However, as it only cost US\$400 to manufacture, the Thai government went ahead with its plans to offer a compulsory license. Although this was acceptable in terms of the TRIPS agreement, it nevertheless came at a cost because Abbott retaliated with an aggressive lobbying campaign and by refusing to make new drugs available to Thailand during the life of the compulsory license (T’Hoen, 2008; Ford *et al*, 2007).

In 2007, Merck was also forced to reduce ARV prices in Thailand (for Efavirenz to US\$244 per patient per year) after the government offered a compulsory license to import a generic equivalent from India. When Merck refused to offer Brazil a price lower than US\$580, the Brazilian government also issued a compulsory license (for the first time ever) and started importing Efavirenz from India (from a company which pays royalties to Merck) whilst building up domestic capacity to produce it in the future (*ibid*). Brazil reduced its costs by \$30 million as a result, and the proportion of the Brazilian Health Budget allocated to Efavirenz fell from 12% to 4% (Simão, 2008). Note, however, that Brazil chose not to go down the Thai government’s route of offering a

compulsory license for Kaletra – but instead came to an agreement with Abbott – an agreement which was considered prejudicial to Brazil’s interests by Brazilian activists, who subsequently launched a lawsuit against both Abbott and the Brazilian government (Costa-Chavez *et al*, 2008).

The option of importing (rather than producing) generic equivalents is important because most developing countries lack the necessary capacity to produce ARVs domestically, and in most cases it probably does not make sense to divert resources into developing a domestic pharmaceutical industry (Kaplan and Laing, 2005). TRIPS originally required that goods produced in one country under a compulsory license be predominantly for domestic use (Article 31.f), but in 2003, the WTO agreed to a partial waiver, which was formalised as an amendment to TRIPS in 2005. Although some bureaucratic procedures are required (for example, Indian exporters have to obtain permission from the Controller General of Patents) it is now far easier for countries to export pharmaceutical products made under compulsory license (Ram, 2006). This has helped poorer countries access a steady supply of generic ARVs without having to produce them themselves. Indeed, Indian generic manufacturers have made the international rollout of treatment possible: 80% of the ARVs purchased by MSF come from India (as do 70% of those purchased by UNICEF, IDA, the Global Fund and the Clinton Foundation); 91% of the generic ARVs approved by the US Food and Drug Administration for PEPFAR are from India, and the adoption of Indian generics by PEPFAR resulted in cost-savings of up to 90% (T’Hoen, 2008). However, there is concern that as more international pharmaceutical companies register patents in India (a trend made possible after India became TRIPS compliant in 2005) that the role that India plays as the central backbone of the supply of affordable ARVs may increasingly come under threat. Whether this happens depends on how successful India is in limiting the issuing of patents to those demonstrating genuine ‘innovative steps’; on pressure from domestic and international activists on pharmaceutical companies; and on international initiatives to ensure the sustainable supply of new ARVs.

It is important to note that what makes sense for individual countries – i.e. to issue compulsory licenses for the production or import of generic drugs – may undermine the global supply of new ARVs in the longer term. It is alarming that Roche announced, in July 2008, that it would no longer be researching and developing new AIDS drugs. The official reason was that it doubted its capacity to improve on existing drugs. However, the fact that it is becoming difficult for pharmaceutical firms to earn super profits on ARVs no doubt made this strategic decision easier. Greater attention needs to be paid at international level to find mechanisms (such as subsidies and tax-breaks) to incentivise pharmaceutical

companies to continue to invest in new ARVs to combat the ever-present problem of evolving drug resistance. Importantly, the WHO resolved (at its 61st World Health Assembly in May 2008), to work with the WTO as part of its 'global strategy and plan of action on public health, innovation and intellectual property', to secure an 'enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries'.⁴ The new global strategy seeks to support both R&D capacity in developing country (including technological transfer) to harness existing R&D capacity and to promote co-operation between public and private sectors on research and development.

Returning to the national perspective, Figure 1 summarises the many points at which governments can help achieve a sustainable rollout of HAART. Firstly, as noted above, they need to amend their patent laws to include public health provisions in order to be able to issue compulsory licences for domestic production or import. Thus, when Brazil became TRIPS compliant, it passed the Industrial Property Law of 1996 allowing explicitly for the compulsory licensing of ARVs. South Africa made similar changes when the Mandela administration passed the 1997 Medicines and Related Substances Control Amendment Act. Both Brazil and South Africa were subject to (and successfully resisted) significant pressure from USA trade representatives as a result (T'Hoën, 2003).

Secondly, national governments have to make use of the existing legal framework. In this regard, the contrasting experience of Brazil and South Africa is instructive. Between 1999 and 2004, Brazil reduced the average annual per patient cost of HAART from US\$4,350 to US\$1,517 by producing generic copies and bargaining price reductions from pharmaceutical companies (Ford *et al.*, 2007). South Africa under President Thabo Mbeki, however, failed to issue, or even threaten to issue, compulsory licenses for ARVs. Despite having successfully resisted a legal challenge by the Pharmaceutical Manufacturers Association (PMA) over compulsory licensing, the South African government made no moves to support the production or import of generic ARVs. Indeed, it has been argued that the PMA was prepared to drop its court case because by 2001 it had become clear that the Mbeki administration was not interested in issuing compulsory licences for the domestic production of ARVs (Cleary and Ross, 2002). Affordable ARVs have been provided in South Africa mainly because most drug companies classify South Africa as category 1 (simply because it is an African country), because Indian generics have been imported by NGOs such as MSF, because donor funded projects (through the Global Fund and UNICEF) have benefitted from price reductions through the Clinton

⁴ The resolution is available on: http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf

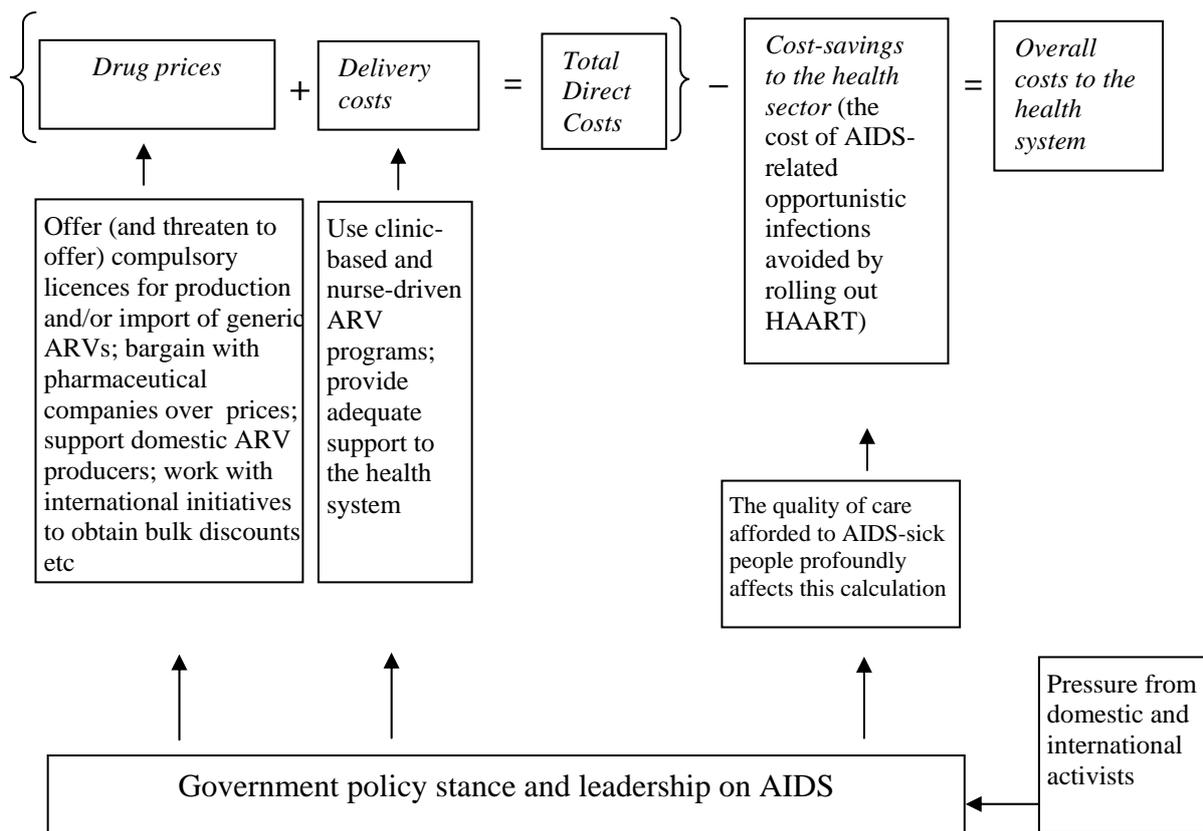


Figure 1: Government influence on Direct and Overall Costs of Rolling out HAART

Foundation, and because activists in the Treatment Action Campaign have shamed pharmaceutical companies into lowering their prices and/or offering voluntary licenses to the emerging generic manufacturing sector.

The threat to issue a compulsory license is more credible (and hence becomes a stronger bargaining tool) the greater a country's capacity to produce its own generics. The third way that national governments may assist in ensuring a sustainable supply of ARVs is thus to develop a local pharmaceutical industry. This involves mobilising other instruments of economic policy such as tariffs, subsidies, tax breaks for research and development, assistance for employee training etc. Brazil, in particular, is known for its strong support for publicly owned laboratories which carry the cost of most of the research and development and reverse-engineering work needed for the production of generic drugs subsequently done by private sector firms (Cassier and Correa, 2003; Kaplan and Laing, 2005). Between 1997 and 2002, the output of the Ministry of Health's centralised laboratory, *Far Manguinhos*, rose seven-fold – largely as a result of the government's determination to enhance the supply of generic ARVs (Cassier and Carrea, 2003).

Although South Africa also has a domestic pharmaceutical industry, no such assistance has ever been provided to producers of generic ARVs. Instead, this industry has been harmed by the long delays involved in negotiating voluntary licenses and obtaining the necessary approval from the Medicines Control Council for generic formulations (Kaplan and Laing, 2005). Rather than assist generic producers, the government awarded tenders to the producers of branded drugs, and placed restrictions on the generic producers (such as limiting the co-packaging of pills). It was only as a consequence of pressure from activists that Merck extended favourable voluntary licences for the import and production of Efavirenz in South Africa.

As shown in Figure 1, governments also have a major impact on the other key component of direct costs, i.e. delivery costs. This includes ensuring that the necessary laboratory capacity exists to conduct CD4 tests. The Brazilian and Thai governments made this a priority, whereas the South African government did not. It is also important for the governments to ensure that there is a sufficient supply of the necessary trained health personnel, and that the design of the public sector rollout is appropriate. Experience from ‘resource-constrained’ environments (i.e. either in poor countries or in poor parts of middle-income countries) indicates that the cost of delivering HAART can be reduced substantially by adopting a relatively simple protocol-based public-health approach that can be rolled out by nurses in clinics (WHO, 2003, 2006; Farmer, 2001; WHO, 2008a: 104; Smart, 2008a) and even by community- and home-based carers (Mermin *et al.*, 2008). Virologic outcomes from pilot programs in South Africa have been shown to match those in Switzerland, thereby demonstrating the efficacy of such low-cost public health approaches (Keiser *et al.*, 2008). The World Health Organisation now explicitly promotes ‘task-shifting’ (from doctors to nurses and from nurses to community workers) as an efficient and effective means of expanding the available human resources for public health (WHO, 2008b). Malawi and Ethiopia have demonstrated how donor funds can be mobilised to promote task-shifting and to address human resource constraints (Smart, 2008b). However, the South African government continues to prioritise doctor-driven, hospital-based ARV rollout sites and a shortage of nurses continues to plague attempts to provide HAART through clinics. Even after MSF had demonstrated that a nurse-driven program could work in a deep rural area, the South African government through a spanner into the works by enforcing a rule that nurses could not prescribe drugs (including ARVs) (Steinberg, 2007: 273).

The total direct costs for a HAART rollout will be higher for countries with greater numbers of patients. Thus, one (socially harmful) way for governments to minimise costs would be simply to fail to provide the necessary services

promptly or efficiently. Again, the contrasting experience of Brazil and South Africa is instructive: whereas the Brazilian government declared its commitment to providing universal and free access to HAART as early as 1996 (Ford *et al*, 2007); it took sustained and concerted action on the part of civil society to force the South African government to change its policy stance in 2003 and begin a (reluctant and slow) HAART rollout from 2004 (Nattrass, 2007a). The South African Health Minister undermined the rollout further by delaying the ARV tender (and then awarding the bulk to producers of branded products), by interfering with attempts by provincial governments to obtain grants from the Global Fund and by sowing confusion within the population about the safety of ARVs whilst promoting untested traditional and nutritional alternative treatments (*ibid*). In so doing, both the supply of HAART services and the demand for them was artificially constrained by government.

The bizarre approach to ARVs by the South African government has been attributed to AIDS denialism at the highest levels (*ibid*), but some have argued that the government was deliberately trying to save money for other development purposes (e.g. Butler, 2005). Given that a HAART rollout (reaching 80% of those who need it) was estimated to require about 12% of the health budget (Cleary *et al*, 2007), it is possible that government simply considered this too high a price to pay in terms of other development priorities forgone. If so, then this conclusion was erroneous because such direct cost calculations do not take into account the cost-savings that occur elsewhere in the health sector as a consequence of HAART-related declines in the number of AIDS cases. This is subsequently discussed in more detail.

3. Overall costs of a HAART rollout

By restoring AIDS-sick people to health, HAART can help reduce costs incurred in those parts of the health sector involved in treating AIDS-related opportunistic infections. However, this effect may erode over time as HAART patients become resistant to their treatment and, if new treatment regimens are not available, will sicken and die. Whether a HAART rollout is cost-effective over the longer-term depends crucially on whether it helps reduce the number of new HIV infections (and thereby the number of future AIDS cases) or not.

A HAART rollout has the potential to reduce the number of new HIV infections because people are less infectious when they have their viral loads suppressed by HAART, and because the availability of treatment encourages more people to be tested and counselled (Graham *et al*, 2007; Montaner *et al*, 2006). Such preventative benefits, of course, are contingent on there not being an increase in

the frequency of sexual risk behaviour, either among HAART patients or in the general population, as a consequence of the availability of treatment. Although there is some concern about potential HAART-related ‘disinhibition’, the existing cohort studies of HIV-positive people of all sexual orientations have found no significant increase in reported risky sexual behaviour. With regard to people on HAART, the available studies suggest that they are, regardless of ethnicity, socio-economic status and sexual orientation, significantly less likely than those not receiving HAART to engage in unprotected sex (Crepaz *et al*, 2006; Kaida, *et al*, 2008; Kennedy *et al*, 2007). The WHO thus concludes that providing HAART is a form of prevention (2008: 26).

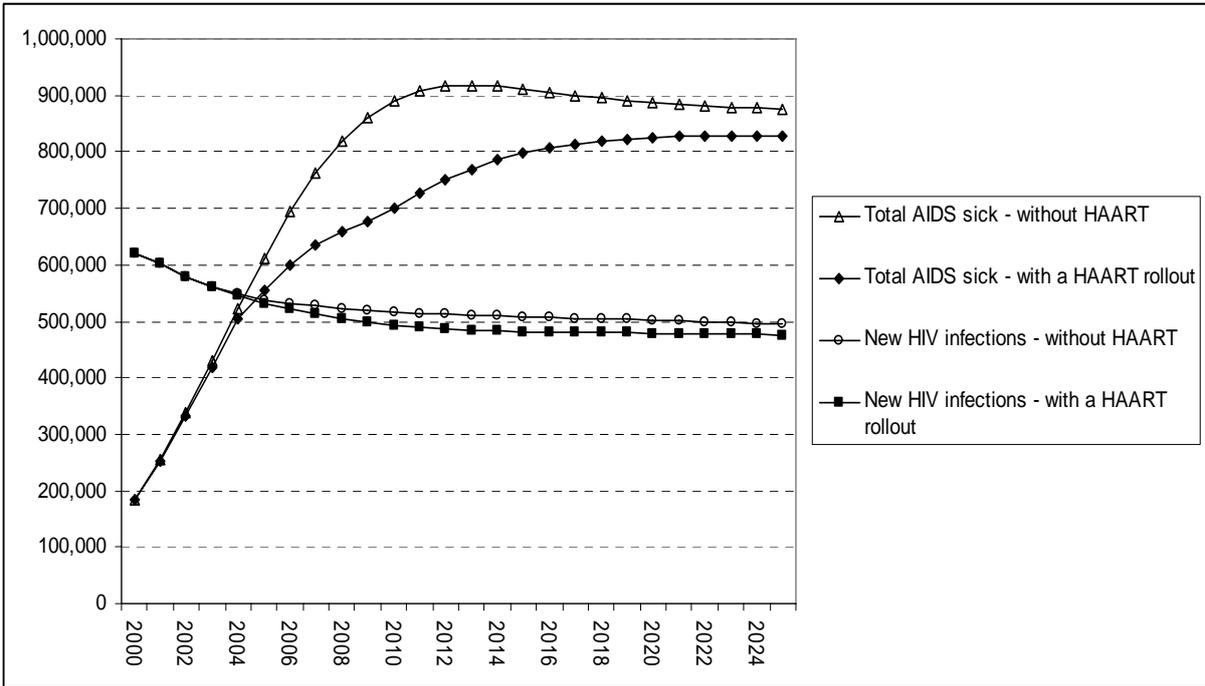


Figure 2: Projections of AIDS cases and New HIV Infections in South Africa with and without a HAART Rollout (projections made using the ASSA 2003 model – available on www.assa.org.za).

In short, the balance of evidence suggests that putting people on HAART will not only extend their lives, but will probably also result in fewer new HIV infections overall. Indeed, using behavioural and clinical parameters drawn from existing studies, this is precisely what the demographic model of the South African Actuarial Society predicts will be the result of a HAART rollout in South Africa (although the effect is relatively small) (Nattrass, 2007b). As can be seen in Figure 2, a gradual HAART rollout, rising to 50% coverage by 2009 and remaining at that level, is predicted to result in fewer AIDS cases and fewer new HIV infections than a ‘no HAART’ scenario. Note that the difference in the

number of AIDS cases between the two scenarios narrows over time. This is because the model assumes (pessimistically) that a public sector HAART rollout will only be able to offer two treatment regimens. This means that once a patient has become resistant to the second available treatment regimen, it is assumed that no further HAART will be provided, and hence the patient will sicken and die of AIDS. Ultimately, the difference in AIDS cases is sustained over time in the model mainly because fewer new HIV infections take place when HAART is available.

Fewer AIDS cases will, of course, take pressure off the government health budget. As summarised in Figure 1, overall costs of a HAART rollout should be calculated as total direct costs over the planning period minus the cost-savings to the health sector. Including the cost savings caused by fewer AIDS cases can have a dramatic impact on the economic calculation – especially when these are so great that they exceed the direct costs of a HAART program, thereby rendering it cost-saving for governments to roll out HAART. This was argued to be the case in Brazil by 2001 when analysts reported that ‘the expense of full and free ART has been counterbalanced by the savings realised in overall AIDS care costs’ (Levi and Vitória, 2002: 2381). Results from pilot projects (Badri et al, 2006) and demographic and economic modelling (Nattrass and Geffen, 2005) suggest that this would also be the case in South Africa if HAART was made available to all who needed it. However, for this to be sustained over time, it is important that ongoing efforts are made with regard to HIV prevention.

4. Concluding remarks and future directions

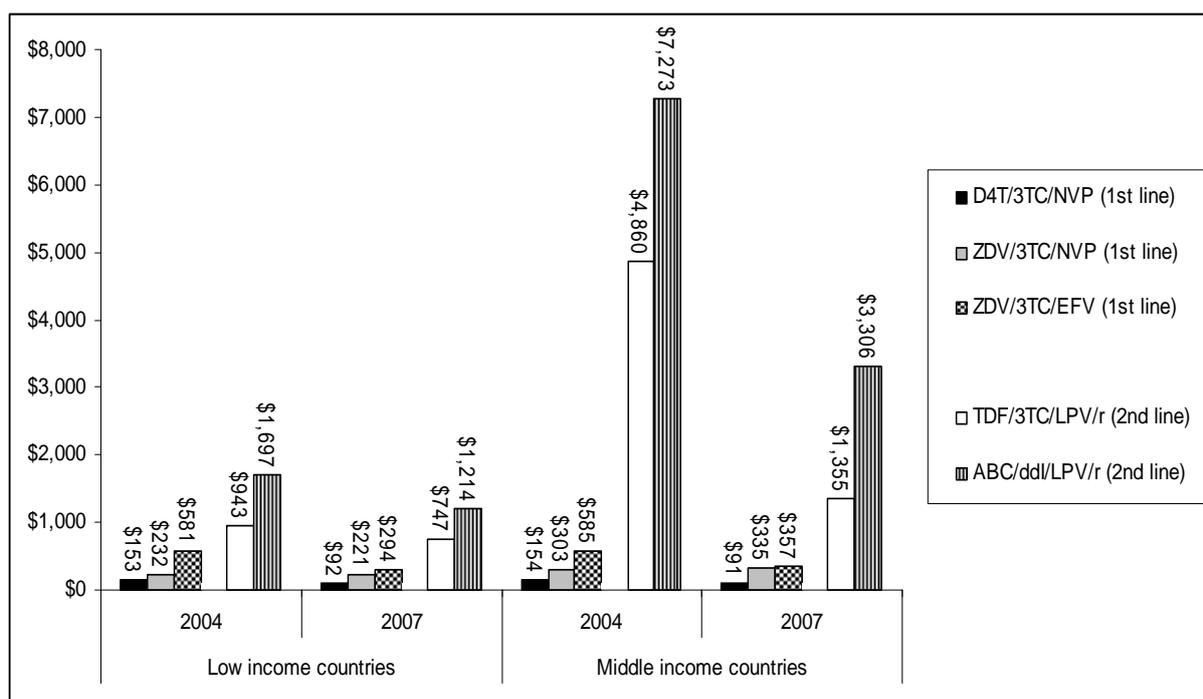
The unprecedented mobilisation of international resources through the Global Fund and PEPFAR together with ongoing pressure from the international treatment access movement has been a crucial mainstay of the global HAART rollout (Smith and Siplon, 2006). This has prompted some analysts to argue that a new form of ‘therapeutic citizenship’ has arisen in which people in AIDS-affected poor countries are able to make political claims on the trans-national global community to obtain treatment for the ill (Nguyen 2005; Ong, 2005; Nguyen *et al*, 2007). However, there are clear limitations to this emerging form of global citizenship. As shown in this paper, national governments play a profound mediating role in shaping the supply, demand and feasibility of a HAART rollout for the national citizens within their borders.

National governments are also important in shaping global discourses on ARV prices and in shaping the emerging moral economy of treatment. The health related TRIPS flexibilities that were introduced by the WTO were made possible

by the mobilisation of global opinion in support of the demand that intellectual property rights should not stand in the way of access to essential medicines. Activists were important players in shaping this emerging consensus – but the role played by national governments in driving the agenda forward was crucial. Brazil, in particular, is masterful at mobilising public opinion by standing up to the USA and shaping what is seen as acceptable. Having fought successfully for the right to issue compulsory licenses, Brazil is now attempting to influence the moral consensus that has guided negotiations through initiatives like the Clinton Foundation to offer the lowest ARV prices to low-income developing countries. At the 2008 International AIDS conference, a speaker from the Brazilian Ministry of Health challenged the prevailing view that low-income and high HIV prevalence should be the only grounds for discounted ARVs (Simão, 2008) – but that actual numbers on treatment should also matter. Interestingly, she argued that access to ‘fair’ prices requires broad support for country initiatives. She highlighted the ‘partners’ which Brazil has had in the struggle – MSF, the Clinton Foundation, and more recently the WHO (following its adoption of the ‘Global Strategy on Innovation for Public Health and Intellectual Property’ which commits the organisation to assisting on a range of levels to ensuring sustainable access to affordable medicines – including assisting developing countries build their own research capacity, and assisting countries make use of TRIPS flexibilities.

This emerging ‘coalition’ among national governments like Brazil, NGO’s like MSF, and international organisations like the WHO and UNAIDS in support of affordable ARV treatment is important strategically and ideologically. It sends a signal to trade negotiators, the WTO, and pharmaceutical companies that standard justifications for patent protection (that it is need to compensate for R&D costs) no longer have moral purchase when it comes to essential medicines and that new incentive structures, public-private partnerships and coordinated bargaining with pharmaceutical companies will increasingly structure the supply and demand for ARVs.

But this will by no means guarantee lower prices. Prices have come down, but second line treatment regimens are still much more expensive than first line regimens, and first line regimens without D4T (which is widely disliked for its side-effects) are much more expensive than with D4T (see Figure 3). As T’Hoen (from MSF) puts it, the situation is still one of ‘drug-by-drug, country-by-country’ ‘hand-to-hand combat’ in order to ensure a sustainable supply of effective ARVs to developing countries.



Source: Data from the Global Price Reporting Mechanism on Antiretroviral Medicines (as reported in <http://www.who.int/hiv/amds/GPRMFeb2008.pdf>). 3TC = Lamivudine; NVP = Nevirapine; TDF = Tenofovir; D4T = Stavudine; ABC = Abacavir; LPV/r = Lopinavir/Ritonavir (Kaletra); ddI = Didanosine; ZDV = Zidovudine (AZT)

Figure 3: Median First and Second Line Regimen Prices (per person per year) in Low and Middle-Income Countries (2004-2007).

Political leadership is key. But while individual leaders may demonstrate different aptitudes and commitment, ultimately they all respond to political incentives: the greater the pressure from civil society, NGOs and activists, the more likely it is that leaders will prioritise a HAART rollout. The important role of treatment activists in South Africa is widely recognised – yet even in the Brazilian case, it was civil society (using skills and tactics from the pro-democracy movement), which prompted government to take action against AIDS (Ford, *et al*, 2007; Levi and Vitória, 2006; Nattrass, 2007a; Beyrere *et al*, 2005). The innovative and synergistic relationship between civil society activists and progressive government officials that arose initially in Sao Paulo in the early 1980s eventually became a model for state and then national policy. Even so, civil society kept a vigilant eye on government, stepping in when they deemed necessary to strengthen the government’s arm (and spine) in its dealing with the WTO and pharmaceutical companies.

Civil society organisations in Brazil are continuing to hold government to account and to pressure officials into taking more aggressive action against

patent holders. This is evident in the legal action against the government over failing to issue a compulsory license for Kaletra (Costa Chavez *et al*, 2008) and in attempts to challenge the constitutionality of Brazilian Patent law – which they see has going beyond the requirements of TRIPS (Raxach *et al*, 2008)). Similarly, it was pressure from Thai activists in 2001 that resulted in ARVs becoming included in universal health coverage (Punpanich *et al*, 2004). Even though the Brazilian and Thai governments are clearly more proactive with regard to ensuring widespread access to HAART than South Africa, activists in both countries keep a vigilant eye on the government to prevent any possible back-sliding. Thus Brazilian activists engaged in street protests in 1999 and 2000 when fiscal constraints threatened the continued provision of ARVs (Oliveira-Cruz *et al*, 2004), and civil society groups in Thailand were quick to support the government when it came under fire from the United States and pharmaceutical companies for issuing compulsory licences (Shadlen *et al*, 2007; Tantivess and Walt, 2006). In India, the Lawyers Collective is very active in opposing applications by pharmaceutical companies for patents (T’Hoen, 2008).

South Africa’s new HIV/AIDS Strategic Plan commits the government to achieving 80% HAART coverage (DOH, 2007). If this is achieved, by 2010 over a million people will be on HAART in South Africa. However, the challenges of reaching this goal are many and continued civil society pressure is going to be needed to hold the government to this goal.

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