Conference report

Financing continued scale-up in HIV treatment: more money for years gained and more years gained for the money

Tuesday 22 – Thursday 24 February 2011 | WP1091
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Summary

The conference brought together a group of influential individuals from across the world, with high level and diverse expertise – including government ministries, civil society and the faith-based sector, industry and the corporate sector, multilateral and bilateral funding agencies and academia. The group addressed one of the most critical challenges facing the global community – how can the tremendous success in gaining access to life saving antiretroviral therapy (ART) for over five million people in developing countries be maintained and expanded? How can more international and – especially – domestic resources be mobilised? And what are the best ways to secure better value for money by improving the efficiency and quality of services, for the people who most need them?

Participants noted the unprecedented high levels of external funding for AIDS treatment, and called on governments and other stakeholders in low and middle income countries to continue to strive for greater self-reliance in their national AIDS response, and use external resources to support a transition away from external dependence. Some countries have achieved remarkable results, and others are exploring how best to achieve this. More emphasis is needed on sustainable financing models and mechanisms, embedded in legislation (through the general budget, social health insurance, special funds and taxes, corporate contributions, and individual payments from those who can afford it).

At the same time, external funding should continue, not least in the interests of global solidarity. However, funders need to make greater efforts to support and leverage national financing, to focus explicitly on funding only evidence-based programmes, and to support countries in driving programme efficiencies and quality, and ensuring that the most vulnerable and affected groups are inclusively engaged and have access to prevention, treatment, care and support services.

There were calls for action to do more, and do it better, and for achieving greater quality and efficiencies in programmes. These included developing new, effective and simpler technologies for diagnosis, treatment and monitoring; further accelerating affordable access through collaborative partnerships and competition; and speeding up quality assurance, regulatory and licensing processes. With regards to programming, priority areas included: taking service delivery closer to, and involving, communities; scaling up integrated disease management approaches for HIV, TB, other chronic infections and non communicable diseases, including reproductive, maternal, neonatal and child health; promoting use of standard treatment guidelines and regimens in national policy; encouraging greater take-up of HIV counselling and testing and earlier initiation of treatment; and investing further in ‘treatment as prevention’ approaches, and scaling up as appropriate. Last but by no means least, effective prevention, especially for key risk populations, continues to be essential.
Setting the scene: celebrating success….

1. Over the last 10 years, the global community has worked a near miracle in enabling people with HIV/AIDS in developing countries to gain access to life saving antiretroviral therapy (ART). In 2000, very few people in low or middle income countries were receiving treatment. At the start of 2011, over five million people were on therapy. UNAIDS reports that by 2009, eight low and middle-countries had achieved universal access to ART (over 80% of people in need according to current treatment thresholds), and 21 additional developing countries had coverage rates of over 50%.

2. The conference emphasised the tremendous achievement represented by this scale-up in access which was made possible through the combined efforts of diverse stakeholders: civil society and people living with HIV/AIDS, national and donor partner governments, private companies, the pharmaceutical industry, faith-based organisations, academia and many others.

3. Unprecedented levels of domestic and international resources have been mobilised, with major financers playing key roles in funding treatment programmes, including the international public private partnership of The Global Fund to fight AIDS, TB and Malaria (Global Fund), the United States Government’s PEPFAR¹ programme and UNITAID². Through the pharmaceutical sector’s investment in innovation, and through generic competition and collaborative partnerships, the cost of first-line antiretroviral therapy has fallen from several thousand US dollars to under US $200 per person per year. Accessible and affordable service delivery models are evolving in partnership with people infected and affected by HIV, and civil society. These are promoting the take-up of testing and early treatment and supporting high rates of adherence to treatment regimens. Over 30 countries have seen declines in overall HIV prevalence.

…and recognising the challenge

4. Participants also recognised the enormous challenges in maintaining and increasing scale-up in access to treatment, calling for national efforts to be further be stepped up in tandem with international mobilisation. The need for treatment is especially acute for millions of people in high-burden low-income countries, especially in sub-Saharan Africa, and in all countries, for members of marginalised groups affected by HIV/AIDS who are at risk of stigma and discrimination, such as men who have sex with men, injecting drug users, sex workers and migrants.

- In the absence of a major breakthrough such as a vaccine or a cure, overall resource needs for HIV/AIDS in low and middle-income countries are projected to increase from the US $13.7 billion spent in 2008 to US $18.5 - $35.5 billion per year by 2031. The resource gap between what is needed and what is available is widening rapidly.

- The need for treatment is growing. Today, nearly half (14.6 million) out of over 33 million people living with HIV need to be on ART. Updated World Health Organisation (WHO) guidelines for initiating treatment at higher CD4 cell levels (from CD4 200 to CD4 350) mean many more people are eligible for ART, but only one-third of those eligible are receiving treatment.

- While there has been progress, scaling up effective prevention interventions remains disappointing, with nearly three million people newly infected each year. The number of new infections is still more than twice the number of people newly placed on ART each year.

- There are signs that contributions to treatment financing through The Global Fund and PEPFAR may be levelling off, in part because of the global financial crisis and its effects on donor governments, foundations and other funders, and also because of other priorities such as climate change mitigation and food security.

¹ PEPFAR is the US President's Emergency Plan for AIDS Relief (www.pepfar.gov)
² UNITAID provides innovative funding for health by scaling up access to treatment for HIV/AIDS, TB and Malaria (www.unitaid.eu)
5. Many felt that further efforts to improve access are in great jeopardy because demand is escalating, and with this, overall costs. At the same time, the dramatic increase in international financing seen over recent years is unlikely to be maintained, in part due to the global financial crisis and also to the rise of other priorities such as food security and climate change. Indeed, global HIV financing fell for the first time in 2009. It is of great concern that over 60% of HIV/AIDS treatment is funded solely by the US government through PEPFAR and The Global Fund.

6. The conference also emphasised that pressure on resources can also bring significant opportunities for national and global stakeholders to accelerate progress. Constrained resources can create positive incentives for programmes to demonstrate better results, to be more accountable and transparent, and to be as effective and efficient as possible; spending money on the right things, and doing them right. The international AIDS treatment movement has amply demonstrated over the last ten years in the developing world, and for two decades before that in the United States and Europe, that success breeds success. Such efforts must now be redoubled.

7. Participants called for a robust and collective response to the dual challenges of growing demand and resource needs:

a) building on success and developing new approaches to mobilising and leveraging resources, both nationally and internationally, and across all sectors, public, private and civil society; and

b) doing more, and doing better in deploying these funds effectively and efficiently, for example in ensuring rapid access in countries to high-quality new medicines and diagnostics at affordable prices, improving decentralised service delivery models that reach and involve people in their communities; integrating services for treatment of all chronic infections; maximising use of innovations in prevention and treatment; and ensuring prevention is based on ‘know your epidemic’ strategies, by prioritising people most at risk.

**Challenge 1: more money for years gained**

**Maximising international resources**

8. There is a need for continued advocacy and innovative thinking to increase international financing for HIV/AIDS treatment. This reflects strong commitments to global solidarity and a collective concern for humanity – recognising that every person, irrespective of who they are and where they live, has a right to health. Increasingly HIV/AIDS funding is not just addressing the AIDS epidemic, but it is also making synergistic contributions to Millennium Development Goals (MDGs) 3, 4 and 5 which focus on gender equality, reproductive, maternal, neonatal and child health.

9. Participants also emphasised the business case for AIDS treatment, urging the development of better data and communications to build greater awareness of the high costs associated with not providing treatment.

10. Failure to increase coverage is affecting the productivity of national economies, of government and private enterprise, and the health and livelihoods of communities, households and individuals. Recent data from South Africa found the HIV epidemic responsible for an annual 0.4% loss in GDP. The evidence base for returns on investments, in terms of both impact on lives saved and value for money, needs to be robust and easy to communicate to politicians and tax payers.

11. Internationally, efforts must continue to: replenish The Global Fund; to maintain and increase other multilateral, bilateral, philanthropic and private sector support; and to expand sources of financing through innovative taxation and other mechanisms (see Box 1). At the same time, funding agencies are seeking to maximise value for money, through improving programme efficiency and effectiveness.

12. The conference welcomed The Global Fund’s new major reform agenda, which will improve risk management at country level and streamline operations away from
fragmented projects to a programme-based approach that is in line with Paris and Accra aid effectiveness commitments. There was special emphasis on building The Global Fund’s ability to respond quickly to country plans, and identified gaps, ideally not constrained by the current Round-based funding system. However, some felt this would be difficult to implement without long-term predictable commitments from donors.

13. Facing domestic pressures to reduce its AIDS financing, the US Government's PEPFAR programme has introduced several measures to increase the understanding of cost and quality drivers and of the interventions required to improve programme design and implementation. These include initiatives for greater alignment with the Global Fund, and support for building capacity in national programmes.

Box 1: Innovative financing mechanisms at global level

The demand for AIDS treatment has promoted creative and innovative responses to mobilise funds internationally. UNITAID has raised over US $2 billion since 2006, largely through an air ticket tax applied to all flights departing from 29 member countries (2008), a progressive tax which raises funds from those most able to afford air travel. With the participation of Brazil, Chile, France, Madagascar, Niger, South Korea, United Kingdom, and other governments, this fund has helped strengthen markets, reduce prices for quality products and accelerated access to new drugs for HIV/AIDS, TB and malaria, especially second-line and paediatric antiretroviral medicines.

More recently, support has been growing for introducing a tax on financial transactions by banks, such as the purchase and sale of assets, unit trusts/mutual funds and derivatives. Known as a Tobin or Robin Hood Tax, it could be implemented globally, regionally or unilaterally by individual nations. Initiated by civil society, the tax is gaining support from economists and politicians across the world, including a growing number of G20 members.

Leveraging national resources for impact

14. It is recognised that different national contexts require different levels and kinds of domestic and external support. In particular:

▪ There is significant and rising need for expanded treatment coverage in high-burden low-income countries, especially in sub Saharan Africa. The AIDS 2031 Commission found that AIDS spending in these countries will continue to represent a large share of health expenditure over the next 20 years, and absorb an estimated 2-6% of nation’s GDPs. External support to enable the needed doubling of resources among these 15-20 countries will be needed.

▪ Among low-burden middle-income countries in Latin America, South East and Central Asia and Eastern Europe, including Russia and China, the need for external support is very different. AIDS spending will represent a more manageable proportion (less than 10%) of health expenditure, and remain well under 1% of GDP.

▪ In contrast, there are several middle-income countries in sub Saharan Africa that already provide around 30% of funds for treatment from domestic sources, but which may also require external support to meet the resource gap.

15. Participants noted some concerning trends in the mix of domestic and external financing in the high-burden low-income countries.

16. Eight out of the ten largest HIV epidemics are in low-income African countries. Most of these continue to rely heavily on external funds for HIV/AIDS treatment costs, providing less than 20-30% from their own domestic resources. Only a few countries provide more than 70% through their own resources. These countries have also seen dramatic substitution of international for domestic resources. The Lancet has reported that in the 2000s, for every $1 external finance to ministries of health in Africa, $0.4 - $1.1 was
removed from the health budget by the ministry of finance\(^3\). In the late 1990s and early 2000s, the majority of African countries reduced their government health spending (as a percentage of total government expenditure), despite experiencing higher rates of economic growth and having signed up to the Abuja Declaration to commit 15% of public expenditure to health.

17. This high level of reliance on external resources for treating significant numbers of citizens with lifelong infection is both unprecedented and unsustainable. It is of grave concern to governments and their people, and to the global community.

18. In contrast, a number of low-income countries have been successful in increasing their domestic contributions to ART treatment. Many more are considering possible additional sources including: additional allocations from national and local budgets allocations; debt relief; special funds; earmarked taxes and levies; expanding social health insurance; and building public private partnerships. Participants argued that, given pressures on the baseline operating budget of a government, specific mechanisms are needed that have both political and popular support.

**Earmarked funding for HIV/AIDS treatment**

19. Nigeria’s HIV treatment initiative was launched by the President in 2001. Although slow to take off, in 2006 it started to draw on funds allocated for health and HIV through debt relief secured through the Heavily Indebted Poor Countries Initiative. By 2006, around 100,000 people were receiving treatment, rising to 400,000 by 2010.

20. Zimbabwe’s ART treatment programme has been successful in reaching over half the people in need of therapy, but many more remain without access. As early as 2000, the government recognised the need to build self-reliance, and established the National AIDS Trust Fund (NATF), financed by a domestic AIDS levy. These measures were backed by strong political commitment and supported by civil society and people living with HIV/AIDS. It is managed by the National AIDS Council, and is transparent and accountable to the Council’s Board. Over half of its funding is now allocated to treatment. Despite a struggling economy, the NATF has been successful in increasing Zimbabwe’s domestic resource allocation for HIV/AIDS. In 2010, it accounted for 10% of the government’s health expenditure, raising about $16 million. Domestic resources from the NATF and the national budget each account for about 25% of the AIDS response, and have helped attract complementary funds from the Global Fund, the US government and others.

**Sharing the costs**

21. The private sector in many countries has also expanded its contribution, recognising the costs and benefits of providing HIV treatment. One example of this is the HIV treatment programme run by Anglo American, the international mining company (Box 2).

22. Social health insurance schemes present a further option for leveraging domestic resources. Social health insurance relies on pooling premiums and risk across all income groups to ensure cross subsidy. HIV can be an insurable risk in low-prevalence populations, as demonstrated by Thailand’s success in achieving universal health care coverage.

23. Thailand is a lower middle-income country that has made impressive progress in the long march to universal coverage. In 1990, social health insurance was introduced, building on three existing schemes for civil servants, low-income groups and communities. In 2001, nearly 30% of the population was still uninsured, but within a year, with strong political support, universal coverage was achieved for the population of 62 million. Less
than 20% of total health expenditure is out of pocket, on a par with the OECD average in 2009. The well-functioning district-based health system means that rich-poor and urban-rural gaps are small. Coverage levels for antenatal care, preventing mother-to-child transmission (PMTCT) of HIV and safe delivery, are nearly 100%.

24. HIV prevalence has declined from 1996 and is now concentrated in specific populations: men who have sex with men; injecting drug users; and sex workers. In 2003, universal ART was rolled out, reaching over 250,000 people in 2011, representing over 75% of those in need. Overall, the HIV/AIDS programme is less than 2% of national health expenditure, and Thailand has increased its domestic share of spending from 85% in 2007 to 93% in 2009. ART is judged as cost effective and affordable, well below the Thai Government’s national benchmark for publicly funded interventions (1 GNI per capita for 1 quality adjusted life year (QALY) gain).

25. In high-prevalence, low-income settings, the social health insurance challenge is greater. Today, health insurance makes up just 4% of Africa’s health expenditure, with most health care financed through out-of-pocket expenditure by households.

Box 2: AIDS treatment is good for business

Anglo American’s comprehensive workplace HIV/AIDS response was launched in response to the risk to its business posed by high HIV infection rates among its employees, who are primarily migrant workers in Southern Africa’s mining industry. The programme is driven by a rights-based HIV policy, and covers employees and their dependents for prevention, treatment, care and support. About 16% (12,000) of employees are HIV positive, of whom 4,000 are on treatment, with 94% uptake of HIV counselling and testing services by employees.

The overall cost of HIV/AIDS to the company amounts to 3.4% of the payroll – an increasing cost which will only be contained by effective prevention. The benefits of providing ART far outweigh the costs: at the individual level, total savings in terms of reduced time off work and health care amount to $219 per month (exceeding costs by $93) – an impressive return of 174% on the cost of providing treatment. The programme has also demonstrated that identifying and starting treatment earlier, when CD4 counts are higher than 250, means that employees can remain healthy with no productivity losses.

Basing programme decisions on population data obtained from high quality information management systems for staff and management feedback has been key to success. Challenges include managing TB effectively, reaching dependents in distant home communities, and tailoring behaviour change campaigns to people’s real-life situations including the likelihood of having multiple concurrent sex partners.

26. In low-income countries, where less than 20% of the population is in formal employment, social health insurance schemes have been beset by the limited size of the risk pool, their failure to include low-income employees and the informal sector, and by the high costs of health care management and quality assurance. There is some concern that the availability of external finance for free treatment undermines the private and public sector’s contribution to the overall response, as companies and governments stop including HIV cover in insurance packages. There has been very limited pooling of external, domestic and corporate resources. The Global Fund has funded just one social health insurance scheme.
27. New models of social health insurance could be a valuable way ahead whereby treatment cover could be affordable. Donors could provide cover for the so-called uninsurable risks (chronic illness such as HIV among the very poorest), effectively subsidising the scheme to enable the participation of private sector investors and health management organisations. Pilot programmes are taking place in Nigeria, led by the Netherlands based Health Insurance Fund, and with a local health maintenance organisation (HMO), Hygeia Nigeria, and supported by the Dutch and US governments, and the World Bank. However, there are concerns that the premium subsidy is unsustainably high.

28. An alternative way forward is a four way co-funding partnership among employers, the government, individuals and donors. The key is to avoid a two-tier approach for the wealthy and the low-income, and to include HIV cover, while ensuring cost effective disease management at the primary level.

**Leveraging impact with external resources**

29. Middle-income countries face particular challenges, and may struggle to secure sufficient resources. Some, such as South Africa, are proposing radical reforms to their health financing and delivery systems to address their high disease burden, which includes HIV/AIDS.

30. Over 5.6 million South Africans are HIV-positive, out of a total population of 50 million. The HIV epidemic is just one aspect of what has been called South Africa’s ‘quadruple epidemic’ of high HIV and TB prevalence, high maternal and child mortality, and a rising non-communicable disease burden including mental health conditions and the effects of violence and trauma.

31. South Africa is largely self-reliant for HIV/AIDS treatment funding, covering 1.3 million people primarily through national and provincial budgets. However, given the scale of need, about 30% is provided by external funders such as The Global Fund and PEPFAR. Costs will rise in 2011 when the new WHO guidelines, which call for earlier ART initiation, are adopted. Supported by PEPFAR, the government has achieved greater efficiency in drug procurement, with a recent international tender that cut costs by over 50% in two years. Laboratory costs are also to be reduced for TB and HIV by 25% over three years. Human resource reforms are underway as well, to enable task sharing by pharmacy, nursing and lay workers. Although coverage of interventions such as PMTCT is improving, new efforts are underway to improve HIV prevention services for other at-risk populations most such as truck drivers, with support from USAID.

32. Efforts to revisit the scope for national health insurance are beginning in South Africa. Drawing on decentralised service delivery models developed in Brazil nurse-led outreach teams are now visiting households and providing prevention and health care, as well as making early referrals. There will be 7,000 teams throughout country, employing 41,000 community health workers. The approach is generating new domestic financial commitments, as the government recognises that effective HIV prevention and early diagnosis and treatment are needed to support renewed efforts to develop a national health insurance system.

33. In low-burden middle-income countries, the HIV/AIDS epidemic is often concentrated in vulnerable groups, who may be marginalised by public services and discriminated against by law and policy. While the domestic contribution has grown, there have been challenges in mobilising national resources for programmes to reach the vulnerable groups. There are exceptions, for example in Ukraine, where a well co-ordinated and capable civil society played a critical role in channelling external funds for effective rights based programmes, and leveraging the domestic response and resources to fund it (Box 3).
Box 3: Civil society in Ukraine: mobiliser, leader, advocate and watchdog

In Ukraine, HIV infection is concentrated among injecting drug users (IDUs), a highly stigmatised and criminalised group. National and international civil society organisations provided early leadership and advocacy for introducing and scaling up evidence based interventions, such as harm reduction measures, substitution therapy and community driven outreach.

At the same time, civil society worked with government to build capacity in the health, social and justice sectors for a sustainable national response. In December 2008, the IDU programme was handed over to government. The epidemic has now stabilised in the IDU population, a significant achievement which has gained much international recognition. The benefits are far-reaching. For example, substitution therapy for over 5,000 people is preventing an estimated $40 million worth of criminal trade in illegal drugs.

Initiatives co-ordinated by civil society, including the International HIV and AIDS Alliance, have resulted in mobilising over $750 million for AIDS and TB from the Global Fund and the US government. Leveraged through these successes, political will has been growing to allocate domestic resources to cover 50% of the response. By 2016, 75% of those on HIV treatment will be financed by the government. There are inherent risks, in that government may not continue to fund NGOs and prevention activities. Indeed, NGOs remain largely dependent on international sources.

Civil society has continued to act as a watchdog on value for money. In the early years, antiretroviral medicines procured by the Ministry of Health were 27 times more expensive than those brought with Global Fund grants. Anti-corruption and transparency efforts have improved the situation, but some medicines remain more expensive when purchased by government.

Calls for action: support national plans and leverage resources

34. Participants called on governments in low and middle-income countries to continue to strive for greater self-reliance for their HIV/AIDS response, and use external resources to support a transition away from external dependence. Some have achieved remarkable results, and others are now exploring how best to achieve this.

35. Countries should take the lead in modelling their epidemics and the best responses, planning effective strategies and predicting costs, identifying the funding gap and optimising domestic funding. There should be more emphasis on sustainable financing models and mechanisms, embedded in legislation (through the general budget, social health insurance, special funds and taxes, corporate contributions, and individual payments from those who can afford it).

36. At the same time, external funding should continue – in the name of global solidarity. International funders should continue providing external support for good programme planning and costing, and to fund any gaps in ways aligned to national budget cycles.

37. Funders need to make greater efforts to support and leverage national financing, to focus explicitly on funding only evidence based programmes and to drive efficiencies and quality. For example, funding should be channelled to mechanisms such as Zimbabwe’s National AIDS Trust Fund, so long as they fulfil essential conditions – they are well managed and implemented, delivering results and proven value for money, and are accountable and transparent.

Challenge 2: more years gained for the money

Better access to ARVs

38. More affordable, high-quality generic products now dominate the market in low and
middle-income countries. There has been tremendous progress in supplying the access market in over 80 lower and middle income countries, and bringing down the prices of antiretrovirals (ARVs), especially first-line and paediatric regimens. Generic formulations now account for nearly 90% of the approximately 20 million packs purchased with PEPFAR funds, up from about 15% in 2005. Tenofovir-based regimens, now included among WHO recommendations for more effective first as well as second-line therapy, have increased in availability from just one African country in 2007 to 13 in 2011, reaching nearly one million patients. There have been concurrent reductions in regimen prices by around 50% to around $200 per annum for first-line treatment. Generic companies have also been able to develop new formulations more rapidly using several originator products. New, ‘single tablet a day’ fixed dose regimens are becoming available at less than $140 per annum, and second-line therapy is now under $500 per annum.

These dramatic gains have been due to several factors.

- Co-operation has improved between originator and generic companies. In particular voluntary licensing partnerships have increased in both number and in capacity to supply the market, following the early example set by GlaxoSmithKline and Aspen Pharma-care (South Africa) in the early 2000s. In 2006, Gilead Sciences launched a major voluntary licensing initiative following its Access Programme’s branded distribution track to distribute its tiered priced products in developing country markets. Through multiple partnerships with generic companies in South Africa and India such as Matrix Laboratories, Gilead grants non-exclusive licenses to enable the manufacture of generic versions of its products. Gilead provides its partners with technology transfer to produce and distribute quality, low-cost products in 95 developing countries. Licensees are able to establish pricing and develop fixed dose combinations and paediatric formulations. Gilead receives a 5% royalty on finished products sales based on the generic price.

- Improved management of supply and demand through better forecasting and procurement practices is enabling long-term agreements, and more supply security and cost savings. For example, UNITAID has funded the Clinton Health Access Initiative (CHAI) to support manufacturing capacity and create demand for more effective regimens and paediatric formulations at country level. There is more price transparency and information in the public domain, such as that published by Médecins sans Frontières.

- Aggregating orders and leveraging buying power to gain discounts and supply chain security have also been critical. In 2009, PEPFAR purchased half its ARVs through pooled procurement. In South Africa, the government has been able to leverage savings on ARVs of over 50% or $650 million through international competitive tender over the next two years, and plans a similar process for laboratory supplies and diagnostics. The Global Fund’s Voluntary Procurement Pool is also aggregating demand among grantees. However, although most low-income countries are now benefiting from more affordable medicines, many people in middle-income countries are not, due to a complex mix of poor and fragmented procurement, industry policy and corruption.

- Requirements by the major treatment financiers have helped drive quality, safety and effectiveness: for The Global Fund this means pre-qualification by WHO or a stringent regulatory authority and for PEPFAR, special arrangements with the US Food and Drug Administration. However, this is not without controversy at country level. The need for investment in domestic industry may not always align with public health or value-for-money concerns.

39. Despite this progress, major challenges remain. There is a significant needs for a wider range of new priority products to simplify treatment and reduce costs, including efforts to improve dosage optimisation, which can decrease side effects, improve dosing schedule and adherence, reduce manufacturing costs and making it easier to co-formulate ARVs as fixed dose combinations. Based on WHO’s 2009 HIV treatment guidelines and the new Treatment 2.0 strategy, a multi-agency working group including UNAIDS, WHO, and UNITAID has identified about 40 missing medicines and formulations for adult and paediatric treatment, as well as several promising products at late stage development.

40. At the same time there are concerns for the future of the generic market and the
implications of full compliance with World Trade Organisation's Trade Related Intellectual Property Rights agreement (TRIPS), and the impact of other measures such as anti-counterfeiting laws, which can affect generic company entry, and free trade agreements, which can include clauses such as data exclusivity agreements that go beyond TRIPs.

41. Voluntary licences clearly offer a viable and critical pathway for bilateral originator-generic company partnerships to expand HIV treatment access while protecting intellectual property rights, and there is clearly scope for further developing the model. The new Medicines Patent Pool, set up in mid 2010, under the auspices of UNITAID, aims to build on the approach. It will enable patent holders – companies, researchers, universities and governments – to voluntarily license their patents under certain conditions, for use by qualified third parties, such as generic companies, which then pay appropriate royalties on the sale of medicines in developing countries. The mechanism will enable a generic company to draw on licenses from several companies to develop and sell a new fixed dose combination product, and also to focus on new formulations for children. Signs are positive; the Medicines Patent Pool has negotiated a licence with the US National Institutes of Health and is in discussion with half the patent-holding companies that make antiretroviral treatments.

42. The debate about the value of compulsory licensing and balancing access and innovation continues. Thailand, which as a lower-middle income country is required to be compliant with TRIPs, used compulsory licensing for selected ARVs on the legal grounds of preventing a public health emergency. Although the strategy reduced ARV prices significantly and enabled greater coverage, some perceive that similar results may have been possible through negotiation, and that the longer-term impact is not yet clear.

43. There is a widely accepted need for getting the balance right between maintaining sufficient incentives for innovation while enabling much better access to new and affordable medicines now. However, as least-developed countries have agreed to comply with TRIPS by 2016, it is important that they update their intellectual property legislation to include the TRIPS flexibilities set out in the Doha Declaration for Public Health, and can use them without facing international disapproval and reprisal, so long as TRIPS conditions are adhered to.

44. National regulatory and licensing processes present very significant bottlenecks to accelerating treatment access. Despite the availability of new ARVs, it may still take two years for these to reach patients. Country medicines regulatory agencies often struggle with capacity and high workload. WHO, CHAI and others are supporting regulatory strengthening, including regional harmonisation in Africa. PEPFAR is also developing and piloting a process, known as PaATH (Pre-approval Access to HIV/AIDS Therapies) whereby governments can agree to use standard packages of information from a stringent regulatory authority to pre-approve new ARVs while the regulatory process is ongoing.

Improved service delivery models

45. As pressure grows to meet mounting needs with available resources, there is a growing emphasis in countries and in the agencies supporting them to collect, analyse and then act on service delivery and programme data. Data on the key cost drivers, including operational research and evaluation of successes and limitations of service delivery programmes, are urgently needed to drive greater quality and efficiency.

46. The main cost drivers for an ART programme are the ARVs (ranging from less than 40 to over 70% of costs), and other recurrent costs including laboratory tests, treatment for other infections, diagnostics, staff. While there is plenty of data on recurrent costs, we know much less about capital investments such as infrastructure and programme support costs, and these may not be included in country or programme budgets.

47. Partly in response to the US Congress’s requests for improved results, PEPFAR has launched a major workstream to make smarter investments: to strengthen use of
economic and financial data to ensure efficient use of resources (costing studies and results linked expenditure analysis); to incorporate innovation with partners for service integration and task shifting; and to develop better health information systems and diagnostics. Already the emphasis on data is bearing fruit. Studies have found large variations in service delivery models and programme costs, which can now be proactively addressed, to help scale up and bring the low and high cost outliers into line.

48. There are many pilots for service delivery models that enable treatment services to be integrated and offered at the community level, and promote voluntary take-up of HIV counselling and testing, and early treatment initiation and adherence, involving people living with HIV or AIDS and their communities. These models often require complex system and policy reforms, such as task delegation for key functions such as prescribing, dispensing, monitoring and adherence support, and the use of new communications and ‘smart’ technologies to support staff or volunteers at all levels.

49. However, there is concern at the lack of processes to ensure these pilots demonstrate cost-effectiveness and scalability, so that effective models can be introduced into national programmes and resourced for scale-up. There are exceptions. In Rwanda, a PEPFAR-sponsored pilot of HIV/TB integration yielded such good results that it was rapidly scaled up to become a national approach.

Continuing investments in effective prevention

50. Proven HIV prevention interventions such as PMTCT are being scaled up. But new and effective approaches such as male circumcision are only slowly gaining ground.

51. Stigma and discrimination, lack of access to services and bad laws can make epidemics worse, driving HIV underground and inhibiting efforts to expand access to life-saving HIV prevention, treatment, care and support. It is welcome that almost all countries explicitly acknowledge or address human rights in their national AIDS strategies, and have programmes in place to reduce HIV-related stigma (UNAIDS’ 2010 report). Progress is also being made in improving women’s and young people’s rights to health and scaling-up access to services.

52. HIV prevention investments do not always follow epidemic patterns. ‘Know your epidemic’, the strategy that seeks to identify and then programme for those at greatest risk, is not used enough. In Eastern Europe and Central Asia, most HIV prevention is still not focused on people at higher risk, such as IDUs, sex workers and their clients, and men who have sex with men. In countries with generalized epidemics, these population groups exist but are often ignored or highly stigmatised. Yet UNAIDS reports that these key populations may account for over 30% of new infections, while prevention spending targeted at them may be less than 1% of the total.

Treatment as prevention

53. There are four categories of treatment as prevention.

a) PMTCT includes the provision of antiretroviral medicines to a pregnant woman and has prevented millions of infections among newborn babies. Treating the mother for HIV further reduces the chances of infection through breast feeding and is more likely to lead to healthy mothers and babies.

b) Post-Exposure Prophylaxis (PEP) involves administering drugs in combination after exposure through unprotected sex or needlestick injury. It is effective against HIV infection if provided within 72 hours and continued for several weeks. Unlike a preventive vaccine it has no permanent prophylactic effect.

c) Pre-Exposure Prophylaxis (PrEP) involves using ARVs as vaginal or rectal microbicides or administering them orally. Both administration modes have recently proven to be effective against infection.
i) Microbicides could provide protection during vaginal and rectal sex, and would expand options for female-controlled prevention. Trials are ongoing for coitally dependent gels and for vaginal rings, which would provide long lasting protection, similar to that provided by the contraceptive rings popular in the USA. Positive results were announced by the CAPRISA 004 microbicide trial in South Africa, in July 2010, using 1% tenofovir gel. Tested with nearly 900 women, this trial was the first to demonstrate proof-of-concept that a microbicide can reduce a woman’s risk of HIV via vaginal sex, with 39% fewer HIV infections among women using the tenofovir gel compared with women receiving the placebo gel. Effectiveness was higher, at 54%, for women with high adherence to the tenofovir gel, compared with high adherers to the placebo gel. Further trials will take place to ensure results are replicable and generalisable. Other ARVs are also being tested for use as microbicides.

ii) There have been several trials of oral use of ARVs, some of which were stopped. The iPrEx trial, in the USA and Latin America, was the first to show effectiveness. Overall there was a 44% reduction in incidence, which rose to over 90% for participants with high adherence and drug levels. There is no evidence yet to suggest that the same class of drugs cannot be used for both prevention and treatment. Indeed resistance was not seen in the trial except among people with acute HIV infection.

More work is needed. WHO is currently conducting eight dialogues at the regional level to review the implications and next steps. There are many questions about the implications of PrEP results for oral use at programme level, and concerns that high levels of publicity will result in self-application, use of costly over the counter drugs and reduced use of condoms.

d) ‘Test and treat’, the final category, refers to the impact of universal and voluntary HIV testing, early treatment for all eligible people, reduction of their viral load and infectiousness, and hence prevention of new infections. There is some evidence for this effect from data in developed countries for groups at high risk with high treatment rates. Trials are ongoing in South Africa, Tanzania and Kenya. While the benefits to communities could be significant, how to maximise cost benefits through targeting and addressing the human rights implications remain major questions.

Calls for action: doing more, better

54. Participants called for the global community to build on these achievements, to do more, and do it better.

Doing better…. With respect to technological advances, market strengthening, technical and systems innovations, and continued mobilisation for prevention, action is needed on ten critical issues.

1. There should be a single-minded focus on developing and ensuring the availability of single tablet regimens, with their great advantages for patient adherence, quality and costs. Greater attention should be given to understanding and reducing the lifetime costs of treatment, which may mean greater expense in the short run. Appropriate technologies for use at point of care are urgently needed, such as viral load and CD4 monitoring. Vaccine research efforts should also be maintained.

2. Continued and collective efforts must be made by all stakeholders to further accelerate access to affordable and effective technologies, to improve demand aggregation and encourage market entry by more suppliers, and to innovate and strengthen sustainable use of new compounds. Robust voluntary licensing arrangements should include, for example, early agreements and full technology transfer, and a joint effort is needed to make the Medicines Patent Pool work.

3. Urgent investments are needed to speed up initiatives to improve product registration and licensing. While maintaining national sovereignty is important, delays of two years in making a product available to populations in need should not be acceptable. Pharmaco-vigilance and post marketing surveillance must also be strengthened, with roles identified for industry as well as government.

4. Increased use of WHO recommended standard treatment guidelines and protocols is
required, accompanied by a reduction in the number and choice of multiple regimens that fragment the market and increase costs. The rollout of UNAIDS’ and WHO’s Treatment 2.0 model is eagerly awaited. This new approach could bring down treatment costs, make treatment regimens simpler and smarter, reduce the burden on health systems, and improve the quality of life for people living with HIV and their families. Modelling suggests that, compared with current treatment approaches, Treatment 2.0 could avert an additional 10 million deaths by 2025.

5. There is a need for earlier HIV counselling and testing and for much earlier inception of treatment. Most people are diagnosed and begin treatment when they are already sick and CD4 counts are well under 200. As well as having implications for their health, late inception also increases the risk of resistance and the likely need for switching to more costly second-line treatments.

6. New service delivery models should prove their worth, and, if they are more cost-effective should be rapidly scaled up. These include providing services close to communities, through task shifting for nurses and pharmacists, improving health information management and monitoring, and involving individuals and communities in improving testing uptake and treatment adherence.

7. Increasing service integration is equally important, especially for HIV and reproductive, maternal, neonatal and child health, TB, other chronic infections such as viral hepatitis and non communicable diseases requiring long term care.

8. We need to find better ways to assess, prioritise and disseminate proven cost-effective innovations in treatment and prevention. New approaches to service delivery have enabled costs to come down while maintaining quality, but there is an urgent need to both share and prioritise these for scale-up. In South Africa, the government and partners are trying to standardise new models through national protocols across public and private sectors, while maintaining an environment where NGOs and academics can innovate and share learning.

9. New advances in treatment as prevention hold great promise but they are not a magic bullet. New approaches do not work best in isolation. Prevention interventions – harm reduction, sexuality education, and structural interventions to increase women’s economic independence and address gender inequality – must be part of the response. Guidance from normative agencies is urgently needed, to support interpretation of the data, and to advise on the implications for the wider AIDS response and country strategies.

10. Last, and very importantly, investment in effective prevention must continue. Without investment in HIV prevention interventions that are proven to work, for the most vulnerable people, new infections and treatment needs will continue to rise.

...with more resources

55. With respect to mobilising and leveraging additional resources, participants identified two critical roles.

a) Governments in low and middle income countries should continue to strive for greater self reliance in their AIDS response, and to use external resources to support a transition away from external dependence. They should take the lead in programme planning and budgeting, identifying the funding gap and optimising domestic funding, with more emphasis on sustainable financing models and mechanisms.

b) International funders should continue providing external support to meet funding gaps, and make greater efforts to support and leverage national financing. They should focus explicitly on funding programmes that use cost effective interventions and that demonstrate success with evidence based approaches, and to drive greater efficiencies and quality services.
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HLSP Institute | March 2011

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Front cover image: James Pursey, courtesy of the Elizabeth Glaser Paediatric AIDS Foundation
Annex A
Pre-Read Compilation Outline

Overview: Financing the Continued Scale-Up of Antiretroviral Treatment

Resources from International Donors

Domestic and Private Investment

Antiretroviral Drug Pricing and Access
- Ruxin J. AIDS Drugs – For Profit Or Not? Forbes Online (Science Business Blog), November 11, 2010. (2 pp)
- Straight Talk With … Ellen t’Hoen. Nature Medicine, 16, no. 12 (December 2010): 1351. (1 p)

Improving Value for Money
- UNAIDS. Treatment 2.0. Special Section in Outlook, 2 (July 2010): 46-53. (8 pp)

Balancing HIV Treatment with HIV Prevention
- Cohen, J. Treatment as Prevention. Science, 327 (March 5, 2010). (1 p)
Annex B
Other key websites

www.gilead.com
www.unaids.org
www.msf.org
www.medicinespatentpool.org
www.unitaid.eu
www.pepfar.gov
www.clintonfoundation.org
www.futureartcosts.org
www.gfatm.org
www.resultsfordevelopment.org
www.robinhoodtax.org