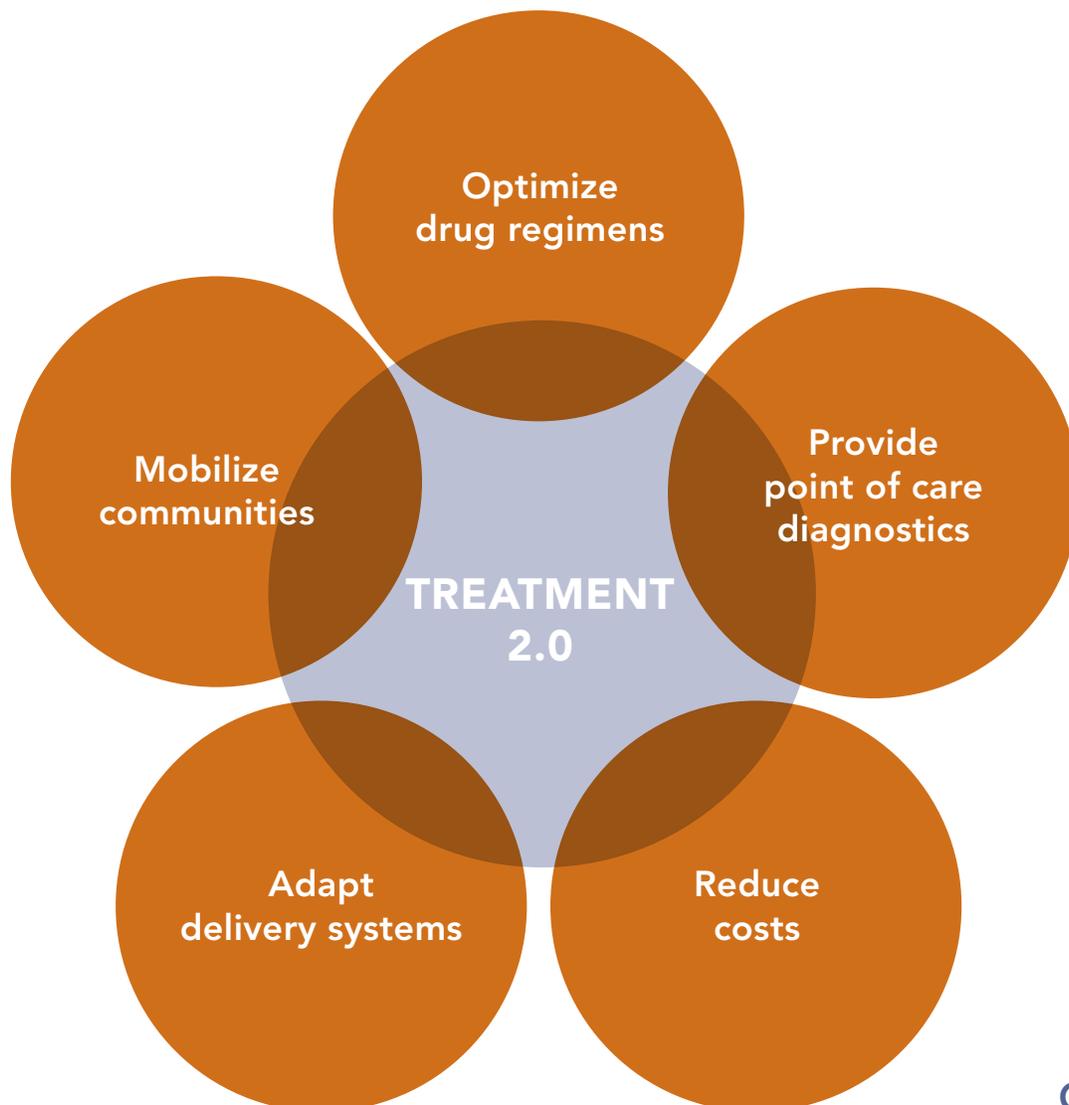


MISSING THE TARGET

10

Communities and the Treatment 2.0 Initiative: *Delivering on the Next Treatment Scale-up*



October 2012

ABOUT ITPC

The International Treatment Preparedness Coalition (ITPC) is a worldwide network of community activists united by a vision of a longer, healthier, more productive life for people living with HIV. ITPC's mission is to enable communities in need to access HIV treatment. As a grassroots movement, ITPC is the community's response to HIV and is driven, led by, and committed to the human rights of those most impacted by the pandemic. ITPC currently works in nine regional networks in Africa, Asia, the Caribbean, Eastern Europe, and Latin America; over the past decade, it has made over 1,000 grants totalling more than \$10 million to community-based organizations of people living with HIV in almost 100 countries. Additional information about ITPC is available at its website: www.itpcglobal.org.

ABOUT MISSING THE TARGET AND THIS REPORT

ITPC's Treatment Monitoring & Advocacy Project (TMAP) contributes a unique perspective to global health advocacy through its *Missing the Target* (MTT) series of reports. The MTT reports, along with related advocacy and capacity-building activities, aim to support civil society advocates to monitor the delivery of HIV/AIDS services in their countries. These advocates hold national governments and global agencies accountable to their commitments to ensure access for all in need. All ITPC *Missing the Target* reports are available online at www.itpcglobal.org.

This 10th *Missing the Target* report (MTT10) focuses on challenges to the scale-up of HIV services as required to implement the Treatment 2.0 framework. That framework refers to an initiative developed and proposed in June 2010 by the World Health Organization (WHO) and Joint United Nations Programme on HIV/AIDS (UNAIDS) that aims to “catalyse the next phase of HIV treatment scale-up through promoting innovation and efficiency gains.”

As with other *Missing the Target* publications, national and local community groups conducted research based on a general template and prepared their country-specific reports. The following countries are included in MTT10: Cameroon, China, Côte d'Ivoire, Honduras, India, Kenya, Morocco and Russia. The full MTT10 report and individual country reports—including French translations of the Cameroon and Côte d'Ivoire reports and a Spanish translation of the Honduras one—are available at the ITPC website: www.itpcglobal.org.

ACKNOWLEDGEMENTS

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INTRODUCTION AND OVERVIEW

Despite enormous gains in treatment access over the past three years, there remain formidable technical, financial and structural challenges to achieving the goal of 15 million people on HIV treatment by 2015, the “15 by 15” target set in July 2011 by governments at the United Nations High Level Meeting on AIDS. Yet potentially effective models and road maps have been developed to promote success. Most notably, the Treatment 2.0 initiative of the World Health Organization (WHO) and Joint United Nations Programme on HIV/AIDS (UNAIDS), launched in June 2010, provides a platform through which governments, communities, and other stakeholders can plan for scale-up of treatment.¹ Furthermore, the initiative served as the basis of an influential strategic investment framework² for HIV/AIDS developed and released the following year, also with UNAIDS support. That framework sets out a model for HIV investment and programming that calls for sharply increased funding in the short term in order to save money (and, of course, millions of lives) over the long run. The investment framework’s conclusions are predicated on the belief that the epidemic can be “controlled” and then turned around with sufficient resources targeted to the best, evidence-based interventions.

Many of the barriers confronting the Treatment 2.0 agenda at the national level can be seen in the work undertaken by community advocates in the eight countries profiled in *Missing the Target 10 (MTT10)*: Cameroon, China, Côte d’Ivoire, Honduras, India, Kenya, Morocco and Russia. Applying the community lens provides an important “reality check for multilateral entities, donors, governments, and civil society groups that already are or should be supporting the framework. The HIV context differs greatly across all eight nations, but the many similar barriers and obstacles to comprehensive treatment scale-up underscore the shared global needs and priorities.

The *MTT10* report builds on earlier work by the International Treatment Preparedness Coalition (ITPC) on the Treatment 2.0 initiative. For example, in 2011 ITPC organized two meetings³ to consider how communities could engage with the initiative and promote it. A critical finding from those meetings and subsequent analysis was that successfully implementing the Treatment 2.0 agenda is only possible when communities fully and comprehensively engage in advocacy and health services. Their engagement is essential because community groups provide stigma-free and friendly services, especially for difficult-to-reach populations, and thus help address gaps in access to HIV treatment and prevention services.

The Treatment 2.0 initiative is based on five inter-related priority work areas, also known as “pillars” (Figure 1). These are:

- **Optimizing drug regimens**—making drug regimens less toxic, more effective, and easier to adhere to, with an ultimate goal of having an effective, affordable, once-daily single pill.
- **Providing point-of-care diagnostics**—making viral load and CD4 cell tests, as well as other diagnostic and monitoring tools, readily available and easier to use. The ultimate goal is a package of simple, affordable, reliable and quality-assured tests (including for other co-infections) available and accessible in low- and middle-income countries.

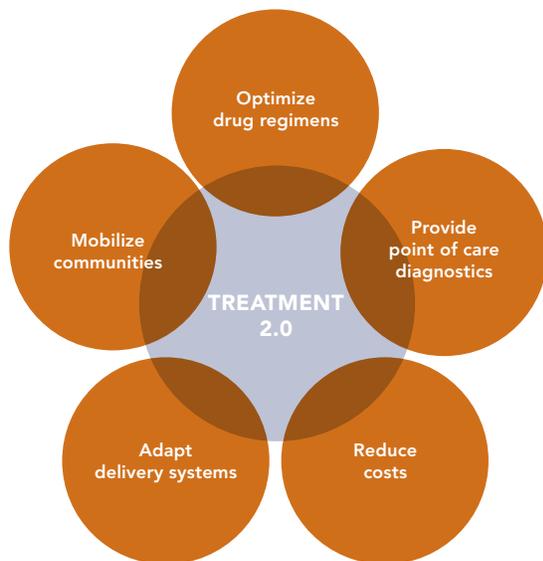
1 Information about Treatment 2.0 may be found on the WHO website at www.who.int/hiv/topics/treatment2/en/index.html.

2 Schwartländer et al (June 2011). “Towards an improved investment approach for an effective response to HIV/AIDS”. *The Lancet*, Vol. 377, Issue 9782: pp 2031-2041.

3 The first gathering took place 3-5 May 2011 in Bangkok, Thailand, and brought together nearly 50 representatives from Asia and Eastern Europe. A second community meeting was held 1-3 June 2011 in Johannesburg, South Africa; attendees included a similar number of representatives from across Africa.

- **Reducing costs**—an overarching workstream that looks at investments required to reach universal access and the 15 by 15 target. Key focus areas include commodity costs (including procurement and production processes), efficiency gains in service delivery and expanded role for communities, and better understanding of how to increase access to generic medicines and encourage competitive prices for newer first- and second-line drugs.
- **Adapting delivery systems**—decentralizing HIV care and treatment services and integrating with primary care services and other non-HIV health services, with increased community engagement in service delivery and improved retention in care.
- **Mobilizing communities**—scaling up community-based advocacy and service delivery to promote access to care and protect human rights. A core part of this effort is ensuring that people living with HIV and key populations (e.g., sex workers, people who inject drugs, men who have sex with men, and migrants) are fully involved in the demand creation, planning, delivery and evaluation of quality-assured, rights-based HIV care and treatment programmes.

Figure 1. Priority work areas of Treatment 2.0



In each of the eight MTT10 country reports, community-sector advocates and representatives examine the challenges to the scale-up of HIV services and treatment under each of the Treatment 2.0 pillars. The research methodology adapted by each country team included several steps beginning with conducting a literature review, interviewing key informants and carrying out focus group discussions for and with people living with HIV (PLHIV) in urban and rural settings. (Of note is that the Russian country team also conducted an online survey amongst nearly 90 PLHIV and the China country team conducted a community-based survey of over 2,000 PLHIV to determine barriers to patient outreach, retention and adherence.) The research was largely carried out in April and May 2012. The key findings from the eight MTT10

country reports are framed in the context of Treatment 2.0 and examined according to the continuum of care (test, treat and retain)—steps and concepts that are critical to treatment scale-up, especially in minimizing the loss to follow-up.

One major challenge identified by all MTT10 teams was the lack of awareness of the Treatment 2.0 concept and framework. Most stakeholders from all sectors, including government, civil society and PLHIV, knew little or nothing about the Treatment 2.0 initiative and its relevance to health services and HIV treatment scale-up. In addition, there was insufficient awareness about the key research and programming priorities underpinning the framework, including:

- the value of treatment-as-prevention, as highlighted in a recent WHO report citing study findings that for every 10 percent increase in the share of people getting antiretroviral treatment (ART), “HIV incidence decreased by 17 percent”;⁴ and
- the Treatment 2.0 agenda’s emphasis on the importance of supporting and engaging communities to ensure efficient and effective scale-up of services.

The following are among the other overarching *MTT10* findings:

For any treatment scale-up to be effective, **communities and other stakeholders must address the challenge of testing and diagnosis.** Worldwide, only 50 percent of PLHIV are aware of their status. In most countries, including the eight ones surveyed, access to a full range of diagnostics is limited. HIV testing is available and supported in most countries, but strategies are often nonexistent or inadequate for linking and retaining those who test positive with broader healthcare systems and structures. As a result, many individuals—more than half in some countries, according to estimates—are lost to follow-up.

One reason identified by this report’s country teams is the poor quality of pre- and post-test counselling, including issues associated with confidentiality, stigma and discrimination, and the length of time between testing and confirmation. In most countries focus group participants noted that public-sector facilities services lacked an open and “welcoming” attitude, often did not guarantee or safeguard confidentiality, and frequently failed to ensure that clear consent was solicited prior to HIV testing. For example, in Russia health workers reportedly emphasize the “limited lifetime” of PLHIV, a fatalistic-sounding comment that reduces incentives for some people to return to and fully engage with the healthcare system. Simple reasons such as high out-of-pocket costs for diagnostics in the case of Honduras, and long waits between initial diagnosis and confirmation as observed in China, prevent some in those countries from seeking treatment.

Far too many PLHIV do not have access to quality ART or adequate treatment support. First-line ART is provided free of charge in public facilities in all eight countries surveyed, but regimens remain less than optimal. Nearly all patients report taking two or more tablets daily, often at more than one time each day. Such complicated regimens increase the risk of non-compliance, especially when information around use and side effects is not adequately provided. In the case of India, Cameroon, and China, regimens containing stavudine (d4T) continue to be purchased and prescribed, nearly three years after WHO first recommended that the drug no longer be offered because of its uncommonly high toxicity.⁵ In several focus group discussions, participants noted that the lack of information and low levels of treatment literacy resulted in a significant proportion of persons taking ART only sporadically or abandoning altogether. Many PLHIV continue to feel the need to hide their status and use of ART due to persistent HIV-related stigma and discrimination, including from close family members, that pervades most societies. (On a more hopeful note, PLHIV respondents in several countries said their families were supportive. Many also cited the importance of peer support groups and other community-oriented structures in helping them cope with and manage their HIV infection and treatment.)

4 WHO (2012). “The strategic use of antiretrovirals to help end the HIV epidemic. Available online at: www.who.int/hiv/pub/arv/strategic_use/en/index.html. The specific reference cited in that report for this information is Tanser F, Barnighausen T, Grapsa E, Newell M-L. “Effect of ART coverage on rate of new HIV infections in a hyper-endemic, rural population: South Africa . 19th Conference on Retroviruses and Opportunistic Infections. 2012. Paper #136LB. Available online at: www.retroconference.org/2012b/Abstracts/45379.htm (accessed 3 July 2012).

5 Stavudine, one of the cheapest antiretroviral drugs, continues to be prescribed for cost reasons in many countries. India’s National AIDS Control Organisation (NACO) has pledged to phase out its use by the end of 2013. As noted in the India country chapter of *MTT10*, advocates are urging quicker action and vow to hold NACO accountable.

Supply chain problems continue to plague healthcare systems for diagnosis, treatment and monitoring. Tests such as CD4 and viral load are often not available in a timely manner or on a regular basis, especially outside of major cities and in rural areas. People living in those areas also suffer disproportionately from stock-outs of antiretroviral drugs (ARVs) that occur regularly at treatment centres in all countries surveyed. Other important medicines for co-infections, including cotrimoxazole prophylaxis and tuberculosis drugs, amongst others, are often unavailable. Such gaps were a major concern among PLHIV respondents, most of whom also decried the **lack of integrated facilities and service delivery structures**. All agreed on the desirability of “one-stop” access to specific HIV-related services as well as others such as treatment for sexually transmitted infections, tuberculosis, viral hepatitis, etc. Their observations deserve attention for reasons other than their own personal convenience and ease: increased and enhanced integration is a critical component of the Treatment 2.0 agenda.

Communities can and do play a valuable role in scaling up HIV-related services and treatment. AIDS Care China has created a model of treatment education and counselling, the “Red Ribbon Centre, and based its programming directly on the interpretation of Treatment 2.0 pillars. As the only country in which such specific implementation of the framework has begun, the China report is different from the others as it provides a case study of how Treatment 2.0 can work in a local context.

More broadly across all countries surveyed, the service delivery role of community-based organizations appears to be increasingly recognized by governments, donors and community members themselves. Much less appreciated to date is the role of community-based organizations in advocacy. This challenge is notable because in nearly all settings community-delivered advocacy helps identify and publicize obstacles to treatment access; addresses stigma and discrimination; aims to change obstructive and discriminatory legal regimes; draws greater attention and funds for scale-up; and seeks to ensure that core health and human rights values and standards are safeguarded, including in regards to trade and intellectual property.

The findings noted above greatly influenced recommendations developed by each country team. Most also identified and suggested remedies to address country-specific challenges and needs. Listed below are the priority changes that are noted by all or nearly all country teams involved in *MTT10*. They are considered crucial concepts and priorities for efforts to re-invigorate HIV treatment scale-up and achieve the Treatment 2.0 agenda:

- End to stigma and discrimination against all PLHIV, which requires removal of discriminatory laws, educating and training service providers, and increasing community engagement in education and services.
- Access to optimal, affordable, and timely diagnostics and treatment, which requires limiting the “loss to follow-up” of PLHIV in the overall treatment process and an end to stock-outs that force treatment interruptions.
- Integration of health services, including expansion by non-medical providers for long-term care and monitoring.
- Financial and capacity-building support for community-based organizations, including on legal and trade issues, access to the most up-to-date information on diagnostics and treatments, treatment literacy, and health financing.
- Advocacy for the right to health, which includes the right to information; access to affordable, accessible, and quality health services and treatment; and harmonization of government policies to protect and serve all residents and visitors.

Support is an essential precondition. It must be associated with care... because it is not enough to provide only drugs.

- Person living with HIV
in Yaounde, Cameroon

CAMEROON AND TREATMENT 2.0: CHALLENGES AND OPPORTUNITIES TO SCALE UP HIV TREATMENT

This country report is part of *Missing the Target 10 (MTT10)*, the 2012 version of a longstanding series on global access to HIV treatment coordinated by the International Treatment Preparedness Coalition (ITPC). *MTT10* focuses on challenges to the scale-up of HIV services as required to implement the Treatment 2.0 framework. As with other *Missing the Target* publications, national and local community groups conducted research based on a general template and prepared their country-specific reports. The following countries are included in *MTT10*: Cameroon, China, Côte d'Ivoire, Honduras, India, Kenya, Morocco and Russia.

The full *MTT10* report and individual country reports are available at the ITPC website: www.itpcglobal.org. Also available at that website are a French version of this Cameroon report as well as a French version of the Côte d'Ivoire report and a Spanish version of the Honduras one.

Cameroon

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ACRONYMS AND ABBREVIATIONS

ART	antiretroviral treatment
ARV	antiretroviral drug
CATAG	Central African Treatment Action Group
CBO	community-based organization
CMA	centre médicaux d'arrondissement
CNLS	Comité National de Lutte contre le Sida
CTA	centre de traitement agréé
FBO	faith-based organization
NGO	non-governmental organization
PLHIV	people living with HIV
STI	sexually transmitted infection
TB	tuberculosis
UPEC	unité de prise en charge
VCT	voluntary counselling and testing
WHO	World Health Organization

Note on text: All "\$" figures in this report are U.S. dollar amounts. All URLs cited were valid as of 1 October 2012.

HIV DRUGS LIST

Many HIV drugs are commonly referred to in an abbreviated format. Listed below are the abbreviated names of all the drugs mentioned in the Cameroon report as well as the full generic name associated with them. Where relevant, brand names of key drugs are also noted. The drugs are grouped by class.

NRTIs (nucleoside reverse-transcriptase inhibitors)	
3TC	lamivudine
AZT	zidovudine
d4T	stavudine
FTC	emtricitabine
TDF	tenofovir
NNRTIs (non-nucleoside reverse transcriptase inhibitors)	
EFV	efavirenz
NVP	nevirapine
Protease inhibitors	
LPV/r	lopinavir/ritonavir (refers to lopinavir being “boosted” by ritonavir)

1. INTRODUCTION AND OVERVIEW

1.1 Methodology

The Central African Treatment Action Group (CATAG) and ITPC Central Africa⁶ conducted a study on the obstacles to accessing treatment and health care relating to HIV infection. Research took place in Cameroon from March to May 2012. Information was collected in three ways: focus group discussions, in-person interviews and a review of documents in both print and electronic versions.

The five focus group discussions included a total of 46 participants, among them 10 men and 36 women. All were HIV-positive. Three of the discussions took place in urban settings, one in a suburban setting and the fifth in a rural area.⁷

Interviews were conducted with 27 individuals, including 14 people living with HIV (PLHIV) between the ages of 27 and 54; a total of 16 representatives of community-based organizations (CBOs); six healthcare service providers (doctors, nurses and psychosocial counsellors); and one policymaker, the permanent secretary of the Central Technical Group of the Comité National de Lutte contre le Sida (National Committee of the Fight Against AIDS, or CNLS).

1.2 Context

HIV prevalence in Cameroon has declined since 2004, falling from 5.9 percent to 4.3 percent in 2011.⁸

6 ITPC refers to the International Treatment Preparedness Coalition, which supported this research. ITPC Central Africa refers to one of its regional coordinating bodies.

7 The urban settings included two focus group discussions in Yaoundé, the capital, and one in Maroua, in the Far North region. The suburban setting was Obala; the rural one was in Godola, in the Far North region.

8 National Institute of Statistics, “Enquête démographique et de santé et à indicateurs multiples (EDS-MICS 2011)”, February 2012. Available online at: <http://www.statistics-cameroon.org/news.php?id=121> (in French).

Prevalence among women, at 5.6 percent, is nearly twice that among men (2.9 percent).⁹ The number of PLHIV is estimated to be 560,000,¹⁰ of whom 55.8 percent are women, and 70 percent of HIV-positive people between 15 and 24 years old are female.¹¹ According to data from September 2010, some 141 new HIV infections occurred each day in Cameroon, which corresponds to six new people infected every hour.¹²

The coverage rate for antiretroviral treatment (ART) has been increasing since 2005, reaching 49.6 percent of those in need in September 2011.¹³ Of those receiving ART at that time, more than two-thirds (68.4 percent) were women. A notable increase in the number of HIV-associated healthcare structures was reported between 2002 and 2011. For example, the number of operational HIV treatment centres rose from just five in 2002 to 149 in 2011 and the number of sites providing vertical prevention services increased from 1,159 to 2,102 over the same period.¹⁴

After tripling within just a couple years, utilization of pre-natal services has stagnated over the past four years at an average of 35 percent.¹⁵ This is important because routine testing for HIV is provided at first pre-natal consultations. Uptake is high when offered: in 2011, 80 percent of pregnant women who attended a prenatal clinic accepted offers to be tested for HIV, and 92 percent of them returned for test results.¹⁶ Yet despite the increase in vertical transmission facilities, national coverage of HIV-positive pregnant women on ART was just 20.3 percent in 2011.¹⁷

Though some of these developments are undoubtedly encouraging, it is worth noting the serious gaps in service provision. Most notably:

- 50.4 percent of antiretroviral drug (ARV) needs,¹⁸ 87 percent of paediatric ARV needs¹⁹ and 77.1 percent of CD4 test needs (provision of CD4 services)²⁰ are not met.

9 National Institute of Statistics, "Enquête démographique et de santé et à indicateurs multiples (EDS-MICS 2011)", February 2012. Available online at: <http://www.statistics-cameroon.org/news.php?id=121> (in French).

10 National AIDS Control Committee (CNLS), "The impact of HIV and AIDS in Cameroon through 2020", September 2010, p.11. Available online at: www.healthpolicyinitiative.com/Publications/Documents/1250_1_Cameroon_EN_Singles_Reduced_acc.pdf.

11 National AIDS Control Committee (CNLS), "The impact of HIV and AIDS in Cameroon through 2020", September 2010, p.12. Available online at: www.healthpolicyinitiative.com/Publications/Documents/1250_1_Cameroon_EN_Singles_Reduced_acc.pdf.

12 National AIDS Control Committee (CNLS), "The impact of HIV and AIDS in Cameroon through 2020", September 2010, p.3. Available online at: www.healthpolicyinitiative.com/Publications/Documents/1250_1_Cameroon_EN_Singles_Reduced_acc.pdf.

13 National AIDS Control Committee (CNLS), "Rapport annuel 2011 des activités de lutte contre le VIH, le Sida et les IST au Cameroun", 2012, p.44. Available online at: www.cnls.org/public/web/IMG/pdf/rapport_annuel_2011_activites_lutte_contre_vih_sida_et_ist_cam.pdf.

14 National AIDS Control Committee (CNLS), "Rapport annuel 2011 des activités de lutte contre le VIH, le Sida et les IST au Cameroun", 2012, p.20. Available online at: www.cnls.org/public/web/IMG/pdf/rapport_annuel_2011_activites_lutte_contre_vih_sida_et_ist_cam.pdf.

15 National AIDS Control Committee (CNLS), "Rapport annuel 2011 des activités de lutte contre le VIH, le Sida et les IST au Cameroun", 2012, p.21. Available online at: www.cnls.org/public/web/IMG/pdf/rapport_annuel_2011_activites_lutte_contre_vih_sida_et_ist_cam.pdf.

16 National AIDS Control Committee (CNLS), "Rapport annuel 2011 des activités de lutte contre le VIH, le Sida et les IST au Cameroun", 2012, p.21. Available online at: www.cnls.org/public/web/IMG/pdf/rapport_annuel_2011_activites_lutte_contre_vih_sida_et_ist_cam.pdf.

17 National AIDS Control Committee (CNLS), "Rapport annuel 2011 des activités de lutte contre le VIH, le Sida et les IST au Cameroun", 2012, p.25. Available online at: www.cnls.org/public/web/IMG/pdf/rapport_annuel_2011_activites_lutte_contre_vih_sida_et_ist_cam.pdf.

18 National AIDS Control Committee (CNLS), "Rapport annuel 2011 des activités de lutte contre le VIH, le Sida et les IST au Cameroun", 2012, p.44. Available online at: www.cnls.org/public/web/IMG/pdf/rapport_annuel_2011_activites_lutte_contre_vih_sida_et_ist_cam.pdf. (Note: The 50.4 percent gap figure is based on this report's figures claiming 49.6 percent ARV coverage among adults.)

19 National Institute of Statistics, "Enquête démographique et de santé et à indicateurs multiples (EDS-MICS 2011)", February 2012. (Note: The 87 percent gap figure is based on this report's figures claiming 13 percent ARV coverage among children.) Available online at: <http://www.statistics-cameroon.org/news.php?id=121>.

20 National AIDS Control Committee (CNLS), "Rapport annuel 2011 des activités de lutte contre le VIH, le Sida et les IST au Cameroun", 2012, p.24 (Note: The 77.1 percent gap figure is based on this report's figures claiming 22.9 percent CD4 test coverage.)

- 73 percent of funding for HIV treatment and health care comes from foreign sources.²¹ This large share is a concern because the overall decline in foreign funding for HIV/AIDS programming has led to shortages in HIV service provision. This is particularly true in Cameroon regarding condoms and biological test reagents (including for CD4 tests), with shortages linked to the withdrawal of World Bank funding and the reduction in funding from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund).

The two main types of facilities that offer HIV treatment and voluntary counselling and testing (VCT) services in Cameroon are CTAs (centres de traitement agréé, or approved treatment centres) and UPECs (unités de prise en charge, or support units). The majority of CTAs and UPECs are located within public health centres, with others within private-sector facilities and those operated by not-for-profit groups (usually faith-based organizations [FBOs]). In general, CTAs are located in big health centres while UPECs are within smaller ones.

In addition to CTAs and UPECs, some health centres offer only VCT services. The centres with only VCT services are generally in rural areas; most are in public facilities, but others are in private-sector ones and those run by a range of non-governmental organizations (NGOs).

2. NOTABLE FINDINGS AND OBSERVATIONS ASSOCIATED WITH TREATMENT 2.0

“Treatment 2.0” is the name of an initiative developed and launched in 2010 by the World Health Organization (WHO) and Joint United Nations Programme on HIV/AIDS (UNAIDS). It aims to simplify and improve the way HIV treatment is currently provided in order to maximize the effect of ART and further scale up access to HIV treatment, care and support. The initiative focuses on innovation and efficiency in HIV programming, including the integration of important new findings such as the preventive effects of ART.²²

WHO and UNAIDS are currently developing various frameworks that will help countries and all stakeholders develop and implement strategies based on Treatment 2.0 principles and priorities. The frameworks will be based on the initiative’s five main priority work areas, also known as “pillars”:

1. Provide point-of-care and other simplified diagnostic and monitoring tools
2. Optimize drug regimens
3. Reduce costs
4. Adapt delivery systems
5. Mobilize communities

The agencies have worked closely with partners at global, regional and country level to explain the Treatment 2.0 agenda in general, and the importance of the five pillars specifically. This effort also seeks to build support for the overall approach, which can only be successful when countries’ HIV programmes and strategies align with it.

Findings and observations obtained through research for this report are organized by the five Treatment 2.0 pillars (Sections 2.1 through 2.5 below). This structure is intended to highlight progress, gaps and challenges in Cameroon regarding expanded and enhanced HIV treatment for all in need.

21 National AIDS Control Committee (CNLS), “The impact of HIV and AIDS in Cameroon through 2020”, September 2010, p.23. Available online at: www.healthpolicyinitiative.com/Publications/Documents/1250_1_Cameroon_EN_Singles_Reduced_acc.pdf.

22 Detailed information about the Treatment 2.0 agenda may be found online at: http://data.unaids.org/pub/Outlook/2010/20100713_fs_outlook_treatment_en.pdf.

Existing awareness of Treatment 2.0 in Cameroon

In general, it appears there is a decent level of knowledge on the Treatment 2.0 agenda among governmental authorities such as the permanent secretary of the Central Technical Group of CNLS. However, people are less informed further down the decision-making chain. Thus, for example, the coordinator of the CTA in Maroua was familiar with the Treatment 2.0 initiative but not the nurses at Ngoya I health centre.

Awareness of the initiative is relatively limited among community groups and PLHIV. Most, though, had general knowledge about key issues associated with HIV treatment and care. Some focus group participants showed high awareness of important elements of the Treatment 2.0 agenda such as the need to reduce drug stock-outs and obstacles associated with intellectual property rights. A focus group participant in Yaoundé noted the following:

Support (psychological, nutritional, and spiritual) is an essential precondition. It must be associated with care in order to encourage patients to accept treatment. A good treatment education is needed, because it is not enough to provide only drugs.

2.1 Provide point-of-care and other simplified diagnostic and monitoring tools

HIV testing

The number of people in Cameroon tested for HIV reached a high of 597,352 in 2008 before dropping each year, to 426,250 in 2011.²³ In urban areas, numerous centres offer HIV testing services. There is a difference between the main cities (Yaoundé and Douala) and other towns, however. While those two cities have more than a dozen centres providing testing services, in Bamenda it is difficult to find more than one. Rural areas are poorly covered, and clients often must travel to other places to receive an HIV test. This is the case for example in Salak, Godola, Manjo and Ngoya.

Moreover, integrated health centres (clinics which mostly exist in rural areas) are not always sufficiently equipped to conduct HIV tests; clients therefore have to go to government medical facilities such as centres médicaux d'arrondissement (CMAs), district hospitals, regional hospitals or reference hospitals located in main towns. They can also go to private clinics, which however are more expensive. Voluntary testing campaigns are not permanent; they are often organized during the Week Against AIDS or in the context of initiatives such as "Holidays without AIDS" launched every year by the CNLS between July and September.

NGOs and PLHIV organizations do not carry out HIV screening; their participation in the testing process is generally limited to pre- or post-test counselling. The entities involved in the purely medical aspect of testing are hospitals both in the public and private sectors as well as not-for-profit groups including FBOs and other NGOs such as the Cameroon National Planning Association for Family Welfare (CAMNAFAW).

HIV tests are available for free for pregnant women and students at all times. They are also free for others during special periods including National AIDS Week (immediately before World AIDS Day); National Women's Week (the week before International Women's Day); National Youth Week (the week before National Youth Day); and the "Holidays without AIDS" initiatives held periodically. Otherwise,

23 National AIDS Control Committee (CNLS), "Rapport annuel 2011 des activités de lutte contre le VIH, le Sida et les IST au Cameroun", 2012, p.39.

healthcare centres offer rapid tests for an official cost of 500 CFA (about \$1).²⁴ However, this official cost is not always respected as some health centres charge higher amounts at times for reasons ranging from “auctioning” off limited supplies of tests to pure graft. Even the 500 CFA amount is difficult for many people to afford, given that most Cameroonian families subsist on less than \$2 a day.

The increasing use of rapid tests is an improvement, but this development also has challenges because the results must be confirmed by other tests. As a result, the overall time from getting tested to receiving confirmed results is at least one week. This gap could be a factor in explaining the number of people who do not return to receive their results.

Many respondents to this research highlighted the absence of pre- and post-test counselling, even though it is required by governmental policy. In practice, this often means that healthcare personnel do not give clients an opportunity to ask questions about the test itself or about HIV more generally; patients also are rarely referred to support groups or other services that may help them after receiving a diagnosis. Several also said they were tested by medical staff without their consent.

Steps reportedly have been taken to improve the situation. For example, PLHIV organizations, government agencies and donors supported a programme training PLHIV to work with public hospitals to advise and monitor newly tested PLHIV. Other similar collaborative initiatives have been launched to implement projects to boost treatment education, with local groups involved including the Association des Femmes Actives et Solidaires (Association of Women Active and Interdependent, or AFASO), Overcomers, Association des Frères Unis de l'Extrême Nord (Association of the United Brothers and Sisters in the Far North, or AFSU-EN), Hope Is Rising Association (HIRASSO) and New Way+.²⁵ Direct engagement of this sort with PLHIV organizations is a way to systematically direct people to support groups.

The majority of focus group participants said they had been tested for HIV on their own initiative, or upon advice from a healthcare professional. When discussing why they agreed to be tested, the majority recall having already manifested symptoms. This indicates that most were diagnosed quite late in the course of infection. Such late uptake of testing underscores the limited success of communication strategies around HIV to boost testing more broadly across society, thus highlighting a failure in existing HIV prevention programmes.

HIV-related stigma and confidentiality breaches are two key barriers to a significant increase in the number of voluntary tests conducted. Reports surface regularly of medical staff improperly disclosing clients' HIV status to others. A participant at the Obala focus group said the following: “It is my senior sister [nurse] who informed me about my HIV-positive results, which had been given to her by the medical staff.”

Monitoring tests

CD4 tests are generally available. However, as with all other key diagnostic tests, they are not available free of charge. The cost of CD4, tuberculosis (TB), viral load and resistance tests are, respectively, 2,500

24 National AIDS Control Committee (CNLS), “Rapport annuel 2011 des activités de lutte contre le VIH, le Sida et les IST au Cameroun”, 2012, p.43.

25 The initial programme was set up through the World Bank-funded Multisectoral AIDS Programme (MAP). Through it, PLHIV were trained and recruited in health centres and then charged with carrying out counselling. Many of the PLHIV are supported by local CBOs, which also provide additional training to help them support their peers in a range of areas from counselling to adherence monitoring.

CFA (\$4.65),²⁶ 1,000 CFA (\$1.85),²⁷ 16,000 CFA (\$30)²⁸ and 150,000 CFA (\$279).²⁹ Moreover, patients often have to pay more due to factors including frequent re-agent shortages and poor-quality (or even outdated) equipment. Thus, for example, getting a CD4 test may cost a patient as much as 21,000 CFA (\$39), which is more than eight times higher than the official fee. The government and NGOs sometimes subsidize patients' costs, but most usually must pay a fee. People without sufficient financial means often are unable to obtain tests at all or delay them.

Although not systematic, the monitoring test most regularly conducted in addition to the CD4 test is TB screening. In cities and secondary towns, diagnosis and treatment are generally offered in the same centres. This is not the case in rural areas, however, where services are limited.

Understanding of the importance of CD4 counts remains low. Almost half of focus group participants did not recall their first CD4 count after being diagnosed with HIV. This may highlight a low awareness of the significance of the CD4 rate by PLHIV.

Most respondents said that they had been referred for medical treatment soon after receiving their HIV diagnosis. They confirmed that in practice, as soon as a person is diagnosed with HIV, he or she is immediately referred to a treatment centre for examination (and to receive a CD4 test).³⁰ The decision to put a patient on ART depends on the results of these biological tests and is made by a therapeutic committee. The time for all steps leading to treatment (if recommended) varies according to several factors, particularly the distance between the patient's home and health facility, the financial capacity of the patient to pay fees, and the frequency of therapeutic committee meetings. The patient may thus wait between less than two weeks and more than one month before knowing whether he or she is to be offered treatment.

2.2. Optimize drug regimens

Cameroon's treatment guidelines align with the latest World Health Organization (WHO) guidance. Thus, for example, PLHIV are eligible for ART if their CD4 count is below or equal to 350 cells/mm³. Also, treatment policies and guidelines prioritize the elimination of d4t in all regimens.

All ARVs provided in Cameroon are generic versions. The most common first-line regimens include the following: AZT+3TC+NVP; AZT+3TC+EFV; TDF+3TC+NVP; TDF+3TC +EFV; TDF+FTC+NVP; and TDF+FTC+EFV. Available second-line regimens usually use two nucleoside reverse-transcriptase inhibitors (3TC, AZT, FTC or TDF) plus a protease inhibitor, usually LPV/r. The proscribing and use of these main ARVs was confirmed by focus group participants on treatment.

Fixed-dose combinations and once-a-day dosing are almost nonexistent as the majority of people receiving treatment take more than one tablet per day, and almost all respondents reported taking tablets twice a day. Another lingering challenge is that although d4T has been officially removed from the official list of recommended drugs, combinations containing it continue to be prescribed in some places.

26 National AIDS Control Committee (CNLS), "Rapport annuel 2011 des activités de lutte contre le VIH, le Sida et les IST au Cameroun", 2012, p.43. Available online at: www.cnls.org/public/web/IMG/pdf/rapport_annuel_2011_activites_lutte_contre_vih_sida_et_ist_cam.pdf.

27 Dongmo, K. "Prévision de l'évolution des principaux indicateurs de la tuberculose au Cameroun", 2010, p.8. Available online at: www.visualstat.com/master/memoires/2010/dongmo/dongmo.pdf.

28 According to a focus group respondent in Obala, 26 April 2012.

29 According to a focus group respondent in Yaoundé, 22 April 2012.

30 Ministère de la Santé (Ministry of Health), Directives nationales de prise en charge par les antirétroviraux des personnes (adultes et adolescents) infectées par le VIH, 2010, p.2.

The vast majority of ARVs are provided by public health facilities—including 23 CTAs (in the main cities) and 117 UPECs—in 100 of 181 health districts. In addition, some private-sector and FBOs also offer ARVs. Regardless of the category of facility (public, private or FBO), first-line and second-line ART is available free of charge.

The availability of free ART does not mean there are no difficulties accessing treatment, however. ART access is contingent upon having had certain key diagnostic tests, including CD4, transaminase and creatinine,³¹ which are confirmed by doctors in a document that enables patients to get prescriptions at pharmacies. Patients must pay a fee for these tests, however, and many poor PLHIV cannot afford them and thus are not able to get ARV prescriptions. Many PLHIV are also not able to meet nutritional requirements in connection with taking a daily ART regimen. Several NGOs have programmes supporting PLHIV to overcome challenges associated with nutrition.³²

There are also important differences between coverage levels around the country. In the big cities and secondary towns, access to centres offering ART is straightforward. In rural settings, it is more difficult to get to ART distribution centres because of the distances involved and the cost of transport. Of 180 health districts in Cameroon, ART facilities are currently located in just 102 (thus corresponding to 56 percent district level coverage).³³

ARV stock-outs occur regularly at the UPECs and approved treatment centres, particularly in secondary towns and semi-urban areas. In such instances there is an almost total lack of drugs; in comparison, medical staff in Yaoundé and Douala often are able to ensure that patients have drugs for one or two weeks while stocks are replenished. These stock-outs have led some PLHIV to build reserves from the parallel market. The presence of this parallel market is, of course, the result of the fact that the ARV distribution system is insufficient. Also, some PLHIV, particularly those who are members of support groups, have developed consistent support mechanisms whereby some people are prepared to share their own drugs until stocks return to normal.

Stock-outs have been known to plague certain areas regularly, thus highlighting major problems with distribution and procurement systems. The individual impact is seen in the accounts provided below from focus group discussion participants:

I spent two successive months (March-April 2011) without any ART because of stock-outs at the approved treatment centre in Maroua.

—HIV-positive woman at focus group in Godola (rural area), 1 May 2012

Since November 2011, there have been frequent interruptions at the CNPS hospital. Pharmacists often give tablets for two weeks instead of a month and advise to call before returning [for a refill]. With these frequent breaks, I have to restock by buying from the black market.

—HIV-positive man at focus group in Yaoundé (urban area), 22 April 2012

31 Ministère de la Santé, Directives nationales de prise en charge par les antirétroviraux des personnes (adultes et adolescents) infectées par le VIH, 2010, p.3.

32 National AIDS Control Committee (CNLS), “Rapport annuel 2011 des activités de lutte contre le VIH, le Sida et les IST au Cameroun”, 2012, pp.49-50. Available online at: www.cnls.org/public/web/IMG/pdf/rapport_annuel_2011_activites_lutte_contre_vih_sida_et_ist_cam.pdf.

33 National AIDS Control Committee (CNLS), “Rapport annuel 2011 des activités de lutte contre le VIH, le Sida et les IST au Cameroun”, 2012, p.42. Available online at: www.cnls.org/public/web/IMG/pdf/rapport_annuel_2011_activites_lutte_contre_vih_sida_et_ist_cam.pdf.

Some participants at the focus group discussion in Godola, in rural Cameroon, said that since 2010 none of them had taken ARVs and cotrimoxazole for 12 months successively without a break. Some patients reportedly have discontinued their treatment because of such frequent interruptions. One participant said the following:

Yesterday, I went to get my medication and could not get any and will go again tomorrow. There have been other times I did not go because I was sick. Three times during the past 12 months, I went and had no treatment. I went 14 days without medication in November 2011 and visited Maroua [the regional capital] five times; seven days without drugs in June-July 2011, when I went three times to Maroua; and seven days in April-May 2012.

—HIV-positive woman at focus group in Godola (rural area), 1 May 2012

Some patients reportedly have given up their treatment because of repeated stock-outs, particularly in rural areas situated far away from HIV care facilities. Other reports indicate that patients sometimes switch regimens not because of clinical indications or requirements, but simply so that they can continue taking ART if their original regimen is experiencing stock-outs. A focus group participant in Yaoundé said the following:

“At the general hospital, drug stock-outs are very rare, [but] there was a period when they switched drugs for two months before returning to the initial regimen.” Such switches are extremely problematic because they can lead to drug resistance and treatment failure, especially when not undertaken for clear, clinical reasons.

Patient compliance appears to be facilitated by sharing their HIV status with a loved one. One focus group participant (in Yaoundé) said the following: “It is my wife and my son who remind me regularly when it is time to take my drugs. My son does not know my HIV status, but he knows that I take tablets each day at precise hours.” Others said they help themselves remain adherent by associating ART with a mobile phone alarm, a TV series, or praying times, among supporting devices.

2.3 Reduce costs

ARVs are imported and paid for by the government through its national budget and external funding, in particular the Global Fund and the Clinton Foundation in terms of paediatric ARVs. In 2010, the total amount spent on HIV treatment, care and support was about \$42 million, of which nearly half (\$20 million) was used to procure ARVs.³⁴ Overall, the Cameroonian government contributes less than half (about 43 percent) of all funding for the AIDS response.³⁵

Overall costs have continued to rise as more people are placed on ART and more facilities are opened to provide medicines as well as associated care, including diagnostic tests. Few efforts to reduce costs associated with service delivery have yet been undertaken. For example, only doctors are allowed to both prescribe and dispense ARVs. This contributes to their heavy workload and decreases efficiency that could be improved by having trained nurses and NGO staff directly involved in treatment delivery. Such a change could also help decentralize care and bring HIV treatment closer to communities. This would likely reduce costs as well as improve the quality of care and adherence levels, especially if patients no longer have to travel long distances to see doctors.

34 National AIDS Control Committee (CNLS), “The impact of HIV and AIDS in Cameroon through 2020”, September 2010, p.23. Available online at: www.healthpolicyinitiative.com/Publications/Documents/1250_1_Cameroon_EN_Singles_Reduced_acc.pdf.

35 National AIDS Control Committee (CNLS), “Rapport annuel 2011 des activités de lutte contre le VIH, le Sida et les IST au Cameroun”, 2012, p.75. Available online at: www.cnls.org/public/web/IMG/pdf/rapport_annuel_2011_activites_lutte_contre_vih_sida_et_ist_cam.pdf.

All first- and second-line ARVs currently procured are generic versions, with most coming from India. Civil society groups in Cameroon have joined global protests against developments that may restrict this pipeline by, for example, tightening Indian patent laws and policies. The debilitating consequences of high-cost ARVs can already be seen in regards to the fact that third-line ARVs are not available in Cameroon because they are too expensive. The main reason is that no generic versions are available.

2.4. Adapt service delivery

The provision of integrated services for HIV, TB, sexually transmitted infections (STIs) and reproductive health is considered to be an important priority by all respondents. However, the management of HIV/TB co-infection continues to suffer from a serious lack of coordination. Currently the national TB programme operates 216 specialized treatment centres while the national HIV/AIDS programme has around 150 (CTAs and UPECs).³⁶

Integrating care at these more than 370 total facilities would achieve greater coverage for people living with both conditions and also ensure that HIV/TB co-infection is treated more systematically and effectively. The current divided structures means that even if an ART regimen exists and is recommended for a co-infected individual, the reference and feedback system between UPECs/CTAs and the TB centres is weak.³⁷ This is a major and growing problem given that more than one-third (38 percent) of TB patients are HIV-positive.³⁸

Some general healthcare facilities provide a wide range of integrated services: family planning, prevention and treatment of STIs, antenatal care, paediatrics and social assistance, prevention and/or treatment of TB, and prevention and management of opportunistic infections. For example, the following offer integrated HIV and TB treatment services: Jamot hospital in Yaoundé, the regional hospital in Maroua, the Laquintinie hospital in Douala, the regional hospital in Nkongsamba, and the regional hospital in Bamenda. In addition, the regional hospital in Maroua offers integrated treatment services for HIV, TB and hepatitis C.

However, within these healthcare centres, it is recognised that the integration of additional services affects the quality of HIV treatment, even if patients believe that this move towards integrated services is important and necessary. The negative impacts can be explained by the fact that the increase in workload associated with the integration of services is not always accompanied by additional resources (staff, equipment, space, etc.). Effective integration is also slowed by inherent problems associated with the insufficiency of funding to deal with diversification of services; the lack of adequate human resources; the shortage of health facilities; and the absence of policies and procedures to build staff capacity.

As noted previously (Section 2.3), only doctors are authorised to prescribe and dispense ARVs. Most believe themselves to be the only ones adequately prepared for that responsibility and think they have sufficient time to carry out effectively. Yet doctors and patients have far different expectations regarding what is “sufficient”. Doctors report setting aside 15 to 20 minutes for each patient, but most other

36 Dr Zoung-Kanyi Bissek (MINSANTE), Dr Elat Jean Basco (CNLS), Dr Milengue Pascal, “Dépistage de la TB et prophylaxie a l’isoniazide chez les PVVIH: expérience du Cameroun”, 2012, p.5. Available online at: www.stoptb.org/wg/tb_hiv/assets/documents/MeetingDocs12/Day%201/D%C3%A9pistage_TB_et_prevention_INH_Cameroun_ACB.pdf.

37 Dr Zoung-Kanyi Bissek (MINSANTE), Dr Elat Jean Basco (CNLS), Dr Milengue Pascal, “Dépistage de la TB et prophylaxie a l’isoniazide chez les PVVIH: expérience du Cameroun”, 2012, p.14. Available online at: www.stoptb.org/wg/tb_hiv/assets/documents/MeetingDocs12/Day%201/D%C3%A9pistage_TB_et_prevention_INH_Cameroun_ACB.pdf.

38 Dr Zoung-Kanyi Bissek (MINSANTE), Dr Elat Jean Basco (CNLS), Dr Milengue Pascal, “Dépistage de la TB et prophylaxie a l’isoniazide chez les PVVIH: expérience du Cameroun”, 2012, p.4. Available online at: www.stoptb.org/wg/tb_hiv/assets/documents/MeetingDocs12/Day%201/D%C3%A9pistage_TB_et_prevention_INH_Cameroun_ACB.pdf.

respondents think that amount of time is not nearly enough from patients' perspective and needs. In addition, it appears that doctors often over-estimate their ability to provide HIV/AIDS services as comprehensively as might be needed. In rural areas, most notably, each doctor covers a substantial population and a vast territory (often several councils) and has various medical and administrative responsibilities—management of patients; implementation of vertical transmission services; supply of drugs, materials and equipments, etc. By definition he or she thus has inadequate time to provide quality patient care. In large cities there are many more doctors in each HIV care unit. However, those units tend to have a much larger number of patients, a factor that limits their doctors' quality of service.

PLHIV usually bear the brunt and consequences. A focus group participant from Yaoundé, the president of an association of PLHIV, stated the following:

Often, one is obliged to pay (because of corruption) for some services [that are supposed to be provided for free], such as the renewal of ARV prescriptions. We are obliged to do so because it is at the Yaoundé Central hospital that there are the most qualified specialists.... Sometimes, the doctors there consult us without even looking at us.

Few PLHIV respondents said they have received any help from the government regarding comprehensive HIV services. Many stated, though, that they had received support from NGOs, including advice, employment opportunities, training, financial help, social assistance, medical aid, nutritional and spiritual support, and technical support to run their organizations. Such statements and perceptions indicate that many HIV-positive individuals retain negative impressions of the government even though the public sector does offer important HIV-related services such as free ART. In other areas related to HIV treatment, however, patients generally experience only frustration and obstacles that they associate with the government. For example, negative experiences at healthcare centres—lack of warm or comforting “welcome”, administrative hassles, long waiting lists, slow and delayed service provision, etc.—greatly influence broader impressions of the government's capacity and quality in service provision. In light of such experiences, PLHIV find it difficult to understand that the government plays a significant and indispensable role in treatment.

2.5 Community mobilization

The NGO sector is an important player in the fight against HIV/AIDS. All parts of the country, rural and urban, are covered by PLHIV organizations, through local groups or local representatives of networks with national or regional coverage. PLHIV groups and key populations provide most activities around treatment (care, support, advice, reference). However, they are not involved in the distribution of ARVs. Their involvement is limited to encouraging access to ARVs through advice, education and reference activities. This restriction is in large part due to the government's desire to control the distribution of ARVs. The exclusion of NGOs has had the effect of making CBOs consider (perhaps subconsciously) that ARV distribution is not a priority objective. However, taking into account the importance of ARVs, some CBOs have developed capacity-building activities for healthcare staff on ARVs. Most have received support for such activities from both domestic and external experts and donors.

Though excluded from direct treatment service delivery, CBOs do offer all kinds of counselling and advice, including in regards to HIV testing and vertical transmission services. Many also offer specific services including case management; support for home and hospital visits; psychological, social, spiritual and nutritional care; and references for treatment of TB, hepatitis, STIs, fungal infections, etc.

The involvement of PLHIV through these NGOs generally leads to improved outcomes, both at the national level and with members. ARVs became free of charge in 2007 thanks in part to the strong mobilization of PLHIV associations. Numerous PLHIV rediscovered their love for life and starting making plans for the future after having joined a support group. Joining such groups helps them comply better with treatment and prompts them to develop strategies and mechanisms to deal with stigmatisation, discrimination and even ARV stock-outs.

Although none of the support groups which PLHIV belong to distribute ART, most are involved in promoting treatment literacy among their members and at ART centres. Additional areas that support groups often focus on are advocacy, efforts to address HIV-related stigma and discrimination, and awareness-raising.

The government provides some support for PLHIV support groups and community organization. Yet most nevertheless have limited human and financial capacity. In general, staff include a small number of employees (rarely more than one full-time person), and activities tend to be organized and delivered on a volunteer basis. Few organizations have a technical advisor—someone who is responsible for supporting the group in terms of their organizational development. In this highly voluntary context, CBOs are permanently in need of training.

3. KEY CHALLENGES

This section summarizes some of the main challenges identified during research to an enhanced and expanded HIV response in Cameroon. Improvements in such areas are considered critical for the effective adoption and implementation of the Treatment 2.0 framework in the future.

Unequal coverage by testing and treatment services

In general, urban areas are more likely to be covered than semi-urban and rural areas. Patients in non-urban areas are less aware of HIV in general, including the potential need to be tested, and if HIV-positive must travel long distances to care facilities where stock-outs are common.

Insufficient (and late) uptake of testing

Awareness-raising efforts have not been very effective in prompting uptake of HIV testing among the general population. This observation is based on the fact that the majority of respondents made the decision to be tested after the appearance of the first symptoms of opportunistic infections.

Insufficient access to effective, comprehensive ART

The following, many of which were discussed in Section 2, are the key obstacles to effective, comprehensive ART in Cameroon:

- Nutritional issues: some poor or destitute PLHIV lack regular access to the necessary food and nutrition that enable them to take ART regularly and easily (without side effects, etc.).
- Costs associated with treatment, including for office visits and diagnostic tests, can be prohibitive. Patients generally must pay for all tests, including those that must be carried out regularly.
- Repeated stock-outs of ARVs.
- Inconvenient distance from treatment centres, particularly in rural areas.
- Congestion at some treatment centres, particularly those that provide free care (and thus receive high levels of funding and subsidies). This slows down the service and means patients are subject to long waiting times.

- Myths about HIV and treatment associated with religion. Some church pastors claim that HIV can be overcome through faith and holy water, and their followers often follow their instructions and do not seek medical treatment or care. These churches are thus a significant barrier to effective HIV/AIDS programming as they are increasing in number both in urban and rural areas.

The persistence of HIV-related stigma and discrimination

Respondents indicate that stigma and discrimination remain extensive throughout society. The problem remains common in healthcare settings, with examples such as one treatment centre in Yaoundé setting up a dedicated area for receiving PLHIV that is called the “accused camp” by some medical staff. Others cited regular insults and condescending attitudes towards PLHIV patients in almost all treatment centres. These acts of stigmatisation belie a poor understanding of effective medical and psychosocial care techniques for PLHIV. A focus group participant from Obala said the following: “I have seen (even in 2012) scenes at a Yaoundé hospital where doctors shout loudly at a patient regarding his or her HIV status in the presence of many people.”

Other areas where HIV-stigma and discrimination are particularly difficult to overcome include the following:

HIV infection can create instability within couples and families. Several PLHIV respondents said they had been abandoned by their partners after telling them of their HIV status. Based on anecdotal evidence from around the country, a non-negligible proportion of PLHIV are often ostracized and not asked to attend social events such as weddings and family get-togethers. A focus group participant from Yaoundé said the following: “A young member of our group had to leave the family residence because she was isolated and stigmatized in her own family.”

Although few PLHIV respondents said they had lost their jobs or had limited access to employment, this finding likely reflects their not disclosing their HIV status at the workplace. The fact that they keep their HIV status secret reflects their perception of the dangers (e.g., harassment and dismissal from a job) facing them if their HIV status were to become known. Currently there are no specific laws or policies protecting PLHIV against discrimination, although some provisions of civil, penal or labour acts can be used to protect PLHIV rights.

Limited involvement of the civil society sector in the provision of testing services as well as ART delivery

NGOs do not offer testing services and are not allowed to distribute ARVs. However, in a context where public-sector HIV care units are only established in 56 percent of health districts (100 of 181), NGOs are usually closer to patients. In addition, they tend to uphold confidentiality better and are less stigmatizing compared with hospitals, which are considered by PLHIV to be places where they might face stigma and discrimination.

Limited integration of HIV treatment programmes with those addressing TB and other illnesses linked to HIV

Few hospital centres offer both care for PLHIV and for people affected by TB and other illnesses related to HIV such as hepatitis C. On an institutional level, although HIV and TB treatment are now provided free of charge (TB since 2002, HIV since 2007), they are provided through different programmes with little linkage between them. This is a major gap as TB is among the most commonly contracted opportunistic disease for PLHIV. Patients facing the combination of both diseases are generally obliged to visit different hospitals (or access different services in the same hospital) and have multiple doctors.

Such arrangements and systems are inefficient and difficult for patients to deal with, especially when they are physically weak.

4. RECOMMENDATIONS

Decentralized territorial coverage of testing and treatment services should be emphasized

The Ministry of Public Health should facilitate close collaboration between the National Centre for Essential Medicines (CENAME) and CNLS to improve the system of supplying and distributing drugs, reagents and other medical inputs. This is essential to reduce stock-outs.

The Ministry of Public Health should accelerate decentralisation of treatment of PLHIV by better integrating healthcare centres in rural areas into the ARV distribution system. This would help reduce the distances patients have to travel to other towns for treatment and care

CATAG/ITPC Central Africa should strengthen the capacity of community actors in terms of lobbying and advocacy so they have more influence in prompting health authorities to cover the gaps observed in the provision of health services.

HIV testing uptake should be increased

All stakeholders—government, CBOs (including associations of PLHIV), NGOs and donors—should intensify awareness-raising activities at all levels of society as to the benefits of testing. The Ministry of Public Health and CNLS should train and retrain people involved in pre- and post-test counselling and better enforce the requirement that such services are provided.

HIV-related stigma and discrimination healthcare settings should be addressed

The Ministry of Public Health and CNLS should train and regularly retrain medical staff (doctors, nurses) on HIV-related stigma and discrimination. This should be combined with steps to increase involvement of PLHIV in providing support to and following up with their peers in testing and treatment centres.

Greater involvement of NGOs in the provision of testing services as well as ART delivery should be facilitated

The Ministry of Public Health should consider integrating PLHIV organizations in the provision of testing services and the distribution of drugs. This effort would involve training and an acceptance of the critical importance of task-shifting. Another important step in this regard would be to allow nurses at health facilities to dispense ART and provide basic monitoring activities.

Steps should be taken to integrate HIV treatment into the overall public health system and structures

The Ministry of Public Health should integrate HIV-related services in order to reduce travel and inconvenience for patients, many of whom must visit different hospitals that may sometimes be in different towns. Integration should also include TB treatment and care. The best option would be for all relevant health services to be provided in all facilities, which would improve healthcare outcomes in general.

The government should eliminate all fees for HIV testing and for monitoring and diagnostic tests such as CD4 and viral load tests

Even small fees discourage uptake as they can be unaffordable to poor patients and their families in particular. The need to pay for critical tests puts a strain on many patients' resources and often contributes to them withdrawing from the healthcare process.

CHINA AND TREATMENT 2.0: CHALLENGES AND OPPORTUNITIES TO SCALE UP HIV TREATMENT

This country report is part of *Missing the Target 10 (MTT10)*, the 2012 version of a longstanding series on global access to HIV treatment coordinated by the International Treatment Preparedness Coalition (ITPC). *MTT10* focuses on challenges to the scale-up of HIV services as required to implement the Treatment 2.0 framework. As with other *Missing the Target* publications, national and local community groups conducted research based on a general template and prepared their country-specific reports. The following countries are included in *MTT10*: Cameroon, China, Côte d'Ivoire, Honduras, India, Kenya, Morocco and Russia.

The full *MTT10* report and individual country reports are available at the ITPC website: www.itpcglobal.org. Also available at that website are French versions of the Cameroon and Côte d'Ivoire reports and a Spanish version of the Honduras one.

China

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ACRONYMS AND ABBREVIATIONS

ART	antiretroviral treatment
ARV	antiretroviral drug
CBO	community-based organization
China CDC	Chinese Centre for Disease Control and Prevention
IDU	injecting drug user
MARP	most-at-risk population
MoH	Ministry of Health
MSM	men having sex with men
NCAIDS	National Centre for AIDS/STD Prevention and Control
NGO	non-governmental organization
PLHIV	people living with HIV
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
VCT	voluntary counselling and testing
WHO	World Health Organization

Note on text: All "\$" figures are U.S. dollar amounts. All URLs cited were valid as of 1 October 2012.

HIV drugs list

Many HIV drugs are commonly referred to in an abbreviated format. Listed below are the abbreviated names of all the drugs mentioned in the China report as well as the full generic name associated with them. Where relevant, brand names of key drugs are also noted. The drugs are grouped by class.

NRTIs (nucleoside reverse-transcriptase inhibitors)	
3TC	lamivudine
d4T	stavudine
AZT	zidovudine
TDF	tenofovir
NNRTIs (non-nucleoside reverse transcriptase inhibitors)	
EFV	efavirenz
NVP	nevirapine
Protease inhibitors	
LPV/r	lopinavir/ritonavir (refers to lopinavir being “boosted” by ritonavir)

1. INTRODUCTION AND OVERVIEW

1.1 Methodology

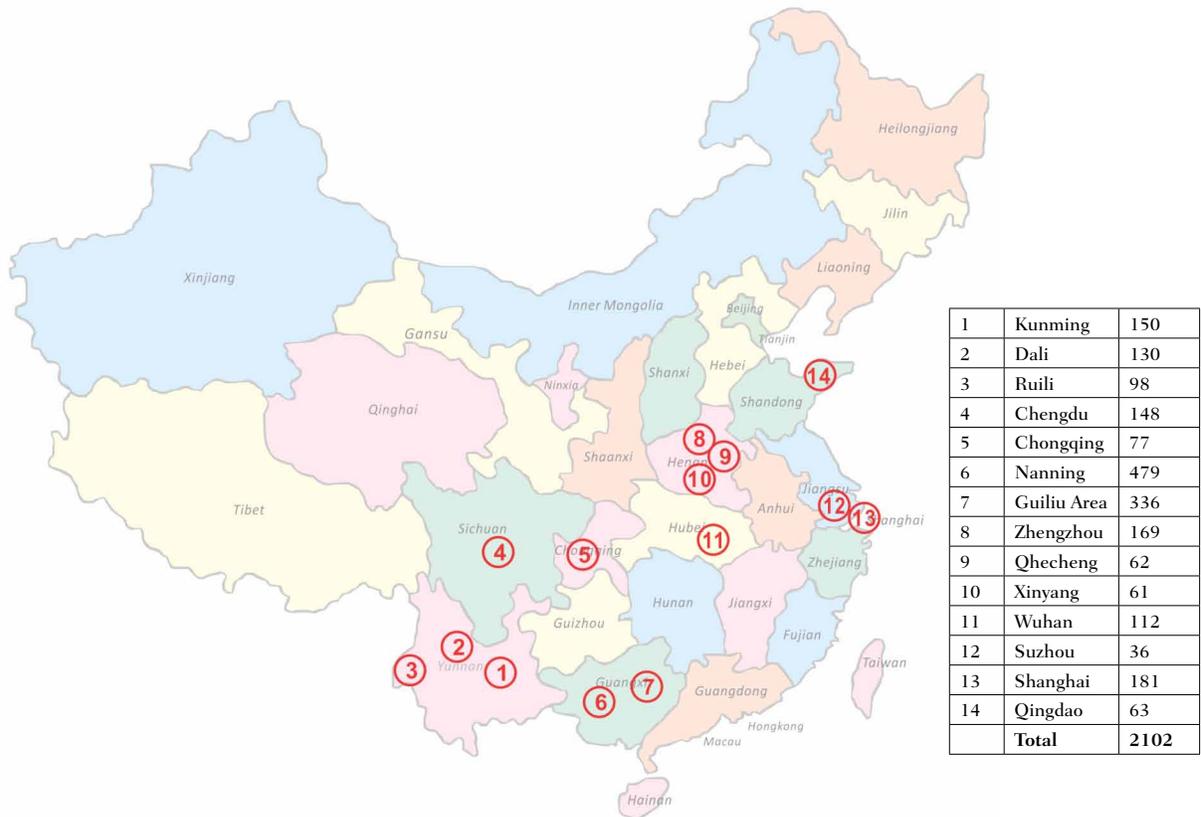
Research for this report was conducted during the first half of 2012. It involved a literature review; an online survey of 2,102 people living with HIV (PLHIV);³⁹ and individual and focus groups interviews with a total of 62 people (16 clinicians/doctors, 7 health bureau officials, and 39 PLHIV). The online survey questionnaire and interview template were designed by ITPC China in close consultation with PLHIV groups from around China and an independent consultant. Individual and focus group interviews were conducted by representatives from 18 community-based organizations (CBOs) from 16 cities and counties, together with ITPC China staff and volunteers.

The 16 cities/counties covered by this report are located in eight provinces: Guangxi, Henan, Hubei, Jiangsu, Shandong, Shanghai, Sichuan and Yunnan. The areas were chosen for geographic variety and to include those with both high and low disease burden (for China) and high and low per capita income. According to government data, more than 60 percent of PLHIV are from five provinces of China (Yunnan, Guangxi, Sichuan, Xinjiang and Guangdong); three of those provinces were included in this research. Figure 1 below shows the geographic distribution of respondents to the online questionnaire.

After the collection of online surveys, ITPC China staff re-interviewed at least 10 percent of the respondents by telephone for verification and quality check of information collected online. All interview teams provided a full list of interviewees, but personal information from those lists is not publicly available in order to safeguard confidentiality.

39 The gender ratio of PLHIV surveyed reflected the demographics of the epidemic in China. Seventy-one percent of survey participants were male, with the remaining 29 percent female. The gender ratio of PLHIV in China is 23.8 percent female and 71.4 percent male, according to estimates from 2011. Source: 2011 China HIV/AIDS epidemic estimates, November 2011; China Ministry of Health, UNAIDS and WHO. Available online at: www.chinaids.org.cn/n1971/n2151/n777994.files/n777993.pdf.

Figure 2. Geographic distribution of online survey respondents



Previous analysis conducted by both government and non-government bodies had shown that patient outreach, retention, and adherence are all major challenges to China’s HIV response.⁴⁰ However, much of that previous analysis was done with limited community-level data, making it extremely difficult for health authorities and other stakeholders to identify and confirm (with solid evidence) the root causes of patient drop-out, poor adherence, or other treatment barriers. In order to identify these root causes, and to be able to propose possible solutions to address them, the 2012 community-led research analyzed more than 2,000 surveys. It is therefore among the most comprehensive data-collection exercises conducted in China in regards to HIV.

1.2 Context

According to official government estimates, China was home to about 780,000 HIV-positive people at the end of 2011.⁴¹ HIV treatment is provided through the national HIV/AIDS control and treatment plan (the “four free and one care” policy⁴²) that was announced in December 2003. The programme has since expanded rapidly: by December 2011, approximately 120,000 people had started taking antiretroviral

40 See, for example, F Zhang et al (2011). “Effect of earlier initiation of antiretroviral treatment and increased treatment coverage on HIV-related mortality in China: a national observational cohort study. *The Lancet*, Volume 11, Issue 7, pp. 516-524.

41 2011 China HIV/AIDS Epidemic Estimates, November 2011; China Ministry of Health, UNAIDS and WHO. Available online at: www.chinaids.org.cn/n1971/n2151/n777994.files/n777993.pdf.

42 This policy refers to the following: free ARV drugs, free prevention of mother-to-child transmission, free voluntary counselling and testing, free schooling for children orphaned by AIDS, and care to people living with HIV/AIDS.

treatment (ART), up from only 30,000 in 2007.⁴³ Despite this increase, at least another 100,000 are thought to be in need of ART. The government hopes to reach them through its plan to put another 150,000 on treatment over the next four years.⁴⁴

The treatment scale-up plan is a key part of China's AIDS Action Plan 2011-15, which aims to reduce HIV incidence and AIDS mortality by 25 percent and 30 percent, respectively, by 2015. To reach these national targets, major changes have to be made for improving HIV services delivery systems and optimizing efficiency and cost of treatment. The active involvement of CBOs is recognized in the National Action Plan as an important element of efforts to achieve the targets.

Among the challenges are that, according to the Chinese government's own estimates,⁴⁵ a substantial number of people progress to full-blown AIDS each year. This points to late HIV diagnosis, which continues to be a huge obstacle to the Chinese government's aim to scale up effective ART and reduce HIV incidence and AIDS deaths.⁴⁶ A related concern is that less than half of PLHIV currently know their status.

Recent revisions of the treatment guidelines have improved treatment and diagnostic regimens available to PLHIV. However, local implementation of the guidelines has faced numerous institutional, bureaucratic, and budgetary barriers, which collectively have affected not only the number of people receiving ART but the overall quality and effectiveness of the treatment they finally receive.

1.3 Treatment 2.0 and 'cascade of care'

This report assesses the research results with a goal of identifying key barriers and challenges to HIV treatment and care in China. It uses as a foundation the principles of the Treatment 2.0 framework (summarized below) as well as the "cascade of care" model, which refers to the overall HIV treatment process from initial screening to initiation into ART with regular follow-up services. (Figure 2 shows the steps in the ideal "cascade of care" model.)

Three main themes guided the investigation and analysis:

Accessibility: what are the existing services and what are the main barriers to accessing the services?

Costs: what resources (e.g., time and money) does it take to use the services, and how much of a barrier is this for patients?

Quality: what is the experienced/perceived quality of services, and how does it affect treatment outcomes?

"Treatment 2.0" is the name of an initiative developed and launched in 2010 by the World Health Organization (WHO) and Joint United Nations Programme on HIV/AIDS (UNAIDS). It aims to simplify and improve the way HIV treatment is currently provided in order to maximize the effect of ART and further scale up access to HIV treatment, care and support. The initiative focuses on innovation and efficiency in HIV programming, including the integration of important new findings such as the

43 2011 China HIV/AIDS Epidemic Estimates, November 2011; China Ministry of Health, UNAIDS and WHO. Available online at: www.chinaids.org.cn/n1971/n2151/n777994.files/n777993.pdf.

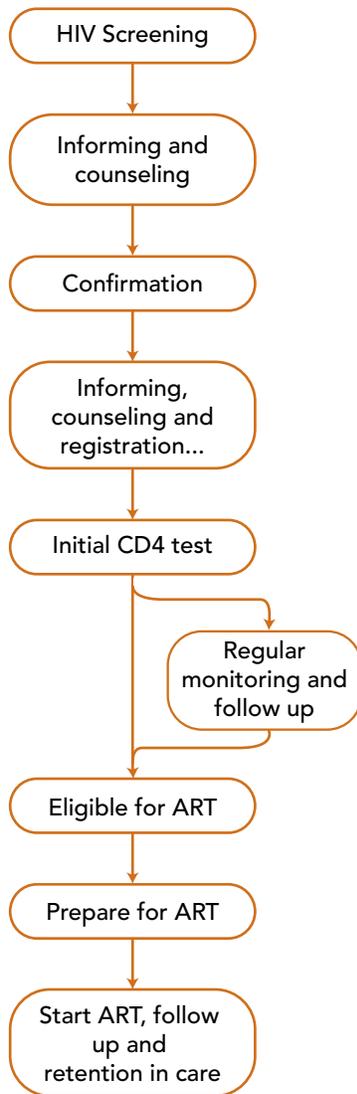
44 From NCAIDS presentation "HIV/AIDS in China" delivered at Yunnan Provincial AIDS Care Centre, March 2012.

45 2011 China HIV/AIDS Epidemic Estimates, November 2011; China Ministry of Health, UNAIDS and WHO. Available online at: www.chinaids.org.cn/n1971/n2151/n777994.files/n777993.pdf.

46 "Getting to Zero in China", UN Programme of Support for China's AIDS Response 2011-2015, October 2011.

preventive effects of ART.⁴⁷ UNAIDS and WHO are currently developing various frameworks that will help countries and all stakeholders develop and implement strategies based on Treatment 2.0 principles and priorities. The frameworks will be based on the initiative’s five main priority work areas, also known as “pillars”:

Figure 3. Ideal cascade of care for HIV treatment



1. Provide point-of-care and other simplified diagnostic and monitoring tools
2. Optimize drug regimens
3. Reduce costs
4. Adapt delivery systems
5. Mobilize communities

The agencies have worked closely with partners at global, regional and country level to explain the Treatment 2.0 agenda in general, and the importance of the five pillars specifically. This effort also seeks to build support for the overall approach, which can only be successful when countries’ HIV programmes and strategies align with it.

Findings and observations obtained through research for this report are organized by four of the five Treatment 2.0 pillars (see Sections 2.1 through 2.4). This structure is intended to highlight progress, gaps and challenges in China regarding expanded and enhanced HIV treatment for all in need. (Note: The one pillar that does not have its own section in this report is “Reduce costs”. The reason is that research for this report focused primarily on only one issue related to costs: those borne by patients for various HIV-related treatment and care needs. That information is integrated into the other four sections.)

2. NOTABLE FINDINGS AND OBSERVATIONS ASSOCIATED WITH TREATMENT 2.0

2.1 Provide point-of-care and other simplified diagnostic and monitoring tools

Of the slightly more than 2,000 PLHIV surveyed, 930 respondents had an ART-initiation baseline CD4 count below 200. This indicates late and limited uptake of HIV testing and/or poor referrals to treatment services. One reason HIV testing uptake is relatively low

is that it is not often voluntary in nature. More than two-thirds (69 percent) of PLHIV respondents to this survey said they had been tested in a compulsory manner, including:

- At a hospital (42 percent of survey respondents): mandatory pre-hospitalisation and pre-surgery testing, outpatient screening and pre-delivery screening

47 Detailed information about the Treatment 2.0 agenda may be found online at: http://data.unaids.org/pub/Outlook/2010/20100713_fs_outlook_treatment_en.pdf.

- Screenings organized by local branches of the Chinese Centre for Disease Control and Prevention (China CDC), including for members of vulnerable populations (10 percent of survey respondents)
- Pre-blood donation (3 percent of survey respondents)
- Routine tests (6 percent of survey respondents): these include health check organized by employer, pre-marital health check (compulsory in some regions), and health check for those who apply for health certificates.
- Closed settings (0.44 percent of survey respondents): testing in prisons, re-education camps and drug detoxification centres

Nearly all of those who said they were tested in a compulsory manner added that they received little or no pre- and post-test counselling. Referrals and linkages to care were limited as well. Only 18 percent of respondents discovered their status through a comprehensive voluntary counselling and testing (VCT) initiative, a finding that confirms the generally weak level of HIV awareness in China. People engaged in high risk behaviours are not aware of their risks, or they lack to access to client-centred HIV counselling and testing services. Due to fear of stigma, most people engaged in high-risk behaviour do not actively seek HIV testing services.

In principle, the government is committed to providing HIV testing free of charge to all,⁴⁸ including members of most-at-risk populations (MARPs). However, there are some important exceptions to this policy that mean many people end up paying for an HIV test. Most notably, patients are charged fees for hospital-based HIV screening, and individuals who do not want to provide their real names when tested also must pay a fee. (The second option is essentially pointless in the long run because the real name based system is directly linked to the entitlement of free ART. A confirmation result certificate with the person's real name and identification is a condition for receiving free ART in all provinces.). Prices for screening tests vary from region to region. The average price for one ELISA test is about RMB 50 (\$8),⁴⁹ plus any hospital registration fees.

In addition, some peripheral costs restrict access to testing for some people. All those who test positive must have a confirmation test, and such tests are usually provided only at a few places in a municipality or at a provincial China CDC lab. The cost of transportation to and from the confirmation lab can be a major barrier for poor patients, especially in rural areas.

Once confirmed to be HIV-positive, all PLHIV are meant to receive a set of initial diagnostic tests, including a **CD4 test**. However, the survey revealed a serious gap in the provision of these services. For example, one-third of the PLHIV respondents said they waited for more than three weeks to get their first CD4 test after their HIV diagnosis was confirmed. A major reason for such delays is that in low-burden areas, CD4 reagents are often procured in limited amounts and patients must travel lengthy distances to have their blood drawn on certain dates (e.g., once every month). Such delays increase the potential loss of contact with PLHIV and contribute to "loss to follow-up", which the Chinese government acknowledges is a significant barrier to scaling up ART coverage.

Current policies state that *prior to ART initiation*, all PLHIV should receive at least one CD4 test a year for free. In provinces where central government policies are implemented well, they can get two or even

48 Confirmation testing is nationally real name based. No anonymous confirmation testing is available.

49 This is the price for tests using locally made reagents. The price is higher when imported reagents are used.

more free CD4 tests a year. In Yunnan, for example, policies call for non-ART-taking PLHIV with previous CD4 tests below 400 to receive a CD4 test every six months.

According to the national free ART manual, *after initiating treatment* PLHIV should receive regular monitoring tests, including CD4 tests, every three months for the first year, and at least two CD4 tests in the following years. The survey results found limited compliance with these standards. More than 60 percent of PLHIV respondents said they only had either one or two CD4 tests during their first year on ART. The lack of access to a suitable number of free CD4 tests prompts many PLHIV to pay out of pocket for such tests on occasion. Each test costs an average of RMB 200 (\$32), an amount that many cannot afford very often (if at all), especially in poorer rural areas.

During the early years of the national treatment programme, **viral load testing** was irregular or unavailable in many provinces due to lack of equipment or expertise (or both). The central government recently has invested heavily in equipment, and new guidelines require that all PLHIV on ART should be provided at least one free viral load test per year. That requirement seems to be largely met. Eighty-one percent of 1,661 respondents (PLHIV on ART) replied that they had received at least one viral load test, with most of them (64 percent) saying they took one such test every 12 months.

Although most PLHIV respondents were able to receive viral load tests, the survey revealed serious delays in getting the results. Only 26 percent said they could usually get their result within 30 days after taking the test. For 40 percent, it often took more than two months to receive the results, with 14 percent saying they usually had to wait more than three months. Such lags are troubling. A delay of two or three months can have a big impact on doctors' ability to make accurate and timely diagnoses, adjust ART regimens, or assess patient adherence or other problems before such problems negatively affect treatment outcomes. In addition, PLHIV who are informed of their viral load results extremely late—or never receive their results—may not get an accurate picture of their current status. Gaps of that sort are a concern from the standpoint of maximizing their treatment literacy.

As noted previously, viral load tests are available for free to registered PLHIV. However, they usually must pay out of pocket if they want more frequent tests, such as more than once a year. More frequent testing is often medically meaningful and useful. Yet for most patients, the costs of such tests are prohibitive, ranging from an average of RMB 550 (\$87), for a test with local reagents, to RMB 1,200 (\$190) for one with imported reagents.

Most survey respondents (86 percent) reported paying for some or all of other routine monitoring tests (liver/renal function tests, etc). Altogether, the average amount that each respondent paid during the last six months for various diagnostic tests was RMB 642 (\$102). This finding reveals a critical flaw in the Chinese ART programme. Despite the national policy to provide “free and reduced cost” treatment to PLHIV, and despite central government allocations to local China CDCs and departments of health to cover related costs, these essential monitoring tests are being used as a profit-making mechanism by local hospitals. The health of many PLHIV is at risk because the expectation and need to pay such fees are a heavy financial burden for many poor patients.

2.2 Optimize drug regimens

Since 2010, the National Centre for AIDS/STD Prevention and Control (NCAIDS) has recommended initiating ART when CD4 levels drop below 350 (as per most recent WHO recommendations). At the time research for this report was conducted, most provinces had adopted the new level—though a few reportedly continued to base initiation on the previous 200 CD4 count.

The discrepancies by province are at least partly due to the fact that the NCAIDS' shift has not been reflected in the national treatment guidelines. The currently applicable national free ART manual was published in December 2007. Since mid-2011, the national China CDC has been working on a revised version, based on the latest WHO recommendations and HIV epidemic trends in China. Yet the release of these revised guidelines has been repeatedly delayed due to concerns and conflicts among different parties.

The lack of revised treatment guidelines can be problematic and confusing for PLHIV without extensive knowledge or awareness about HIV treatment and policies. The guidelines still in place call for ART to be initiated when CD4 levels fall below 200 cells/mm³. But according to research respondents from the health administration, China CDC and hospitals, PLHIV with CD4 counts up to 350—and in some cases even greater than 350, if other health problems are indicated—are in reality eligible now for ART in most places that the research covered. The confusion for both patients and caregivers stems from the fact that this new eligibility criterion, which has been adopted by NCAIDS as part of the national HIV/AIDS plan, has not been introduced as part of the national treatment guidelines. Therefore, as noted by one China CDC official, it is often up to PLHIV themselves to “make the request to initiate early treatment”. The problem of course is that without knowing the benefits and possible risks of earlier ART initiation, or even the possibility of earlier initiation, it is extremely difficult for PLHIV to make such a request.

The practice of early ART initiation also includes, in some regions, providing ART as early as possible to the HIV-positive member in serodiscordant couples and pregnant women, regardless of their CD4 levels, in order to prevent secondary transmission. Pressure is likely to grow to expand such eligibility in light of research showing the long-term benefits of beginning ART soon after testing positive, regardless of CD4 count.

However, many government officials have opposed the idea of early ART initiation, arguing that it would increase the financial burden of the national free ART programme. The financial pressure on China's treatment programme has been exacerbated by the fact that some of the cheap locally produced generic antiretroviral drugs (ARVs) are no longer recommended by WHO. A notable example is d4T (stavudine), which the WHO now recommends against using. In China, d4T is very cheap—the government procurement price is approximately \$6.50 per patient per month—compared to the price for the usual substitute, TDF (tenofovir), about \$30 per month. This price differential creates a strong incentive to keep or put patients on d4T—and thus financial considerations may be preventing China from rapidly expanding access to improved ART regimens. In what appears to be a short-sighted cost-saving effort, some Chinese doctors proposed that PLHIV newly initiated on ART should receive a combination including d4T for six months, then AZT, and then, as a last option, the more expensive TDF.

The reluctance to eliminate d4T can be seen in the survey results. Of the 1,661 survey respondents on ART, 304 reported using d4T-containing regimen, with slightly more (325) reporting they were on TDF-containing regimen. In a recent baseline analysis done by grantees of ITPC China Small Grants, 2,497 out of 10,497 clients were still using d4T. And of 836 clients with hepatitis B co-infection, only 119 were on TDF.⁵⁰

50 ITPC China and AIDS Care China baseline analysis of ITPC China grantees. Unpublished information available upon request from ITPC China (personal communication with research consultant, September 2012).

With few exceptions, free ART through the national programme is exclusively provided in state-run clinics or hospitals. As noted previously, in order to be eligible for free ART drugs, a patient must register with his/her real name and identification card/number.

The following eight ART combinations were officially available in the regions that the research covered: AZT+3TC+LPV/r; AZT+3TC+NVP; AZT+3TC+EFV; d4T+3TC+NVP; d4T+3TC+EFV; TDF+3TC+NVP; TDF+3TC+EFV; and TDF+3TC+LPV/r.

However, although every regimen listed above should be free of charge for those who need it, currently there is not full availability of TDF, EFV and LPV/r in many places. In particular, due to limited availability of TDF within the government treatment programme, some PLHIV in China on the final three regimens must pay the retail price for TDF, which is approximately RMB 1,400 (US \$222) per month. In addition, patients often experience difficulties in obtaining LPV/r free of charge because it is used primarily for second-line treatment. Research indicates that some patients must pay the full retail price of that drug out of their own pocket.

Many PLHIV have to bear other costs as well when obtaining ART. On average, the PLHIV covered by this research spent RMB 58 (\$9.20) for transportation for each medical visit. More than 180 of the 1,661 PLHIV on ART said that they also had to find accommodation for their monitoring visits, as the designated ART hospital was too far from their homes to complete the return trip in one day. The costs for accommodation including those related to transport were on average RMB 100 (\$15.90) per visit to facilities.

A total of 261 PLHIV respondents also said they paid for other medications, including traditional Chinese medicines, vitamins and other mineral tablets, TB medicines, antibiotics and methadone. Their average monthly expenditure during the last six months for such medications was RMB 669 (\$106).

2.3 Adapt delivery systems

I went to the infectious-disease hospital to get a health check (screening test). Then I went to the [local] China CDC to get something called an application form, which I took back to the hospital. After that, I had to go to the China CDC again to hand in the application form. Then I waited to start my treatment. The process was quite annoying.

—Xiao T, PLHIV (interviewed in April 2012)

The [designated ART hospital] is very far from the city. Transportation is extremely inconvenient. It takes a whole day for the patient to pay one visit. And since the tests, including CD4 and viral load, are done collectively—for patients from the same district—there are concerns about the privacy and confidentiality of patients, given that those getting tested at the same time are often from the same towns and villages. It is also difficult to ensure quality when CD4/viral load testing is done in this collective way.

—A CDC doctor (interviewed in April 2012)

The Chinese government's response to HIV prevention and treatment is poorly coordinated, with different aspects of the work being done by general hospitals, infectious-diseases hospitals, mother and child hospitals, local China CDCs, TB institutes, detention facilities, and other government facilities. HIV screening tests are widely available in most hospitals and China CDCs. However, confirmation testing—

necessary for anyone hoping to join the free ART programme—is only available in the China CDC system, and mostly allocated to China CDCs at or higher than prefectural/municipal level. Prescription/initiation of ART can be practiced at designated infectious-disease hospitals and/or China CDCs.

The following is one example provided by healthcare personnel on how an HIV-positive individual would initiate ART if all expected steps of the current structure are followed.

- Process: i) apply for ART at a China CDC facility; ii) get health check at designated hospital; iii) receive prescriptions from the hospital; iv) return to China CDC to wait for ART initiation.
- Certificates needed:
 - For all: confirmation test result (China CDC), most recent CD4 result (China CDC and/or hospital)
 - For locally registered resident: ID card
 - For non-locally-registered residents: temporary residential ID card
 - In some places, a “certificate of financial difficulties” is also required in order to get free ART. This certificate must be issued by another government department, and increases the risk that one’s HIV status will be revealed (as non-medical staff are even less accustomed to keeping such information private)

As the above example illustrates, the existing system is inconvenient and time-consuming for PLHIV. They need to travel back and forth between different facilities for different reasons, thereby increasing the potential for obstacles, delays and problems to their efforts to get on ART even if clinically and clearly eligible.

The following are other issues of note regarding service delivery:

- Treatment for TB is also supposed to be free in China. However, TB treatment and related services are provided by facilities called TB prevention institutes, which are normally separate from HIV treatment facilities and under the administration of China CDCs. To date, there is no integrated system for PLHIV who need to be referred between the two facilities (for diagnosis, treatment, or ongoing monitoring).
- *Hukou*/residence system-induced problems. This used to be a major barrier, with people in need of ART and other services barred from receiving them where they live unless they are officially registered as a resident of that area. *Hukou*-related obstacles still exist in many cities and provinces, but they tend to be financial more than procedural. Non-registered people can often receive services, including ART and other HIV-related ones, but they may not be available free of charge as they would be for registered residents.
- Insufficient human resources at facilities. Most ART services are provided in a special ward of designated hospitals (generally the infectious-disease hospital); therefore, the overall quality of services is directly related to the management and policies of that facility, staff attitudes, and resources allocated to the local treatment programme. Lack of sufficient human resources is a major constraint to effective service delivery for PLHIV.

Researchers for this report interviewed staff and patients at six key designated ART hospitals in Guangxi and Yunnan provinces and found out that each ART doctor was managing, on average, 713 people on ART. Among them, one doctor had to manage as many as 1,239

people. The workload for these doctors is thus very heavy and, in the absence a proper support system, the potential quality of treatment services is almost certainly compromised. More than half of PLHIV respondents (53 percent) said they typically spoke to their doctors for less than five minutes during each visit, with an additional 25 percent reporting an average of just six to 10 minutes. The situation is made worse by policies barring all but doctors from administering most services for PLHIV, even those (such as handing out ARVs) that could be undertaken by other healthcare personnel if task-shifting were expanded.

2.4 Mobilize communities

A growing number of CBOs are involved in HIV/AIDS work in China. However, their involvement is heavily managed by the Ministry of Health (including its local health departments), government-run hospitals and local China CDCs. CBOs, made up of both PLHIV and other community members, are mainly involved in testing mobilization for the screening of MARPs—e.g., injecting drug users (IDUs) and men who have sex with men (MSM). Their work in this area includes distributing prevention information and condoms to MSM and sex workers, and providing some services such as clean needles to IDUs.

Some CBOs provide more professional and independent HIV-related services, including in regards to treatment. Several of these groups work in higher-prevalence provinces such as Yunnan, Sichuan and Guangxi. Many have managed to maintain a high degree of autonomy even though they also rely on cooperation with local officials and doctors. Although such CBOs have limited budgets and often work out of small spaces, their work has been largely welcomed by PLHIV as well as personnel from local health administrations, hospitals and China CDCs. The following comments from the research illustrate such support for CBOs' work:

Doctors are in charge of giving drugs and seeing patients. [Yet patients] say, "You guys are not sick like us, how would you know our problems in taking the drugs?" If patients are involved in educating their peers, it would be all different. They can be more convincing.

—ART doctor

Your service is really helpful. And you are considerate of my health.

—Comment on Tongle Group, a CBO, by a PLHIV respondent

It is so important to have community-based organizations to be involved in the HIV/AIDS work, particularly towards those who are difficult for us to reach. They have good reputation in the community and understand the needs and culture of the community members. ... Maybe, they can do better than us, the professionals.

—China CDC official

AIDS Care China is one of the most developed and effective groups providing treatment-related services to PLHIV.⁵¹ Active in Guangdong, Guangxi, Hubei, Yunnan provinces, its model of treatment education and counselling called the "Red Ribbon Centre" model has been adapted by facilities in several other provinces. It has also established two ART clinics (in Nanning and Wuhan) that currently are the only

51 The Red Ribbon Centre model has received considerable attention outside of China as well. For example, it was the subject of a profile in the Treat Asia section of the website of amfAR, The American Foundation for AIDS Research. Available online at: http://www.amfar.org/Articles/Around_The_World/TreatAsia/2009/AIDS_Care_China%E2%80%9494Model_Partnership_Provides_Red_Ribbon_AIDS_Care/.

independent, NGO-run treatment facilities in China. These clinics have ART doctors, China CDC workers and grassroots organization members working together to provide integrated services to PLHIV. (The model and its developers have faced operational challenges. For example, the Nanning facility was closed in June 2012 by local health officials on the excuse that commercial clinics are not entitled to treat HIV/AIDS.⁵²)

The community members play a direct and crucial role at these clinics, providing treatment education, counselling and follow-up support to patients. According to a doctor from the local China CDC, “There are community-based group members working in the [AIDS Care China] clinic. PLHIV receiving ART there told us that they were very satisfied with the clinic’s work. They thought it was like home—they could say whatever they want to. They are very happy.”

3. KEY CHALLENGES

Many of the main challenges identified during research to an enhanced and expanded HIV response in China are discussed in Sections 2.1 through 2.4. This section summarizes some of them and others. Improvements in all of these areas are considered critical for the effective adoption and implementation of the Treatment 2.0 framework in the future.

Insufficient HIV testing uptake and access

Many PLHIV in need of treatment are not currently receiving it, often because they are not aware of their HIV status. Health authorities at all levels are relatively passive in terms of developing and implementing effective strategies to encourage people to be tested. As noted in Section 2.1 of this report, a large proportion of new PLHIV are identified only when they present at hospitals, at which HIV testing is compulsory for various unrelated procedures. Only a small number of PLHIV respondents said they were encouraged to come forward by themselves for an HIV test. Given concerns about confidentiality and harassment, many people, especially members of MARPs, are understandably reluctant to get tested even if they know they may be at risk.

Limited and late uptake of HIV testing reduces the effectiveness of ART. Many PLHIV have dangerously low CD4 levels when they finally receive a diagnosis, often in a hospital setting.

Published research by NCAIDS and China CDC shows that the two strongest risk factors for HIV-related mortality are not receiving ART and having a CD4 count of less than 50 when first declared eligible for treatment.⁵³

Lack of integration makes comprehensive treatment complex and cumbersome

The current system is complicated and confusing, and even varies from region to region. The lack of treatment service integration makes it difficult for many PLHIV to easily navigate. For example, China CDC facilities normally manage PLHIV and provide ARVs; designated infectious-disease hospitals take care of other, often related medical issues, such as treatment for opportunistic infections; and TB care is available only at designated TB centres. Meanwhile, for pregnant women who are HIV-positive,

52 China-Wire, “Protests mount over free AIDS clinic’s closure”, 6 June 2012. Available online at: <http://china-wire.org/?p=20913>.

53 F Zhang et al., “Effect of earlier initiation of antiretroviral treatment and increased treatment coverage on HIV-related mortality in China: a national observational cohort study. *The Lancet*, Volume 11, Issue 7, pp. 516-524, July 2011.

services to prevent mother-to-child transmission are only available in women and children's health centres, to which large number of migrant women⁵⁴ have limited access (if any) in most regions.

Stigma, discrimination and lack of "human touch" in service delivery.

HIV-related stigma and discrimination are widespread throughout China, and many PLHIV face "double" or "triple" discrimination if they are (for example) IDUs or sex workers. Many are unwilling to disclose or discuss their HIV status to family members and friends. They often see designated hospitals and China CDCs as the places they can trust and where they presumably can get needed support and information. Yet most doctors and staff, even those who are aware of the major problems associated with stigma and discrimination, have too little time to spend with individual patients. Both patients and doctors note that there is little follow-up from healthcare personnel, even after important diagnostic and monitoring tests are taken.

Financial burden on PLHIV from direct and indirect costs

As noted throughout this report, PLHIV generally have to pay various fees for important health services, even (in some cases) for services that are supposed to be available free of charge. The financial burden is overwhelming for many. According to many respondents, costs associated with treatment for opportunistic infections (OIs) are among the most problematic.

Far too common are instances in which PLHIV and their families have exhausted their savings on treating OIs. Some respondents said they had had to leave hospitals without being fully treated because they could not afford to pay the expected costs of treating their OIs.

In addition to such treatment-specific costs, most PLHIV face difficulties with indirect costs associated with obtaining HIV treatment and care—including transportation, accommodation and food.

Lack of optional, and optimal, ART combinations

Availability of different ART combinations is limited in China, especially in less developed regions with higher prevalence such as Guangxi, Yunnan and Xinjiang provinces. Despite its widely known side effects and toxicity, d4T is still prescribed by many doctors. The lack of listed optional ART combinations also means that PLHIV in many areas must pay out of pocket if they want or need an ARV not currently available. This requirement places an additional cost burden on PLHIV who already face other cost-related challenges.

Many PLHIV lack "ownership" of their own health

Many of the challenges, issues and problems noted throughout this report are connected with the fact that many PLHIV are unable or unwilling to have "ownership" for their own health. This is related to the following:

- Health professionals generally make little effort to help PLHIV understand their own health. After years of taking ART, many PLHIV do not even know what drugs they are taking, what tests they are having and why they should take those tests. Such lack of information and awareness makes many of them passive and/or uncertain how they should engage.
- PLHIV usually are not in a position to choose what services they want to get. They are rarely given options as to what kind of tests and medicines to take. Such lack of power also contributes to feelings of helplessness and reliance.

54 "Migrant" in Chinese terminology refers to people whose residential registration (*hukou*) is different from where s/he live. *Hukou* usually decides one's social welfare entitlements, including medical services.

Among the negative impacts of such lack of “ownership” are poor adherence among many PLHIV. That problem could be addressed in part with better treatment literacy, but healthcare personnel rarely have the time and inclination to provide such information to PLHIV patients. CBOs offer such important services, but many PLHIV have little contact with them.

4. RECOMMENDATIONS

Most of the complications, confusions and challenges regarding HIV services and treatment in China can be linked to systemic issues. Therefore, the recommendations below are focused on practical changes that can be made to the systems. The overall goal is to lay the groundwork for adoption and integration of elements of the Treatment 2.0 framework over time.

Recommendation area 1: The roles and involvement of CBOs in HIV treatment should be strengthened at different levels.

The national government, led by the Ministry of Health (MoH), should take the lead in changing policies and priorities to ensure greater engagement by community groups in all provinces. The first important step would be to give legal status to CBOs and allow them greater leeway to raise funding from a wide range of sources, including internationally.

As funding from international donors to HIV/AIDS work in China is decreasing rapidly, it is time for the government and government-run facilities to recognise the invaluable and irreplaceable roles that CBOs play. They often offer comparative advantages over China CDCs, hospitals and other “formal” facilities. *In particular, CBOs across the country should be allowed and supported to do the following:*

- Organize, run and expand VCT services as part of an effort to increase testing uptake. CBOs should be allowed to conduct such efforts on an anonymous and confidential basis, a critical factor that could help them reach more MARPs in particular.
- CBOs can support health professionals such as China CDC workers, doctors and nurses so that their time can be used more strategically. The Red Ribbon Centres set up by AIDS Care China in different cities provide a useful model. Their success to date highlights the benefits of community members working with ART doctors and nurses in supporting PLHIV treatment education and ART adherence, as well as in providing psychological help.
- CBOs should be able to compete for government funding at an equal level for service provision. China is moving towards a stage in which social services are gradually contracted to private and other players. CBOs should be included in the selection list and allowed to access relevant funding from government.

CBOs should be allowed to offer ART and treatment for opportunistic infections. Changing laws and policies to allow this engagement could help ease the burden on the national ART programme. In many settings, CBOs are likely to be able to provide such services more efficiently and cheaply, and would have access to a larger number of PLHIV. Adequate training and monitoring would be necessary, but there are already successful models that can be replicated or adapted.

Recommendation area 2: The national MoH, working collaboratively with its provincial counterparts and CBOs representing PLHIV, should develop and implement a new quality assurance system linked to incentives.

In the past decades, China has been focused on quantity, but not sufficiently on quality, in HIV/AIDS work. For example, substantial efforts and investments have been put into scaling up tests and covering more people, but the results have not been particularly impressive as targets are routinely missed. Furthermore, most of the indicators set for local China CDCs, hospitals, and even CBOs are quantity-based. Better and smarter indicators are needed now for all stakeholders.

An improved quality assurance system should also be linked to the financing, funding and incentives that different facilities receive. For example, a system can be established to assess the performance of different CBOs. The assessment results can be publicised with details on an open platform. Donors, government departments and other supporters can access this platform when they need to make a decision on who they want to work with and support.

Another important point for quality assurance is the involvement of PLHIV. They are the ultimate clients, but have not been able to be involved in the assessment of their service suppliers. Their views, comments and feedback should be fed into the quality assurance system and have some impact on the facilities that provide services to them.

Recommendation area 3: The national MoH, working collaboratively with its provincial counterparts and CBOs representing PLHIV, should undertake an initiative aimed at simplifying and integrating health services for PLHIV.

There are historic and political reasons behind the complicated and confusing HIV/AIDS service system. Regardless of those reasons, however, PLHIV bear the brunt of the current dysfunction. Systemic reform is needed to help PLHIV know who to ask for information and support, where to go, and what to do if they have a problem. A simple and practical step to take is to set up an integrated system which at least includes the following functions.

- Screening, confirmation and other important monitoring tests
- ART initiation and distribution
- Counselling and other psychological support for PLHIV
- Treatment education and adherence strengthening
- Screening and treatment for TB, hepatitis B and hepatitis C
- Screening and referral for non-communicable diseases (NCDs)

The two NGO-run clinics in Nanning and Wuhan (mentioned above), offer a template for such an integrated system. While establishing an integrated and simplified service system at a large scale may not be feasible, at least in the short term, this model can be piloted by non-profit and/or private players such as CBOs, private clinics and hospitals. Such a step would be in-line with the government's policy of "encouraging social forces to establish medical facilities,"⁵⁵ and would provide an important alternate model for more efficient, affordable, patient-friendly service provision.

*The doctors don't see PLHIV if
the person isn't ill. The doctors
don't have time for us.*

- Person living with HIV in Abodo Sud,
Côte d'Ivoire

CÔTE D'IVOIRE AND TREATMENT 2.0: CHALLENGES AND OPPORTUNITIES TO SCALE UP HIV TREATMENT

This country report is part of *Missing the Target 10 (MTT10)*, the 2012 version of a longstanding series on global access to HIV treatment coordinated by the International Treatment Preparedness Coalition (ITPC). *MTT10* focuses on challenges to the scale-up of HIV services as required to implement the Treatment 2.0 framework. As with other *Missing the Target* publications, national and local community groups conducted research based on a general template and prepared their country-specific reports. The following countries are included in *MTT10*: Cameroon, China, Côte d'Ivoire, Honduras, India, Kenya, Morocco and Russia.

The full *MTT10* report and individual country reports are available at the ITPC website: www.itpcglobal.org. Also available at that website are a French version of this Côte d'Ivoire report as well as a French version of the Cameroon report and a Spanish version of the Honduras one.

Côte d'Ivoire

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ACRONYMS AND ABBREVIATIONS

ART	antiretroviral treatment
ARV	antiretroviral drug
CBO	community-based organization
INS	Institut National de la Statistique de Côte d'Ivoire
MSLS	Ministère de la Santé et de la Lutte contre le Sida
MSM	men having sex with men
NGO	non-governmental organization
PNPEC	Programme National de Prise En Charge
PLHIV	people living with HIV
STI	sexually transmitted infection
TB	tuberculosis
WHO	World Health Organization

Note on text: All "\$" figures are U.S. dollar amounts. All URLs cited were valid as of 1 October 2012.

HIV drugs list

Many HIV drugs are commonly referred to in an abbreviated format. Listed below are the abbreviated names of all the drugs mentioned in the Côte d'Ivoire report as well as the full generic name associated with them. Where relevant, brand names of key drugs are also noted. The drugs are grouped by class.

NRTIs (nucleoside reverse-transcriptase inhibitors)	
3TC	lamivudine
ABC	abacavir
AZT	zidovudine
DDI	didanosine
TDF	tenofovir
NNRTIs (non-nucleoside reverse transcriptase inhibitors)	
NVP	nevirapine
Protease inhibitors	
LPV/r	lopinavir/ritonavir (refers to lopinavir being "boosted" by ritonavir)

1. INTRODUCTION AND OVERVIEW

1.1 Methodology

Research for this study was conducted through the following methods: i) a literature review of both online and printed materials, ii) individual interviews and iii) eight focus group discussions. The interviews were held with 13 people living with HIV (PLHIV) currently on antiretroviral treatment (ART), eight health professionals and representatives from 10 community-based organizations (CBOs).

The PLHIV interviewed individually comprised eight men and five women, including one person from the population of men who have sex with men (MSM), two sex workers, and three men in the armed forces. Of the 13 interviewed, eight were from urban areas while the other five were from rural or semi-urban areas. Four were between the ages of 19 and 25, with the remainder between the ages of 26 and 50.

Of the eight health professionals interviewed individually, five were from the public sector and the other three from the private sector. Of the 10 representatives from CBOs, seven were from rural areas.

A total of 53 PLHIV participated in the eight focus groups, three of which were held in urban environments and the remainder in rural settings. Six of the eight groups included six participants each. The other two had seven and 10 participants. Of the 53 total participants, nine were on first-line ART regimens, 29 on second-line regimens, and two on third-line regimens. The majority (32) were women. The average age was 39, and participants had been living with HIV for an average of seven years.

1.2 Context

A number of military and political crises affected Côte d'Ivoire between 2000 and 2011. These multi-faceted crises reduced the health and living conditions of most people; for example, poverty levels increased significantly between 2002 (38.4 percent) and 2009 (46.8 percent).⁵⁶

56 Stratégie de Réduction de la Pauvreté DRSP 2009, Ministère d'Etat, Ministère du Plan et du Développement.

According to research on HIV conducted by the Institut National de la Statistique de Côte d'Ivoire (National Statistics Institute, or INS), in 2005 overall HIV prevalence was estimated to 4.7 percent. The rate varied nationally, with prevalence higher in urban areas (5.4 percent) and lower rates in rural areas (4.1 percent). However, overall prevalence was lower a few years later, at 3.4 percent, according to INS estimates from 2009.⁵⁷ Women are more affected than men. Among people aged 15-24, for example, HIV prevalence among women (according to the 2009 INS estimate) was 6.9 percent, compared with 2.4 percent for men. Despite the decline in overall HIV prevalence in recent years, Côte d'Ivoire still has the highest rate in West Africa.

The populations most at risk, according to the 2009 Côte d'Ivoire Poverty Reduction Strategy Paper,⁵⁸ include i) young people having their first sexual experience between the ages of 15 and 17, ii) adult women who are the victims of sexual violence and sexual abuse, iii) serodiscordant couples, iv) sex workers, v) lorry (truck) drivers, vi) soldiers, vii) teachers, viii) individuals with a sexually transmitted infection (STI), and ix) people living with tuberculosis (TB). In regards to people living with TB, it is notable that an estimated 42 to 49 percent of them are co-infected with HIV, according to studies from the Programme National de Prise En Charge (National Programme for Care of People Living with HIV /AIDS, or PNPEC), the country's national programme to support people living with HIV.⁵⁹ Other groups considered at high risk include MSM, who are increasingly visible in the country, and injecting drug users (who are not visible).

According to PNPEC, in 2010 there were 428 facilities providing antiretroviral treatment (ART) across Côte d'Ivoire.⁶⁰ The number of patients on ART has increased steadily according to official data, from 49,179 in 2007 to 89,410 by the end of 2011.⁶¹ Nevertheless, it is assumed that many, if not most, PLHIV needing ART are not yet receiving treatment. This assumption is based on the most recent UNAIDS estimate (from 2009) that the country is home to some 450,000 PLHIV.⁶²

Efforts to scale up treatment have encountered numerous socio-cultural, financial, infrastructural and other capacity-related difficulties. National treatment guidelines have been adapted to comply with the most recent World Health Organization (WHO) treatment recommendations, from 2010. However, research indicates that the new guidelines have not been implemented or enforced across much of the country. Policy makers interviewed for this report said the delay stems from the lack of a clear mandate to implement them.

Some steps have recently been taken to overcome this lag. According to the general director of the government's AIDS response, the Ministère de la Santé et de la Lutte contre le Sida (Ministry of Health and the Fight against AIDS, or MSLS) issued a decree in May 2012 aimed at ensuring that the new guidelines are distributed to all stakeholders. The decree also aims to assist officials in revising procurement plans to take into account the estimated needs for ARVs as per the WHO recommendations.

57 2010 National Report on the fight of HIV Infection in Côte d'Ivoire, CNLS, p. 10.

58 Stratégie de Réduction de la Pauvreté DRSP 2009, Ministère d'Etat, Ministère du Plan et du Développement

59 As per the Programme National de Prise En Charge (PNPEC). Available online at PNPEC's website: www.pnpec.ci.

60 As per the Programme National de Prise En Charge (PNPEC). Available online at PNPEC's website: www.pnpec.ci.

61 As per the Programme National de Prise En Charge (PNPEC). Available online at PNPEC's website: www.pnpec.ci.

62 As cited on the UNAIDS website (accessed 1 September 2012). Available online at: www.unaids.org/en/regionscountries/countries/ctedivoire/.

2. NOTABLE FINDINGS AND OBSERVATIONS ASSOCIATED WITH TREATMENT 2.0

“Treatment 2.0” is the name of an initiative developed and launched in 2010 by WHO and the Joint United Nations Programme on HIV/AIDS (UNAIDS). It aims to simplify and improve the way HIV treatment is currently provided in order to maximize the effect of ART and further scale up access to HIV treatment, care and support. The initiative focuses on innovation and efficiency in HIV programming, including the integration of important new findings such as the preventive effects of ART.⁶³

WHO and UNAIDS are currently developing various frameworks that will help countries and all stakeholders develop and implement strategies based on Treatment 2.0 principles and priorities. The frameworks will be based on the initiative’s five main priority work areas, also known as “pillars”:

1. Provide point-of-care and other simplified diagnostic and monitoring tools
2. Optimize drug regimens
3. Reduce costs
4. Adapt delivery systems
5. Mobilize communities

The agencies have worked closely with partners at global, regional and country level to explain the Treatment 2.0 agenda in general, and the importance of the five pillars specifically. This effort also seeks to build support for the overall approach, which can only be successful when countries’ HIV programmes and strategies align with it.

Findings and observations obtained through research for this report are organized by the five Treatment 2.0 pillars (Sections 2.1 through 2.5 below). This structure is intended to highlight progress, gaps and challenges in Côte d’Ivoire regarding expanded and enhanced HIV treatment for all in need.

Existing awareness of Treatment 2.0 in Côte d’Ivoire

There appears to be little awareness about the Treatment 2.0 initiative among government officials, service providers, community groups and PLHIV. Part of the problem is that most documentation on the agenda is in English. Also, as yet there has been no community mobilization around Treatment 2.0 in West Africa in general.

2.1 Provide point-of-care and other simplified diagnostic and monitoring tools

HIV testing

The national policy on HIV testing is promoted through the development of innovative strategies supporting testing and associated counselling by both service providers and community groups. The policy also aims to raise awareness about HIV as part of an effort to boost testing uptake.

According to a PNPEC official interviewed in May 2012,⁶⁴ HIV tests are provided free of charge and were available in 733 of 1,283 front-line healthcare facilities. Tests are offered in both public facilities and not-for-profit ones including non-governmental organizations (NGOs), faith-based organizations, and private-sector providers. Mobile testing is also offered by NGOs going door-to-door. Rapid tests are increasingly available.

63 Detailed information about the Treatment 2.0 agenda may be found online at: http://data.unaids.org/pub/Outlook/2010/20100713_fs_outlook_treatment_en.pdf.

64 As cited during an interview with Dr Tapé, M&E expert at PNPEC.

Most respondents to this research agree that the centres run by NGOs offer the best service in terms of welcoming attitudes and confidentiality. Several stated that confidentiality is not always guaranteed in public-sector facilities and the clear consent from clients is not always solicited or obtained, especially if a patient is seriously ill.⁶⁵

National guidelines require pre- and post-test counselling, but research respondents said that such counselling is not always provided. As observed from answers to questions posed to individual interviewees about pre- and post-test counselling, 39 percent of PLHIV who were interviewed said they did not think pre-test counselling was conducted correctly because counsellors do not spend enough time with clients to provide adequate information. In addition, 12 percent of those interviewees said that when they were tested for HIV, their service provider did not seek consent before taking blood. Many focus group participants also mentioned that pre-test counselling was not always provided, adding that it is not “complete” even when given. Most added that the time allocated for post-test advice was not always sufficient. Such limitations may explain cases of some people not accepting their HIV status after testing positive, which seems to be a particular issue among young people under the age of 25.

According to national guidelines, all those who test positive are supposed to be referred to relevant healthcare facilities. However, nearly one-third (31 percent) of PLHIV interviewed for this research said they had not been referred to a facility upon receiving their positive HIV test results. (The main reason for such a large share appears to be related to the fact that most interviewees tested positive during the recent military and political crises,⁶⁶ a period in which the number and quality of treatment and care facilities were diminished.) An even larger share (39 percent) said they had not been referred to a support group. Such observations indicate that far too little effort has been made to help move clients into care and support after they receive their HIV diagnosis.

Diagnostic tests

CD4 tests are offered to HIV patients in the context of the initial examination upon entering treatment for HIV and also for monitoring afterward. However, these tests are not available free of charge. Many PLHIV respondents complained about the fact that diagnostic tests such as CD4 and viral load tests have to be paid for even though ART, among other services, is available for free. For example: “We have lost our jobs and don’t have the means to pay for the various diagnostic tests. Why don’t they make it free, like the HIV test?”⁶⁷ One PLHIV on ART interviewed in Duekoue reported that patients usually must pay up to 15,000 CFA (more than \$27) for a viral load test.

While national coverage of voluntary counselling and testing (VCT) is relatively high, coverage of CD4 and viral load test services is low. Viral load tests are only conducted in four laboratories in Côte d’Ivoire, and only for patients whose first-line treatment has failed. Resistance testing is also theoretically available to patients presenting second-line failure. Yet access to such testing is difficult as it is only provided by a single laboratory in the country.

65 According to a community counsellor during a focus group discussion in Bardo on 1 May 2012.

66 During the decade of political and military crises in Côte d’Ivoire, through the middle of 2011, many healthcare facilities were not operational in the northern part of the country (nearly 60 percent of the total land). Such facilities were more regularly open in the south, but they generally experienced severe shortages of medicines, equipment and qualified personnel.

67 As cited by an HIV-positive man during a focus group discussion in Bouaké on 2 May 2012.

2.2 Optimize drug regimens

Since August 2008, ART has been provided for free throughout Côte d'Ivoire, but until recently treatment eligibility was restricted to those with CD4 counts below 200 cells/mm³. As noted earlier in this report, the MSLS has revised treatment directives to comply with the updated 2010 WHO treatment recommendations, but implementation has been limited. Implementation and subsequent enforcement will require dissemination of the guidelines to all service providers along with specific injunctions that people should be offered treatment when their CD4 counts fall below 350. As of August 2012, it was not clear when effective implementation would take place to ensure that the new guidelines are understood and followed across the country.

Prescription of ART is, in theory, exclusively conducted by doctors trained in caring for PLHIV. Yet due to the limited number of such doctors, nurses renew prescriptions and administer the drugs in some rural and semi-urban centres. Research on the feasibility of officially allowing and encouraging task delegation of this sort has been initiated by the MSLS with support from Jhpiego (an international, non-profit health organization),⁶⁸ and the results are expected by the end of 2012.

Eighty-three percent of PLHIV interviewed individually for this report were on ART; of them, 93 percent were on a first-line regimen. Those figures are similar to national data indicating that 96.7 percent of patients are taking a first-line combination.⁶⁹ First-line ART regimens most often prescribed in the country are AZT+3TC+NVP and AZT+3TC+LPV/r. Fixed-dose combinations are available for both of those regimens. All drugs prescribed through the public sector, where most Ivorians receive their care, are generic versions.

Clinics offering ART are unevenly distributed in terms of health districts. Most are concentrated in urban settings, particularly in Abidjan, the economic capital. PLHIV contacted for this research regularly noted transportation-related obstacles in regards to obtaining ART in other parts of the country. For example, an HIV-positive woman said the following during a focus group discussion:⁷⁰ “It is difficult to find the money to go to hospital. If you are in San Pedro you pay 400 CFA (about \$0.75) to go to get your drugs; if you are on the periphery you pay 800 CFA, and those who come from villages such as Grand-Grabo pay up to 1,000 CFA.”

Some participants said that the supply chain works well, but others said stock-outs of some products occur from time to time. Their observations are reinforced by a report from the government's Technical Committee of ARV Management, which reviewed stocks in May 2012.⁷¹ One ARV product out of stock completely at that time was ABC+3TC (600/300 mg). Others were deemed to be available in insufficient quantities, including ABC 20 mg syrup, TDF (300 mg), AZT+3TC (300/150 mg); and DDI 200 mg oral. These findings indicate a serious overall problem because, most notably, pills containing AZT+3TC are part of the most commonly prescribed first-line regimens.

Other obstacles in regards to ART access include HIV-related stigma and discrimination, which remains deeply embedded throughout Ivorian society. Many clients feel they need to hide their status and the fact that they are receiving ART. A 37-year-old HIV-positive woman in a focus group said the following:⁷²

68 Jhpiego is the acronym for the Johns Hopkins Program for International Education in Gynecology and Obstetrics.

69 Rapport annuel des indicateurs VIH dans le secteur santé 2009. August 2010.

70 As cited during a focus group discussion in San-Pedro on 1 May 2012.

71 2010 National Report on the fight of HIV Infection in Côte d'Ivoire, CNLS.

72 As cited during a focus group discussion in San-Pedro on 1 May 2012.

“People hide to take their drugs; if the husband is first, he hides it from his wife; if the wife is first, she hides it from the husband. So it’s a game of hide-and-seek that’s taking place.” Another focus group participant, a community counsellor, said the following:⁷³ “I don’t take my drugs when there is someone in my room. I’ve been known to skip taking them if someone stays for any length of time.” And in one final example of what people feel they must do, another focus group participant said the following:⁷⁴ “As soon as my aunt knew I was taking ARVs, the usual cutlery I used was put aside and if I touched a glass, this became automatically unusable for the other members of the family.” **2.3 Reduce costs**

The current prices paid by the government for the two most commonly prescribed ART regimens are as follows:

AZT+3TC+NVP = \$11.8 per month per person, or about \$142 per year

AZT+3TC+LVP-r = \$42.5 per month per person, or about \$510 per year

The funds to pay for most ARVs are provided by partners including the U.S. Presidents Emergency Plan for AIDS Relief (PEFAR), the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the World Bank. The government pays less than 2 percent of ARV purchasing costs from its own budget. That relatively small share is reflected in the fact that the government has never come close to meeting the specifications of the 2001 Abuja Declaration, through which African governments pledged to allocate 15 percent of their budgets to public health.

The country has taken initiatives to strengthen its ability to manage intellectual property rights and to contribute to innovation and the promotion of public health, including the creation of the Ivorian Office for Intellectual Property in 2005. The country is also a signatory of the Bangui Agreement,⁷⁵ approved by heads of states in 1977 and intended to serve as the basis for intellectual property rights in West and Central Africa. However, that agreement is decades-old and has never been reviewed or adapted to take into account the global TRIPS agreement, which has specific provisions regarding patents and intellectual property.⁷⁶ The country’s reliance on generic ARVs underscores its exposure to potential restrictions on patent laws and policies, especially in countries such as India. The need to ensure access to lower-priced generics will only increase as more patients need to move to second- and third-line regimens for which few affordable options currently exist.

2.4 Adapt service provision

Increased integration is considered an important priority to adapt and improve HIV treatment, care and support. ART provision is currently linked with other HIV-related services, particularly in the public sector, through integrated facilities offering vertical transmission services, HIV testing and treatment of STIs. TB diagnosis centres also offer HIV tests and prescribe and dispense ART for co-infected patients. Few dedicated services exist for drug users in public-sector facilities. The main NGO working with drug users, Croix Bleue, has not yet offered HIV treatment in its range of services.

73 As cited during a focus group discussion in San-Pedro on 1 May 2012.

74 As cited during a focus group discussion in Bouaké on 30 April 2012.

75 Accord Portant Revision de l’Accord de Bangui du 02 Mars 1977 Instituant ne Organisation Africaine de la Propriété Intellectuelle.

76 TRIPS refers to the Agreement on Trade-Related Aspects of Intellectual Property Rights, an agreement negotiated through the World Trade Organization (WTO) in the 1990s to introduce intellectual property rules into the multilateral trading system. The TRIPS agreement included several “flexibilities” that signatories could use to ensure access to essential products such as HIV drugs without issuing patents. Most of the world’s countries, including Côte d’Ivoire, are TRIPS signatories.

Côte d'Ivoire has established a national programme to address hepatitis. Hepatitis B treatment is integrated into HIV treatment and care, but services are only available in tertiary healthcare establishments such as university hospital centres. No treatment is available for hepatitis C, and very little is known about its prevalence among HIV-positive people or the population in general.

Coordinated services are considered a priority in regards to TB; according to a 2011 report by the National Tuberculosis Programme, 24 percent of patients on TB treatment were co-infected with HIV in 2010.⁷⁷ All TB prevention, testing and treatment centres offer HIV testing as well as ART in conjunction with TB treatment. However, all TB centres are located in urban areas, which means that comprehensive treatment for co-infected individuals is only available in cities. Many healthcare districts currently have no such facilities. Also of note is that only a handful of the more than 400 facilities offering ART were providing TB testing and treatment in 2010, according to PNPEC.⁷⁸

HIV care and support services are carried out by many civil society organizations and PLHIV groups, usually with the financial and technical support of development partners. However, results from this research show that only 31 percent of PLHIV on treatment who were interviewed were receiving support from an NGO. (Yet at the same time, 62 percent said they had joined a support group.)

Representatives from community organizations interviewed said they offer palliative care (75 percent of those surveyed), treatment for side effects (50 percent), case management (63 percent), treatment of opportunistic infections (63 percent) and cotrimoxazole prophylaxis (63 percent). Some NGOs with substantial capacity have hired health professionals who can dispense ART. Community organizations are highly involved in HIV prevention, but it is often difficult to coordinate their efforts or evaluate their performance as some are not official or listed. Moreover, monitoring systems are inefficient, data collection tools are not harmonised, and communications structures are weak and not fully integrated into a national system.

In general, both community groups and the government lack management capacity to collect and disseminate information and resources that would help improve overall HIV service delivery. The government intends to strengthen HIV prevention through the creation of a central department for prevention and treatment and by prioritising interventions to improve prevention in the context of the National Strategic Plan (NSP) 2011-2015.⁷⁹

The need to improve service delivery was noted by most respondents, many of whom stressed the poor quality of care offered in public facilities. Several respondents criticized the lack of motivation among care workers (including doctors) in the public sector. An HIV-positive woman said the following during a focus group discussion:⁸⁰ “At the public hospital in Abobo Sud, the doctors don't see PLHIV if the person isn't ill. If you are not lying down it is the counsellors who issue prescriptions. The doctors don't have time for us.”

77 Rapport du programme Nation de la Tuberculose / bilan des activités de co-infection TB-VIH, May 2012.

78 As per the directory of ARV treatment sites in 2010 from Programme National de Prise En Charge (PNPEC). Available online at PNPEC's website: www.pnpec.ci.

79 The full text of the National Strategic Plan (NSP) 2011-2015 is available online at: http://www.aidstar-one.com/focus_areas/prevention/resources/national_strategic_plans (in French only).

80 As cited during a focus group discussion in Abobo Sud (Abidjan) on 30 April 2012.

2.5 Community mobilization

In Côte d'Ivoire, civil society organizations (CSOs) involved in the fight against HIV are highly organized and coordinated. They work together through contexts such as the Council of Civil Society Organizations, the Network of People Living with HIV, the Ivorian Youth Network, the Côte d'Ivoire Media Professionals Network, the Churches Network, and the Ivorian Network of Women's Organizations. This enables concerted action in terms of community support and the fight against discrimination and stigmatisation. Findings from focus group discussions indicate that most PLHIV have benefited from NGOs' efforts, as suggested by this comment:⁸¹ "The support group enabled one person who had recently tested positive to be reassured by the older members." Yet at the same time, research indicates that awareness of NGOs' involvement is not universal. "I know that NGOs exist to fight against AIDS, but I don't know what they really do," said one focus group participant.⁸² Awareness is particularly low in the north and west of the country, largely due to those areas being relatively isolated during the civil strife in recent years.

PLHIV networks support national efforts aimed at improving the way that PLHIV are treated. Among the services they provide are home visits, discussion groups, and psychological and spiritual support for PLHIV. Individuals leading these networks are trained by the National Treatment Programme for PLHIV. The training covers modules relating to care and support, compliance with treatment and positive prevention.

However, most community organizations maintain that the government does not possess sufficient institutional and programme capacity, including in regards to fundraising and lobbying, to make their activities more effective and long-term at the national level. Few receive external financial support, including from the government. The lack of financial resources means that they largely rely on volunteers, a situation that makes their workforces unstable and inadequately motivated.

Another notable issue regarding community mobilization is that legal and cultural barriers make it extremely difficult to undertake HIV prevention and treatment work with and for marginalized populations and most-at-risk populations (MARPs) such as MSM and sex workers. Many NGOs and community groups recognize that an important priority for the future will be monitoring health systems and government responses regarding these populations' access to high quality and equitable health services. Greater efforts may be needed to address the negative consequences of criminalization of sex work and same-sex practices and the extensive stigma associated with them.

Community groups also agree on the need to mobilize to ensure continued access to essential medicines, including generic versions of ARVs. Such efforts require greater understanding of complicated legal and trade issues. Building and sustaining the meaningful involvement of PLHIV in policy and programme development remains the overarching priority in regards to interaction with the government.

3. KEY CHALLENGES

This section summarizes some of the main challenges identified during research to an enhanced and expanded HIV response in Côte d'Ivoire. Improvements in such areas are considered critical for the effective adoption and implementation of the Treatment 2.0 framework in the future.

81 As cited during a focus group discussion in Abobo Sud (Abidjan) on 30 April 2012.

82 As cited during a focus group discussion in Yopougon (Abidjan) on 25 April 2012.

Delays in implementing updated treatment guidelines

The lengthy civil war, which ended in March 2011, delayed efforts toward updating national treatment guidelines and developing plans to implement them. The MSLS's May 2012 decree calling for implementation and enforcement is an important step in the right direction, but effective implementation can only be achieved if the necessary drugs and commodities are available. Training of healthcare personnel is essential, as is ensuring that the revised procurement plan can accommodate the expected increase in the number of people eligible for ART under the new guidelines.

Lack of funding for anti-HIV activities

Treatment 2.0 also can only become a reality if sustainability is assured, which means additional funding for HIV services must be made available. A shift in strategy is needed. Funding for the fight against HIV to a large extent comes from abroad;⁸³ as noted previously, ARVs are almost entirely (98 percent) purchased by PEPFAR and the Global Fund. The heavy dependence on external funding for implementing the national plan creates a bottleneck in terms of meeting the commitments for creating national strategies based on the Millennium Development Goals for 2015 in terms of the gradual reduction in external support. The lack of funding also limits the ability to scale up HIV treatment services, as is needed under the new treatment guidelines and to comply with the Treatment 2.0 agenda more broadly.

Lack of provision of quality services

A national study⁸⁴ into the early warning indicators of resistance to ARVs identified a number of weaknesses in how PLHIV are treated with ART. No healthcare site has achieved all the objectives set for the five indicators evaluated. Actual prescription practices regarding ART have not always been in line with national directives; a high percentage of people have been “lost” after starting care; many patients do not appear to be taking the most effective first-line regimens a year after starting treatment; and almost all sites have experienced ARV stock-outs. These results show the necessity of improving ARV prescription practices and strengthening strategies to help with treatment compliance.

Lack of programme and operational capacity of community organizations engaged in caring for and supporting PLHIV

Community organizations do not have sufficient institutional and programme capacity, including to undertake fundraising and to lobby for more effective work at the national level. The gaps are particularly large outside of Abidjan and other major towns, though the extent of the problems is unclear due to a lack of up-to-date mapping of stakeholders and organizations providing HIV-related services. Community organizations' activities are not supported by the government, and the national coordination framework established by community networks is non-operational due to lack of effective leadership. Financial support provided to organizations by external technical and funding partners is not always what is truly needed because it often focuses on short- and medium-term projects. Support from those external partners should instead prioritize longer-term activities such as capacity-building.

Persistent HIV-related stigma and discrimination

This is the biggest obstacle to overcome in terms of scaling up HIV treatment and care and, over time, implementing the Treatment 2.0 framework. Research for this study indicated that most PLHIV were not satisfied with the way they have been received in healthcare centres, with several saying they experienced discriminatory behaviour. One focus group participant observed that “as soon as you

83 MSLS, PSN 2001-2015: The proportion of the national budget devoted to health has remained less than 5 percent, of which less than 0.25 percent is allocated to the fight against AIDS.

84 MSLS. Evaluation of early warning indicators of HIV resistance to ARV in Côte d'Ivoire, 2011 Study report.

[present for an HIV test], everyone automatically thinks that you are HIV-positive and you are stigmatised.”⁸⁵ A participant at another group said the following:⁸⁶ “Public hospitals create stigma in the reception system both in terms of disposition towards patients and the behaviour of healthcare workers.”

The high level of stigma is assumed to be behind the following negative outcomes, among others:

- The low rate of attendance at testing centres: less than 10 percent of the population has been tested for HIV.⁸⁷
- The lack of optimal usage of treatment services: PLHIV are often reluctant to seek out regular care because they assume healthcare workers discriminate against them.
- The low compliance with ART: For example, PLHIV avoid taking medication in the presence of other people, including members of their own households.
- The lack of social and community integration of PLHIV: The general population has limited awareness of and understanding of HIV, and self-stigmatisation is common.
- The impoverishment of PLHIV, which is due to unemployment, burdensome healthcare costs, etc.

4. RECOMMENDATIONS

The government should implement and enforce the new national treatment guidelines, based on the 2010 WHO recommendations, which were officially adopted in May 2012. This priority activity should be accompanied by the following steps on the part of the government (particularly the MSLS), all of which are aimed at improving HIV treatment in the country:

- Raise awareness of the new guidelines among all actors (public, private and community)
- Allocate the necessary funds to implement activities and services that ensure the guidelines can be effectively operationalized
- Adapt a monitoring and evaluation framework, including management tools
- Increase funding for anti-HIV activities
- Aim to build capacity for programmes and organizations to develop projects to deliver treatment
- Seek more funding from the international community to ensure rapid scale-up
- Allocate a greater share of the national budget to health in general, and to HIV activities in particular. Ideally the government should start moving to meet the 2001 Abuja Declaration pledge to allocate 15 percent of the national budget to health every year.

PNPEC should be updated and revised to strengthen the capacity of healthcare provision. This effort should include the following activities:

- training for service providers in the public, private and community sectors;

85 As cited by during a focus group discussion in San Pedro on 1 May 2012.

86 As cited during a focus group discussion in Abobo Sud (Abidjan) on 30 April 2012.

87 UNGASS Country Report, 2010.

- creation of rural testing and treatment services;
- increase in diagnostic capacities, including biological monitoring; and
- systematic integration of PLHIV support groups into testing, care and treatment centres.

The MSLS and NGO networks should strengthen programme and operational capacity of community organizations engaging in caring for and supporting PLHIV. This effort should include the following activities:

- support for the coordination and management of community organizations;
- undertaking a mapping of stakeholders and the work of community actors to better understand what is currently being provided and what is needed; and
- increasing financial support to community organizations.

Community groups should advocate with the MSLS to promote and roll out task-shifting across health systems. The goal of this effort should be to allow nurses, community health workers, peer educators and CBOs to provide a greater range of services, including in regards to HIV treatment. This advocacy effort is important if the recommendation immediately above is to be approached successfully.

The MSLS should strengthen the provision of public information and education in terms of HIV prevention and treatment of HIV. This effort should include the following activities:

- educating families regarding HIV testing and treatment;
- involving community leaders in developing prevention and management policies and standards;
- involving PLHIV to a greater extent in activities to prevent and treat HIV;
- developing and implementing strategies to improve the socio-economic integration of PLHIV; and
- developing, implementing and supporting programmes to reduce HIV-related stigma and discrimination, including at healthcare facilities.

HONDURAS AND TREATMENT 2.0: CHALLENGES AND OPPORTUNITIES TO SCALE UP HIV TREATMENT

This country report is part of *Missing the Target 10 (MTT10)*, the 2012 version of a longstanding series on global access to HIV treatment coordinated by the International Treatment Preparedness Coalition (ITPC). *MTT10* focuses on challenges to the scale-up of HIV services as required to implement the Treatment 2.0 framework. As with other *Missing the Target* publications, national and local community groups conducted research based on a general template and prepared their country-specific reports. The following countries are included in *MTT10*: Cameroon, China, Côte d'Ivoire, Honduras, India, Kenya, Morocco and Russia.

The full *MTT10* report and individual country reports are available at the ITPC website: www.itpcglobal.org. Also available at that website is a Spanish version of this Honduras report and French versions of the Cameroon and Côte d'Ivoire reports.

Honduras

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ACRONYMS AND ABBREVIATIONS

ART	antiretroviral treatment
ARV	antiretroviral drug
CBO	community-based organization
MSM	men having sex with men
PLHIV	people living with HIV
STI	sexually transmitted infection
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

Note on text: All "\$" figures are U.S. dollar amounts. All URLs cited were valid as of 1 October 2012.

HIV drugs list

Many HIV drugs are commonly referred to in an abbreviated format. Listed below are the abbreviated names of all the drugs mentioned in the Honduras report as well as the full generic name associated with them. Where relevant, brand names of key drugs are also noted. The drugs are grouped by class.

NRTIs (nucleoside reverse-transcriptase inhibitors)	
3TC	lamivudine
ABC	abacavir
AZT	zidovudine
FTC	emtricitabine
TDF	tenofovir
NNRTIs (non-nucleoside reverse transcriptase inhibitors)	
EFV	efavirenz
Protease inhibitors	
LPV/r	lopinavir/ritonavir (refers to lopinavir being “boosted” by ritonavir)

1. INTRODUCTION AND OVERVIEW

1.1 Methodology

Three methodological techniques were used to carry out research for this report: a literature review, in-depth interviews and focus group discussions. Among the documents reviewed were data and policy papers from the Ministry of Health (MoH), studies compiled by non-governmental organizations (NGOs), and reports from multilateral entities such as the Pan American Health Organization.

In April and May 2012, researchers conducted a total of 18 interviews: 12 with people living with HIV (PLHIV); three with representatives from community-based organizations (CBOs) working in the field of HIV; two with service providers from public-sector health facilities; and one with the government official who coordinates national AIDS programme activities throughout the country. With the exception of the programme coordinator, who was interviewed in the capital of Tegucigalpa, all other interviewees were based in the Cortés and Atlántida departments in the northern part of the country, home to at least 60 percent of HIV cases reported as of December 2011.⁸⁸

Four focus group discussions were conducted in March and April 2012 with participants who share common characteristics. The first group comprised HIV-positive women and men from the Garífuna⁸⁹ community of Tornabé, a rural area in Atlántida department. There were nine participants, six women and three men, whose ages ranged from 28 to 69 years; the time since diagnosis ranged from three to 10 years. Seven of them were on antiretroviral treatment (ART); of those, one was on a first-line regimen, four were on a second-line regimen, and one was receiving “salvage” therapy.

The second group comprised seven HIV-positive men from the city of San Pedro Sula in Cortés department. Their ages ranged from 24 to 54; the time since diagnosis ranged from three to 16 years.

88 As noted in documentation provided to UNAIDS from the Honduran government in March 2012 .

89 The Garífuna people are descendants of Carib, Arawak and West African people.

All participants were on ART: one on a first-line regimen, four on a second-line regimen, and two were receiving “salvage” therapy.

The third group comprised five HIV-positive individuals, four women and one man, in the city of Puerto Cortés in Cortés department. Their ages ranged from 37 to 64; the time since diagnosis ranged from 5.5 years to 12 years. All participants were on a second-line ART regimen.

The fourth focus group comprised nine HIV-positive women in San Pedro Sula. Their ages ranged from 15 to 42; the time since diagnosis ranged from two to 15 years. Five participants were on a second-line ART regimen; three were receiving “salvage” therapy; and one was not on ART at the time.

1.2 Context

*The HIV situation in the study area*⁹⁰

From 1985 until December 2011, a total of 30,026 individuals were diagnosed with HIV in Honduras. Nearly two-thirds (60 percent) of those cases were among people living in the Sula Valley, in northern part of the country (and including the departments of Cortés and Atlántida). HIV prevalence nationally is estimated to be 0.68 percent, though with regional variations: prevalence along the northern coast, at nearly 0.91 percent, is much higher than elsewhere.

More than 90 percent of transmissions are related to heterosexual sex, with the number of cases among women higher than among men. About two-thirds of HIV-positive people (67.3 percent) were between the ages of 20 and 39 when diagnosed. As such, it can be concluded that the epidemic continues to predominantly affect young people of reproductive age who are economically active.

Concentrated epidemics are also observed among sex workers (4.6 percent prevalence nationally, as per data from a few years ago), members of the Garifuna community (5 percent) and men having sex with men (MSM), at 9.9 percent.⁹¹ No reliable estimates or data are currently available regarding HIV prevalence among prisoners and injecting drug users, so it is not clear whether HIV may be categorized as “concentrated” among those populations.

The context of access to treatment and care for PLHIV

The Honduran government began providing access to antiretroviral drugs (ARVs) in 2002 with 250 people. Starting in 2008, accelerated access to ART began thanks to support from the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) as well as the opening of comprehensive healthcare centres for people living with HIV.⁹² Thirty-nine of those centres now exist, located in the main municipalities. According to a study conducted by the Central American Network of People with HIV (REDCA+) in 2011,⁹³ patients assessed the quality of the centres’ services to be satisfactory. An ARV Panel coordinated by the National HIV Programme and comprising healthcare providers from the specialized centres is currently operational in Honduras. The panel focuses on clinical care issues primarily and has no influence or responsibilities regarding programming. The panel does not include representatives from civil society or any PLHIV.

Self-help groups in Honduras

90 Information in this section is obtained from the following two sources: i) UNAIDS, Presentation on Treatment 2.0, Alberto Stella, April 2012; and ii) documentation provided to UNAIDS from the Honduran government in March.

91 Secretaría de Estado de Salud, CDC, Encuesta Centroamericana de Vigilancia del Comportamiento, 2006.

92 These specialized facilities are known in Spanish as Centros de Atención Integral para las personas con VIH (CAI).

93 REDCA+ Regional Programme, Study on the quality of services for people living with HIV in Honduras, 2011.

The National Association of People with HIV/AIDS in Honduras (ASONAPVSI DAH) is made up of self-help groups for PLHIV. The association currently has 64 affiliated groups located in 16 of the country's 18 departments. These groups are open and permanent, and most members are adult women.

2. NOTABLE FINDINGS AND OBSERVATIONS ASSOCIATED WITH TREATMENT 2.0

“Treatment 2.0” is the name of an initiative developed and launched in 2010 by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO). It aims to simplify and improve the way HIV treatment is currently provided in order to maximize the effect of ART and further scale up access to HIV treatment, care and support. The initiative focuses on innovation and efficiency in HIV programming, including the integration of important new findings such as the preventive effects of ART.⁹⁴

WHO and UNAIDS are currently developing various frameworks that will help countries and all stakeholders develop and implement strategies based on Treatment 2.0 principles and priorities. The frameworks will be based on the initiative's five main priority work areas, also known as “pillars”:

1. Provide point-of-care and other simplified diagnostic and monitoring tools
2. Optimize drug regimens
3. Reduce costs
4. Adapt delivery systems
5. Mobilize communities

The agencies have worked closely with partners at global, regional and country level to explain the Treatment 2.0 agenda in general, and the importance of the five pillars specifically. This effort also seeks to build support for the overall approach, which can only be successful when countries' HIV programmes and strategies align with it.

Findings and observations obtained through research for this report are organized by the five Treatment 2.0 pillars (Sections 2.1 through 2.5 below). This structure is intended to highlight progress, gaps and challenges in Honduras regarding expanded and enhanced HIV treatment for all in need.

Existing awareness of Treatment 2.0 in Honduras

The Treatment 2.0 framework appears to be largely unknown in Honduras. None of the interviewees or focus group participants engaged in this research were aware of it.

2.1 Provide point-of-care and other simplified diagnostic and monitoring tools

According to focus group participants, health centres and public hospitals are among the places where HIV testing is offered. (NGOs reportedly offer HIV testing in Tegucigalpa, but none do in the area covered by this research.) However, participants emphasized that some of these facilities do not provide medical care for HIV infection. This was confirmed in interviews with representatives of community organizations.

The almost total consensus of focus group participants was that they did not receive any type of counselling when getting tested. One woman said that no one counselled her as to what a positive HIV test result meant, and a year later she became pregnant and her baby was later diagnosed with HIV. She

94 Detailed information about the Treatment 2.0 agenda may be found online at: http://data.unaids.org/pub/Outlook/2010/20100713_fs_outlook_treatment_en.pdf.

believed that had she understood the positive test result, she would have been able to prevent the transmission of HIV to her child.

Shortcomings and inconsistencies persist in compliance with patient counselling protocols, which mandate pre- and post-test counselling. Of the 12 participants from vulnerable populations, only two said they had been informed that they could decline an HIV test; just three were told that the results were confidential and would not be shared with anyone; only three said they had received explanations of what the test consisted of and what the meaning would be of a negative or positive result; and just two said they were given time to ask questions.

With regard to diagnostic tests, only a few focus group participants said they had had CD4 and viral load tests performed on a routine basis. Some mentioned that healthcare providers had explained to them that due to a lack of resources, these tests were not available. A government official interviewed for this report dismissed claims that these essential tests are often not available, arguing that CD4 and viral load tests are offered routinely with the frequency specified by the national protocol.⁹⁵

Cost to the patient is another challenge regarding diagnostic tests. In Honduras, patients must pay for all tests, with costs averaging around \$20 per test for CD4 and viral load tests. And finally, two other obstacles to consistent availability of diagnostic tests are structural. One is a lack of qualified staff, a situation that is especially problematic given that efforts to decentralize health care are still ongoing. The other is that access to necessary diagnostics is hindered by the limited number of facilities where they are provided. Of the 39 comprehensive healthcare centres for people with HIV, only six have the multi-disciplinary personnel and laboratory services' capacity to perform CD4 tests and provide comprehensive HIV services.⁹⁶ Analysis of viral load tests, meanwhile, is centralized in the main laboratory of the national health system, in Tegucigalpa.

One other important diagnostic, genotype tests, are not available in Honduras. That is expected to change soon. According to the government official interviewed,⁹⁷ Honduras has been part of a Meso-american project for 24 months and is currently processing the donation of a genotyping sequencer.

2.2 Optimize drug regimens

HIV treatment provision is governed by the National Guidelines for Care of People with HIV. These guidelines have been updated to comply with the 2010 WHO recommendations.

In Honduras, ART is only provided in government-run clinics; ARVs are not available from private healthcare providers or other non-governmental sources. From 2002 through 2011, a total of 11,536 people had access to ART; of this number, a total of 8,355 were on ART in December 2011.⁹⁸ Over that period, the survival rate 12 months after initiating ART was 84 percent. The distribution of people receiving ART in December 2011 was as follows:

95 As cited during an interview with Dr. Hector Galindo from the Ministry of Health, 12 April 2012.

96 As noted in documentation provided to UNAIDS from the Honduran government in March 2012.

97 As cited during an interview with Dr. Hector Galindo from the Ministry of Health, 12 April 2012.

98 The National STD/HIV/AIDS Programme, HIV Statistical Report of December 2011.

TYPE OF REGIMEN	ADULTS	CHILDREN	TOTAL
1st-line therapy	6,440	602	7,042
2nd-line therapy	1,162	132	1,294
Salvage therapy	17	2	19
TOTAL	7,619	736	8,355

The most frequently prescribed first-line ART regimens, most of which comprise generic drugs, are ABC+EFV+NVP; AZT+3TC+LPV/r; and TDF+AZT+3TC.⁹⁹ None of the regimens currently prescribed are available as fixed-dose combinations. Even though ARVs for both first- and second-line treatment are available for free, patients must pay a “recovery fee” when getting them. The amount of this fee is between \$10 and \$20 per month. Such fees are commonly required for a wide range of health services in Honduras, not just those associated with HIV.

Third-line regimens are not currently provided through the public sector. In 2011, a group of civil society organizations, the Committee for Access to Comprehensive Healthcare for People with HIV (the Committee), processed two public complaints before human rights panels to demand that the government support the 16 individuals then taking salvage therapy. (Then, as now, all on such regimens only get treatment via donations from international non-governmental organizations or churches). In addition, the Committee demanded that the government make such regimens available in the country more broadly. Neither the health secretary nor any other government official has to date responded to the request.

Treatment effectiveness and optimization has also suffered from policy decisions. From November 2011 through February 2012 there were four changes in the suppliers of first-line ARVs; this situation was confusing for PLHIV given that at each visit they received drugs of different texture, colour and taste. According to those interviewed and in focus group discussions, they rarely received any information or counselling about the changes from healthcare personnel. Some patients reported experiencing side effects after starting on the different versions. Such impacts put patients at risk for non-adherence with ART, which can cause treatment abandonment rates to worsen.

Those rates are already extremely high. According to a December 2011 report of a cohort of people receiving ART, approximately 20 percent of people who started treatment eventually abandoned it. The main reasons people stop treatment are difficulty in getting to facilities because of long distances; stock-outs; and wariness when presented with different versions of what could be the same medicines (e.g., as noted above, the different colours, shapes and textures).

More generally in regards to adherence, most focus group participants agreed that taking ARVs regularly can be difficult—because of reasons including side effects, tablet size and unpleasant taste. They said that members of their family, especially sons and daughters, are the main motivation for adhering to treatment. Some mentioned that family members regularly remind them to take the right dose at the right time; others said they use alarm clocks to help them remember. Several added that looking and feeling well motivates them to continue taking their medication and receiving care.

99 Organización Panamericana de la Salud, “Tratamiento antirretroviral bajo la lupa: un análisis de salud pública en Latinoamérica y el Caribe, 2012. Available online at: http://new.paho.org/hq/index.php?option=com_docman&task=doc_view&gid=17504&Itemid=

Drug shortages were reported to be a serious problem by focus group participants. Some adult patients reported receiving paediatric formulations during periods of stock-outs. Others mentioned insufficient supply that required returning at a later date. One participant of the women's focus group in San Pedro Sula stated: "During a period when I would go, they would give me a two-week supply. They would say, come back later since there's not enough to be able to give you all of it."

2.3 Reduce costs

Honduras is a small market and thus not commercially attractive for multinational pharmaceutical drug manufacturers. Neither brand-name nor generic ARVs are manufactured domestically. The ARVs that are currently distributed in the country—nearly all of which are generic versions—are imported by the government through the Pan American Health Organization (PAHO) and the Global Fund's voluntary pooled procurement (VPP) mechanism. Both the government and the Global Fund finance ARV purchases, with the government gradually assuming a larger share in recent years.

Honduras is a signatory to the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). It has also signed the Central American Free Trade Agreement (CAFTA) with the United States, which includes rules that are often characterized as "TRIPS-plus".¹⁰⁰ Joining CAFTA could restrict access to affordable ARVs and other essential medicines in the future because of restrictive intellectual property requirements in the agreement. Therefore, civil society groups have started advocacy efforts aimed at ensuring that the government guarantees the "right to health".

Though high, the prices the government pays for ARVs have remained stable due to the lack of competition. The following are a few examples of prices for one person per month for selected ARVs:¹⁰¹ ABC = \$15.89, TDF+FTC = \$11.50, LPV/r = \$35.00 and TDF = \$7.00.

2.4 Adapt service delivery

According to service-provider respondents, the integration of ART services with other key health services appears to be a reality in Honduras, including family planning, treatment for sexually transmitted infections, prenatal care, maternal care and child health and welfare. Not all focus group participants had the same impression, however. Several said that HIV and TB services are not integrated—although some added that patients with HIV and TB are nevertheless receiving necessary care for both infections. One participant from the Tornabé focus group noted the following: "The community health centre provides HIV testing and counselling, and it also provides assistance and treatment for tuberculosis.... One problem, though, is that it needs to expand its physical facilities."

One service provider interviewed¹⁰² noted that despite efforts to improve integration, the quality of services remains a concern in many places: "The barriers to obtain integration are lack of funds, lack of staff, different reporting formats and irregular supplies."

100 TRIPS refers to the Agreement on Trade-Related Aspects of Intellectual Property Rights, an agreement negotiated through the World Trade Organization (WTO) in the 1990s to introduce intellectual property rules into the multilateral trading system. The TRIPS agreement included several "flexibilities" that signatories could use to ensure access to essential products such as HIV drugs without issuing patents. "TRIPS-Plus" refers to subsequent efforts by some governments, including the United States, to limit other countries' use of these flexibilities, including by getting countries such as Honduras to mandate lengthier patent protection on originator-brand medicines.

101 Lidice López Tocón for Hivos, "Dime dónde vives y te diré cuánto cuesta tu tratamiento antirretroviral: un breve estudio sobre los precios de medicamentos en cuatro países de Centroamérica", 2012. Available online at: <http://www.onusida.org.gt/inicio/229-dime-donde-vives-y-te-dire-cuanto-cuesta-tu-tratamiento-antirretroviral.html>.

102 Interview in San Pedro Sula, 19 April 2012.

Individuals living in rural areas of Honduras generally find it far more difficult to access HIV services because nearly all HIV-specific facilities are in larger towns and urban areas.

2.5 Mobilize communities

Community groups currently provide services including information and education (including distribution of education materials), counselling, provision of condoms and self-help groups. They do not offer services such as HIV testing and care, including disbursement of ART, because they are not permitted to do so under Honduran government policies.

Community-based advocacy on higher-level concerns such as intellectual property issues is generally conducted in the capital, Tegucigalpa. CBOs and PLHIV in other areas are more likely to focus on immediate concerns such as drug stock-outs, which continue to occur on occasion in many treatment facilities.

Most HIV-positive focus group participants and interviewees said they had been engaged with community groups in various ways. For example, several mentioned that they had participated in both prevention activities and social mobilization on commemorative days such as World AIDS Day (1 December) and Solidarity Day (in May).

3. KEY CHALLENGES

This section summarizes some of the main challenges identified during research to an enhanced and expanded HIV response in Honduras. Improvements in such areas are considered critical for the effective adoption and implementation of the Treatment 2.0 framework in the future.

Patients often are poorly educated on HIV treatment essentials, including the importance of adherence and clinical management of side effects. Self-help groups can help address these challenges, but often patients are not referred to them by caregivers. Lack of connection with other PLHIV and absence of emotional support are among the main reasons some patients discontinue treatment.

Although not mentioned in any of the focus group discussions or interviews for this report, the **relatively high ARV prices and the influence of intellectual property agreements and laws** threaten the achievement of universal access to drugs in Honduras. The resulting inefficiency and obstacles can be seen in the far-too-extensive variety of ARVs distributed in the country, some of which are donated, and the periodic drug shortages that occur.

Comprehensive health care is compromised by **insufficient availability of qualified healthcare personnel and lack of funds** to provide important services. This challenge was frequently mentioned in the focus group discussions and interviews.

Lack of patient confidentiality and privacy with regard to HIV status remains a problem in healthcare settings. In some contexts, it appears that the main reason is lack of awareness among caregivers regarding HIV. Participants in the focus group of women in San Pedro Sula mentioned that they preferred to travel to sites relatively far from their homes in order to maintain confidentiality and obtain adequate care. One participant stated: “Even though there is a closer site, I prefer to travel to where there is understanding of HIV” and the staff do not discriminate.

Confidentiality concerns were also raised in regards to some locations where HIV testing is currently offered. Such places include educational institutions, workplaces and other public spaces. Workplace

testing was seen as especially worrying given the possible consequence of loss of employment if all aspects of testing were not conducted confidentially.

Healthcare centres for PLHIV, including those that dispense ARVs, usually are **unable to provide treatment for opportunistic infections**. Personnel often do not issue referrals to other facilities where such services are provided.

Laboratory services continue to be centralized, with CD4 tests analyzed only in tertiary level hospitals and with only one laboratory in the entire country able to analyze viral load tests. Partly as a result, it can take several months for results to be ready, and in some cases results are lost or samples decay.

Community participation continues to be weak and its influence is limited, as was noted in focus group discussions. Though many PLHIV interact with community groups, they do so only at a basic level. This is due in part to the limited opportunities for them to participate, scant information on the issues that affect them, their lack of empowerment and, in general, their being unaware of the existing mechanisms for participation.

4. RECOMMENDATIONS

Civil society organizations should **promote the empowerment and participation of PLHIV in any area that affects them**, particularly with regard to achieving the right to health in its broadest sense.

With support from like-minded groups abroad, civil society organizations in Honduras should initiate a **comprehensive review process of current intellectual property laws and policies**. Together with health authorities, they should then search for appropriate mechanisms to facilitate affordable and sustainable access to treatment. This effort may require increased advocacy targeting government agencies and officials with responsibility for initiating and implementing relevant policies and laws.

The Ministry of Health should make **more rapid and better progress in decentralizing health services that serve people with HIV**. This would include providing the necessary funds and facilities for healthcare services to integrate further and include other complementary services and support, such as treatment and care for TB and infant and maternal health.

UNAIDS and the Pan American Health Organization (PAHO) should undertake a **stronger effort to explain the Treatment 2.0 framework**, including what it will likely mean in reality, in both the public and civil society sectors in Honduras. Currently there is little awareness of the concept and what kind of steps might be needed to help put it into practice.

The Ministry of Health and National AIDS Programme should identify ways to raise awareness, especially among healthcare personnel, of **the need to safeguard patient confidentiality and privacy**. This effort should be part of a larger one by the National AIDS Programme to monitor the compliance of national guidelines on the care of PLHIV.

If doctors can be trained to prescribe first-line treatment, why not train them on second-line treatment as well?

- Representative of community group in Manipur 136

INDIA AND TREATMENT 2.0:

CHALLENGES AND OPPORTUNITIES TO SCALE UP HIV TREATMENT

This country report is part of *Missing the Target 10 (MTT10)*, the 2012 version of a longstanding series on global access to HIV treatment coordinated by the International Treatment Preparedness Coalition (ITPC). *MTT10* focuses on challenges to the scale-up of HIV services as required to implement the Treatment 2.0 framework. As with other *Missing the Target* publications, national and local community groups conducted research based on a general template and prepared their country-specific reports. The following countries are included in *MTT10*: Cameroon, China, Côte d'Ivoire, Honduras, India, Kenya, Morocco and Russia.

The full *MTT10* report and individual country reports are available at the ITPC website: www.itpcglobal.org. Also available at that website are French versions of the Cameroon and Côte d'Ivoire reports and a Spanish version of the Honduras one.

India

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ACRONYMS AND ABBREVIATIONS

ART	antiretroviral treatment
ARV	antiretroviral drug
ASHA	accredited social health activist
CoE	centre of excellence
DNP	Delhi Network of Positive People
FTA	free trade agreement
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HCW	healthcare worker
ICTC	Integrated Counselling and Testing Centres
IDU	injecting drug user
MoH	Ministry of Health and Family Welfare
MSM	men who have sex with men
NACO	National AIDS Control Organization
NACP	National AIDS Control Programme
NAPCP	National AIDS Prevention and Control Policy
PLHIV	people living with HIV
SACEP	State AIDS Clinical Expert Panel
STI	sexually transmitted infection
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
WHO	World Health Organization

Note on text: All "\$" figures are U.S. dollar amounts. All URLs cited were valid as of 1 October 2012.

103 Others engaged in the process were the following: three focus group rapporteurs (Rajesh Khongbantabam, Jina Nigom and Twinkle Vungngaihting) and two translators (Sunil Aheibam and Alex Loon).

HIV drugs list

Many HIV drugs are commonly referred to in an abbreviated format. Listed below are the abbreviated names of all the drugs mentioned in the India report as well as the full generic name associated with them. Where relevant, brand names of key drugs are also noted. The drugs are grouped by class.

NRTIs (nucleoside reverse-transcriptase inhibitors)	
3TC	lamivudine
d4T	stavudine
AZT	zidovudine
FTC	emtricitabine
TDF	tenofovir
NNRTIs (non-nucleoside reverse transcriptase inhibitors)	
EFV	efavirenz
NVP	nevirapine
Protease inhibitors	
ATZ/r	atazanavir/ritonavir (refers to atazanavir being “boosted” by ritonavir)
DRV	darunavir
LPV/r	lopinavir/ritonavir (refers to lopinavir being “boosted” by ritonavir)
Integrase inhibitors	
MK-0518	raltegravir

1. INTRODUCTION AND OVERVIEW

1.1 Methodology

The Delhi Network of Positive People (DNP+) conducted a survey of the government of India’s HIV treatment programme between 6 April and 11 May 2012. This report focuses primarily on the government because it is the provider of antiretroviral treatment (ART) for the overwhelming majority of people living with HIV (PLHIV) in India and has an extensive prevention, care, support and treatment programme. (Where relevant, however, the private sector is also discussed in this report.)

In accordance with the survey guidelines and questionnaires provided by the International Treatment Preparedness Coalition (ITPC), the survey consisted of the following: i) an analysis of India’s HIV treatment programme and an overview of relevant laws and policies through a literature review; ii) focus group discussions; and iii) in-depth interviews. The survey was conducted in the National Capital Region of Delhi (situated in north-central India) and the state of Manipur (in the northeast). The selection of the survey sites was based on the need to consider both urban and rural perspectives. The two survey sites also present a contrast in regards to the main characteristics of the epidemic in India: HIV in Manipur is concentrated among injecting drug users (IDUs), while the epidemic is more generalized in Delhi, with the majority of infections there associated with heterosexual sex.

In-depth interviews: In-depth interviews were conducted with PLHIV, healthcare workers (HCWs), representatives of community groups and one international organization. Five HCWs were interviewed: three in Manipur and two in Delhi. Of these, three were doctors, one was a nurse and one was a counsellor. Representatives of four non-governmental organizations (NGOs) were interviewed: two in Manipur and two in Delhi. Of these, three were from networks of PLHIV and the other from an organization working on HIV.

Exactly half of the 16 PLHIV interviewed were from Delhi, and the others from Manipur. Eleven of the 16 were men, and the age group ranged from 30 to 50. The years in which interviewees were diagnosed with HIV ranged from 1996 to 2009.

Focus group discussions: Four focus group discussions were held with PLHIV: two in Manipur (in Bishnupur and Churachandpur) and two in Delhi (in the neighbourhoods of Neb Sarai and Jehangirpuri). Of the total participants, 20 were men, 12 were women and six were from the transgender community. In addition, 10 of those who participated were current or ex-drug users living with HIV.

Limitations: Due to time constraints, interviews with government officials were not possible to arrange. Moreover, not all important marginalised groups were represented in the in-depth interviews and focus group discussions. As a result, the report does not highlight issues related to, among others, sex workers; access to treatment for children and young persons; or prevention of vertical transmission. In addition, although the survey raised several issues that will affect the achievement of Treatment 2.0 in India, space constraints have led to the researchers highlighting only some of these issues.

1.2 Context

The Indian government's HIV response dates back to 1990. The primary government body addressing the HIV epidemic in India is the National AIDS Control Organization (NACO), established within the federal Ministry of Health and Family Welfare (MoH) in 1992.¹⁰⁴ (The fourth phase of the National AIDS Control Programme [NACP] was still being drafted when research for this report was conducted.)

India's HIV response is funded by the government of India as well as external donors.¹⁰⁵ As of 2009, an estimated 23.9 lakh (2.39 million) people were living with HIV in India; that corresponded to adult prevalence of 0.31 percent, of whom 39 percent were female and 4.4 percent were children below the age of 15.¹⁰⁶ Although India is considered a low prevalence country, in terms of overall numbers it has the world's third largest population of PLHIV. The HIV epidemic in India is considered to be concentrated, with high HIV prevalence among marginalised populations such as sex workers, IDUs, men who have sex with men (MSM) and the transgender community.¹⁰⁷ The primary mode of

104 The implementation of the programme is decentralised through State AIDS Control Societies (SACs) in each of India's 28 states and seven union territories. In some high prevalence states the programme is even further decentralised through Districts AIDS Control Societies (DACs) as well.

105 Among the external donors are the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), USAID, the World Bank, and the UK Department for International Development (DFID). See www.nacoonline.org/About_NACO/Funds_and_Expenditures (last accessed 8 September 2012).

106 The latest figures used by the Indian government in its reporting on HIV are from the sentinel surveillance 2008-09 estimates. See NACO Annual Report 2010-2011, available at: www.nacoonline.org/upload/REPORTS/NACO%20Annual%20Report%202010-11.pdf (last accessed 8 September 2012).

107 See NACO Annual Report 2010-2011: "The overall HIV prevalence among different population groups in 2008- 2009 (Fig 2.4) continues to portray the concentrated epidemic in India, with a very high prevalence among high risk groups—IDU (9.19%), MSM (7.3%), FSW (4.94%) and STI clinic attendees (2.46%)—and low prevalence among ANC attendees (0.48%)." Available online at: www.nacoonline.org/upload/REPORTS/NACO%20Annual%20Report%202010-11.pdf (last accessed 8 September 2012).

transmission is heterosexual sex, though transmission rates attributed to sharing of contaminated injection material and sexual activity between men are increasing. Within the country, some states that previously had consistently low prevalence are now reporting an increase in numbers of PLHIV.¹⁰⁸

The Constitution of India, in Article 21, recognises the right to life and liberty of every individual; this has been interpreted by the Indian Supreme Court to include the right to health. A key turning point in regards to the government beginning to meet constitutional obligations regarding HIV occurred in 1998 and 1999, when Sahara House and Sankalp Rehabilitation Trust, organizations working on HIV, filed public interest litigations before the Indian Supreme Court seeking to address barriers to healthcare access for PLHIV. In 2002, the government promulgated the National AIDS Prevention and Control Policy (NAPCP), which promoted an HIV response predicated on human rights.¹⁰⁹

In 2004, when the Indian government started providing ART, these along with other HIV-related cases in the Supreme Court became an oversight mechanism on the government programme through several case hearings that continue to this day. Among the important steps that have been taken as a result of these ongoing cases are i) commitments from NACO related to the scale-up of the ART rollout; ii) closer scrutiny of and efforts to address concerns related to private healthcare providers; and iii) most recently, scale up in availability of and access to second-line treatment. (At the time this report was finalized, the long-running main case, *Sankalp Rehabilitation Trust v. Union of India*, was still being heard in the Supreme Court.¹¹⁰) Indian courts have also been active in upholding the rights of PLHIV against discrimination.

2. NOTABLE FINDINGS AND OBSERVATIONS ASSOCIATED WITH TREATMENT 2.0

“Treatment 2.0” is the name of an initiative developed and launched in 2010 by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO). It aims to simplify and improve the way HIV treatment is currently provided in order to maximize the effect of ART and further scale up access to HIV treatment, care and support. The initiative focuses on innovation and efficiency in HIV programming, including the integration of important new findings such as the preventive effects of ART.¹¹¹

WHO and UNAIDS are currently developing various frameworks that will help countries and all stakeholders develop and implement strategies based on Treatment 2.0 principles and priorities. The frameworks will be based on the initiative’s five main priority work areas, also known as “pillars”:

1. Provide point-of-care and other simplified diagnostic and monitoring tools
2. Optimize drug regimens
3. Reduce costs
4. Adapt delivery systems
5. Mobilize communities

108 See NACO Annual Report 2010-2011: “Of the 1.2 lakh... new infections in 2009, the six high prevalence states account for 39 percent of the cases, while the states of Orissa, Bihar, West Bengal, Uttar Pradesh, Rajasthan, Madhya Pradesh and Gujarat account for 41 percent of new infections.” Available online at: www.nacoonline.org/upload/REPORTS/NACO%20Annual%20Report%202010-11.pdf (last accessed 8 September 2012).

109 National AIDS Prevention and Control Policy, Ministry of Health and Family Welfare, Government of India, 2000. Available online at: www.hsph.harvard.edu/population/aids/india.aids.02.pdf (last accessed 8 September 2012).

110 For more information, see Lawyers Collective HIV/AIDS Unit, Current Cases: Sankalp Rehabilitation Trust v. Union of India. Available online at: www.lawyerscollective.org/hiv-and-law/current-cases.html (last accessed 8 September 2012).

111 Detailed information about the Treatment 2.0 agenda may be found online at: http://data.unaids.org/pub/Outlook/2010/20100713_fs_outlook_treatment_en.pdf.

The agencies have worked closely with partners at global, regional and country level to explain the Treatment 2.0 agenda in general, and the importance of the five pillars specifically. This effort also seeks to build support for the overall approach, which can only be successful when countries' HIV programmes and strategies align with it.

Findings and observations obtained through research for this report are organized by the five Treatment 2.0 pillars (Sections 2.1 through 2.5 below). This structure is intended to highlight progress, gaps and challenges in India regarding expanded and enhanced HIV treatment for all in need.

2.1 Provide point-of-care and other simplified diagnostic and monitoring tools

HIV testing

HIV testing and counselling services in India began in 1997. Through the third phase of the National AIDS Control Programme (NACP-III), which ended in 2011, public-sector HIV testing services were consolidated largely in Integrated Counselling and Testing Centres (ICTCs). Those facilities offer integrated HIV services, include testing and monitoring of pregnant women, as well as provide referrals to clinics to treat sexually transmitted infections (STIs) and tuberculosis (TB).¹¹² As of February 2012, NACO had established 9,448 ICTCs, all of which provide HIV testing free of charge. In 2011-2012, more than 17 million people took an HIV test and over 250,000 tested positive for HIV.¹¹³

HIV tests are also available through private laboratories, though such tests are not free and the quality of testing has been an area of ongoing concern.¹¹⁴ In an effort to address such concerns, some states require laboratories conducting HIV tests to obtain licences.¹¹⁵ While NACP-III did not include the same requirement for government-run facilities (e.g., for ICTCs), it seeks to ensure quality assurance for the whole programme including through encouraging certification and accreditation for diagnostic kits¹¹⁶ and for laboratories.¹¹⁷

Quality of counselling

The discussions in the focus group discussions reflected the evolution of the government's testing programme. While many of those who tested in the early years of the epidemic reported having been mandatorily tested, those who have had HIV tests more recently report that tests offered at government facilities are largely voluntary and with counselling.¹¹⁸ However, the quality of counselling remains a particular challenge, as reported by focus group participants who work as outreach workers. According to one PLHIV in Manipur, for instance:¹¹⁹

112 Apart from advice on and services associated with prevention, the ICTCs also provide the following services through linkages: information, education, communication (IEC) and behaviour change communication (BCC); condom promotion; treatment of STIs and linkage to associated services; prophylaxis and early management of opportunistic infections; and TB treatment and ART services.

113 National AIDS Control Programme, Phase III, State Fact Sheets (March 2012). Available online at: www.nacoonline.org/upload/Publication/State%20Fact%20Sheets/State%20fact%20sheet%20March%202012%20.pdf (last accessed 8 September 2012).

114 For instance, the national programme aimed to identify private practitioners at the primary level who provide services to a large number of patients with STIs to encourage them to start "provider-initiated testing and counselling". NACP-III estimated that an additional 12 million tests would be undertaken per year through trained private practitioners by the end of the programme.

115 For example, in Manipur. See Manipur State AIDS Policy 2010. Available online at: http://manipursacs.nic.in/download/3rd_Revised_draft_Manipur_State_AIDS_Policy.pdf (last accessed 8 September 2012).

116 Through the National Institutes of Biologics.

117 Through the National Accreditation Board of Laboratories.

118 It should be noted that the NACP firmly rejects mandatory testing.

119 Focus group discussion, Bishnupur (Manipur), 9 April 2012.

A woman who tested HIV-positive was very angry and vowed to have sex with many men to further transmit the virus. When I spoke to her I realised she never got any counselling and was just given her result. No one helped her understand the test result or counsel her on what it means to be positive, including the kind of support available.

Several focus group participants also raised concerns over confidentiality at some facilities. A counsellor interviewed for the survey echoed similar concerns, pointing out that in some places only a curtain separates the counselling space from the rest of a room. The counsellor also noted that as opposed to earlier in the epidemic, when people getting an HIV test did not know what HIV was, now most people come with information they have received from other sources or the internet. Much of that information is inaccurate or misleading, and thus a considerable amount of time in counselling is spent on identifying and overcoming misconceptions.

Other gaps in adequate counselling were also mentioned during the focus group discussions and in-depth interviews. Focus group participants in Delhi, for instance, highlighted the lack of i) counselling for PLHIV on how to talk to or discuss their status with their children and ii) counselling assistance for their children in dealing with their parents' HIV test result. The importance of counselling was also reflected in the outlook of PLHIV to home test kits. Most PLHIV expressed concern about the possibility of individuals getting a positive test result alone with no counselling or immediate referral to a PLHIV network support. According to one focus group participant:¹²⁰

At the testing centre I found out about treatment and that it was free from the government. I learned that there are many people like me and that HIV can be treated and how it spreads and what precautions I should take. I also found out about the network. If I was at home when I got my test results, how would I get all this information?

Forced testing and provider-initiated testing

PLHIV in the focus group discussions opposed any form of forced testing. Based on their own experiences and accounts they had heard from others, several highlighted continuing concerns about whether HIV testing at ICTCs was truly voluntary and consensual. All focus group participants got an HIV test due to unexplained ill health, the positive HIV test of a spouse or as part of screening tests during pregnancy or when they presented with TB. Those who received such screening tests were not informed that they were being tested for HIV.

The responses from HCWs in relation to provider-initiated testing (PITC) were also interesting. PITC has been criticized in India by legal groups for diluting informed consent standards and creating an imbalance in the doctor-patient relationship.¹²¹ The UNAIDS Reference Group on HIV and Human Rights has also identified concerns with this model, including as far back as 2004.¹²² In India, PITC has been recommended by NACO for pregnant women and those presenting with STIs, the majority of whom are from marginalised groups. Partly for that reason, the nurse and counsellor interviewed equated provider-initiated testing with forced testing. However, the three doctors interviewed were more supportive based on their belief that PITC has some advantages in that it can result in earlier diagnoses.

120 Focus group discussion, Neb Sarai (Delhi), 26 April 2012.

121 Anand Grover, "Legal aspects of HIV testing and counselling in South Asian countries". Presentation given at the Joint WHO/UNICEF/UNAIDS Technical Consultation on Scaling-up HIV testing and counselling in Asia and the Pacific, 4-6 June 2007, Phnom Penh, Cambodia. Available online at: www.searo.who.int/en/Section10/Day1/Afternoon_Session/MrAnandGrover-UNAIDSUNICEFPresAG1.ppt (last accessed 8 September 2012).

122 See, for example: http://data.unaids.org/una-docs/hivtestingpolicy_en.pdf (last accessed 8 September 2012).

Testing and counselling for marginalised groups

The experience with testing facilities also varied for members of marginalised groups. Most transgender and MSM respondents said they felt uncomfortable at government testing facilities, with several saying they were unable or unwilling to ask questions of counsellors. Some suggested that mobile testing clinics may have more success in encouraging testing in their communities. As noted by one transgender participating in a focus group discussion in Manipur: “Most of the counsellors do not know or rather do not have the requisite skill to provide counselling to the MSM and transgender community.”¹²³

Diagnostics

Diagnostics are a major component of the Indian government’s treatment programme. On testing HIV-positive, PLHIV are immediately referred to the nearest ART centre for registration¹²⁴ and to determine whether they should be started on treatment.¹²⁵ A baseline comprehensive laboratory evaluation is done by the government including CD4 test, haemoglobin, liver function tests, screening for hepatitis C, etc.

The functioning of diagnostic facilities, especially in the northeast part of India, has been an ongoing concern for the national treatment programme. According to one PLHIV at the Manipur focus group discussion:¹²⁶

I had to spend a lot of money. It was around 30,000 rupees (\$540) as I was advised by the doctor to go for investigation at a private testing centre. The reason was that either the technicians were not present [at the government facility] or the machines were simply not working.

By contrast, Delhi focus group participants did not report such problems. The common key concern in the focus group discussions and the in-depth interviews in both Delhi and Manipur related to access to viral load testing for second-line treatment (see Section 2.2).

2.2 Optimize drug treatment

The government’s ART roll out programme began in 2004 and has since scaled up considerably. On 4 November 2011, NACO issued a memo updating its ART guidelines¹²⁷ to reflect the new WHO guidelines, including starting treatment at a CD4 count of 350 cells/mm³ and/or in cases of co-infection of TB or hepatitis B or hepatitis C (if the hepatitis is chronic and active).¹²⁸

123 Focus group discussion, Bishnupur (Manipur), 9 April 2012.

124 NACO, “Operational guidelines for integrated counselling and testing centres, July 2007”. Available online at: <http://nacoonline.org/upload/Policies%20&%20Guidelines/20,%20Operational%20Guidelines%20for%20Integrated%20Counseling%20and%20Testing%20Centres.pdf> (last accessed 8 September 2012).

125 For the complete list of diagnostics available from NACO and guidance on how often they are to be conducted, see NACO, “Antiretroviral therapy guidelines for HIV-infected adults and adolescents including post-exposure prophylaxis, May 2007, pp. 25-26. Available online at: <http://nacoonline.org/upload/Policies%20&%20Guidelines/1.%20Antiretroviral%20Therapy%20Guidelines%20for%20HIV-Infected%20Adults%20and%20Adolescents%20Including%20Post-exposure.pdf> (last accessed 8 September 2012).

126 Focus group discussion, Bishnupur (Manipur), 9 April 2012

127 NACO, “Antiretroviral therapy guidelines for HIV-infected adults and adolescents including post-exposure prophylaxis”, May 2007. Available online at: <http://nacoonline.org/upload/Policies%20&%20Guidelines/1.%20Antiretroviral%20Therapy%20Guidelines%20for%20HIV-Infected%20Adults%20and%20Adolescents%20Including%20Post-exposure.pdf> (last accessed 8 September 2012).

128 NACO, status note to be submitted to the Supreme Court, 9 July 2012. Submitted in the case of *Sankalp Rehabilitation Trust v. Union of India*.

In April 2011, NACO also released draft guidelines on second-line ART.¹²⁹ A total of nine ART regimens are potentially available as per those guidelines. Of them, the following four first-line regimens are available at all ART centres: AZT+3TC+NVP, d4t+3TC+NVP, AZT+3TC+EFV, and d4T+3TC+EFV. The other five potentially available regimens require special approval and access. For example, State AIDS Clinical Expert Panels (SACEPs) must approve access to the following two regimens: TDF+3TC+NVP and TDF+3TC+EFV. Meanwhile, the following three regimens are only available at centres of excellence (CoEs), and thus not at ART centres: AZT+3TC+ATZ/r, d4T+3TC+ATZ/r, and TDF+3TC+ATZ/r.

In Delhi, of the 24 PLHIV encountered for this research—16 in the focus group discussions and eight who sat for the in-depth interviews—16 are on the first of those four combinations, seven are on the second regimen and one is on the third regimen. (PLHIV engaged in Manipur were unable to fully identify their medicines.) The majority of participants on d4t reported adverse side effects including facial wasting. Their experience is not unique. After considerable pressure from community groups (see Section 2.5), NACO has announced that it will phase out d4T, a toxic medicine long discontinued for use in the developed world. PLHIV starting treatment now will not be prescribed d4T, and those currently on the medicine will be shifted to AZT or TDF over the next year.

As of March 2012, nearly 15.29 lakh (1.53 million) PLHIV had registered at 355 ART centres and 5.16 lakh (529,000) clinically eligible patients were receiving free ART from the government.¹³⁰ The number of PLHIV receiving treatment in the private sector is unknown. Second-line ART roll out began in January 2008 and is now available at CoEs¹³¹ and at all ART-plus centres across the country; as of July 2012, a total of 4,208 patients were receiving second-line drugs. The decision to provide alternative first line or switch to second line is made by State AIDS Clinical Expert Panels (SACEPs), which have been constituted at all CoEs. SACEPS are supposed to meet once a week to review patients referred to them.

Under the National Paediatric HIV/AIDS Initiative launched in November 2006, nearly 99,000 children living with HIV have been registered in HIV care at ART centres and more than 28,000 are receiving free ART. Paediatric formulations are available at ART centres while second line for children is available at the 10 CoEs and at seven centres of paediatric excellence notified by NACO.

Treatment literacy

All PLHIV involved in the focus group discussions and in-depth interviews are currently on first-line treatment from the government programme and all are taking fixed-dose combinations procured by NACO from generic companies. The Delhi focus group participants were able to identify their medicines, including by their INNs,¹³² and the potential side effects. That was not the case in Manipur, however, where the majority of research participants were unable to fully identify the ARVs they were on or the side effects of these medicines. That finding underscores the need for consistent and effective treatment

129 NACO, “National guidelines on second-line ART for adults and adolescents”, April 2011. Available online at: www.nacoonline.org/upload/Care%20&%20Treatment/NACO%20guidelines%20for%20second%20line%20ART%20April%202011.pdf (last accessed 8 September 2012).

130 Updated by NACO for the Regional Consultation and Planning Workshop on the use of TRIPS flexibilities to access affordable ARV in Asia, 29-31 May 2012 (on file with research team).

131 According to NACO, 10 regional CoEs are being established in the country to provide state of art services for PLHIV and to serve as knowledge hubs, resource centres and centres for training of other doctors on HIV/AIDS. These centres will also have facilities for individuals seeking second-line ART and alternative first-line ART. The centres are the following, as of 8 September 2012: J.J Hospital, Mumbai, Maharashtra; G.H.T.M, Tambaram, Tamil Nadu; RIMS/J N hospital, Imphal, Manipur; STM, Kolkata, West Bengal; BJMC, Ahmadabad, Gujarat; BHU, Varanasi, Uttar Pradesh; MAMC, Delhi; Bowring, Bangalore, Karnataka; Gandhi Hospital, Secundrabad, Andhra Pradesh; PGI, Chandigarh. Updated by NACO for the Regional Consultation and Planning Workshop on the use of TRIPS flexibilities to access affordable ARV in Asia, 29-31 May 2012 (on file with research team).

132 INN = international nonproprietary name. An INN is the official nonproprietary or generic name given to a pharmaceutical substance, as designated by WHO. For example, the INN of d4T is “stavudine”.

literacy and treatment counselling with the community. According to one PLHIV in a Manipur focus group discussion:¹³³

After being put on ART treatment, I haven't received any sort of counselling or information with regard to side effects of ARVs. Taking my dosages of ARVs from the hospital was almost the same as lining up to fill up my cooking cylinder with cooking gas. The process is very mechanical.

Private-sector treatment

HIV treatment is also prescribed by and is available from the private sector, although information about the number of PLHIV accessing treatment from the sector is difficult to gather. Numerous reports have come to light of prescription of irrational regimens or even mono-therapy by private-sector providers. In 2008 and again in 2010, the Supreme Court has directed doctors and hospitals in the private sector to follow NACO's ART guidelines.¹³⁴ Unfortunately little is known regarding the extent to which these directives have been followed.

Adherence

All focus group participants said they understood the importance of adherence, with those who did not get sufficient counselling from ART centres adding that they got it from community groups. Reasons cited for stopping or missing doses related to external factors such as the inability to travel to pick up ARVs or stock-outs at ART centres. Most PLHIV surveyed said they had established a system to help them remember to take their medicines (for instance, according to the timing of a TV serial). Many added that their family members, particularly their children, are the ones who remind them to take their doses. In Manipur, adherence and follow up with PLHIV who are current drug users was considered difficult both by HCWs and representatives of community groups (see Section 2.5 on community mobilization).

Procedural barriers to alternative first-line and second-line treatment

Although the government is now providing second-line treatment, community groups have had a constant struggle to remove barriers imposed by the government largely based on cost reasons (see Section 2.5). Representatives of community groups highlighted the plight of their members in need of second-line treatment and the barriers created by SACEPs. Their concerns were also reflected in the interviews with the HCWs.

Focus group participants and interviewees from community groups reported that the SACEPs often do not meet according to schedule and/or postpone their meetings, both of which pose major problems for PLHIV who are travelling from far and are already failing on their first-line regimen or facing severe side effects. In addition, representatives from community groups questioned why SACEP referral was required for viral load testing to determine treatment failure; in their opinion, doctors prescribing first-line ARVs should be able to decide. The following are among the observations from this research:

For one of our members, we had to get her admitted into emergency care as we waited and waited for the SACEP to meet and decide on her eligibility for alternative first-line or second-line treatment.

—Representative of community group in Delhi¹³⁵

133 Focus group discussion, Bishnupur (Manipur), 9 April 2012.

134 Supreme Court of India Orders in 2008 and 2010 in *Sahara House v. Union of India*, writ petition (civil) no. 535 of 1998 (on file with research team).

135 Focus group discussion, Neb Sarai (Delhi), 26 April 2012.

If doctors can be trained to prescribe first-line treatment, why not train them on second-line treatment as well? The SACEP creates an unnecessary barrier to treatment. PLHIV have to travel great distances and sometimes a number of times to constantly appear before the SACEP with their reports.

—Representative of community group in Manipur¹³⁶

Because our facility does not have a SACEP, it is very hard to constantly explain to our patients why we cannot give them alternative first line. Many present with stavudine [d4t] side effects but we cannot put them on tenofovir [TDF]. We have to send them to the SACEP and they really face a lot of trouble in running from one place to another.

—HCW interviewed in Manipur¹³⁷

Both PLHIV and HCWs also reported repeated problems with obtaining medicines for opportunistic infections.

2.3 Reduce costs

There are several avenues that deserve attention in the effort to reduce costs associated with the government's treatment programme. They include integration and task shifting (discussed in Section 2.4) and improving the procurement and supply mechanism. This section focuses on the topic of generic medicines, an especially important cost-related issue because generic production's impact on reducing treatment costs has been a primary driver for the national treatment programme as well as the treatment programmes across the developing world. (India supplies 80 percent of generic ARVs used in developing countries.)

The government of India procures only generic medicines from Indian companies. The ARVs are procured by NACO at the central government level and then supplied to ART centres across the country. The costs (per person per year) of the different regimens at the prices available to the government through its procurement process are detailed in the table below.¹³⁸ These figures, which were provided by NACO in a note to a May 2012 regional workshop, did not provide information about specific regimens or ARVs.

First-line ART	Rs 5,500 (\$97.95)
Alternate first-line ART	Rs 12,000 (\$214)
Second-line ART	Rs 17,000 (\$303)

While first- and second-line ARVs that are off patent are produced locally, patented third-line medicines are imported by patent holders. As a developing country and a member of the World Trade Organization (WTO), India changed its national patent law in 2005 to comply with the WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS agreement).¹³⁹ The law included several health safeguards, also referred to as TRIPS flexibilities. Among them were a restriction on "evergreening —i.e., the practice of multinational pharmaceutical companies filing patents for new forms and new uses of

¹³⁶ Interview with representative of community group, Imphal (Manipur), 8 April 2012.

¹³⁷ Interview with healthcare worker, Imphal (Manipur), 8 April 2012.

¹³⁸ Updated by NACO for the Regional Consultation and Planning Workshop on the use of TRIPS flexibilities to access affordable ARV in Asia, 29-31 May 2012 (on file with research team).

¹³⁹ TRIPS was negotiated in the 1990s to introduce intellectual property rules into the multilateral trading system. The TRIPS agreement included several "flexibilities" that signatories could use to ensure access to essential products such as HIV drugs without issuing patents.

existing medicines—and a provision allowing any person or entity, including community groups, to file patent challenges.¹⁴⁰

The representatives of community groups interviewed for this report highlighted the use of these safeguards by PLHIV networks in India to challenge patents and patent applications on key medicines to treat HIV and opportunistic infections. For example:

- A patent application for a combination of two existing ARVs, lamivudine (3TC) and zidovudine (AZT), was withdrawn by GlaxoSmithKline PLC in August 2006 after an opposition was filed by the Manipur Network of Positive People (MNP+).¹⁴¹
- A patent application by Boehringer Ingelheim GmbH on nevirapine (NVP) hemihydrate was rejected in June 2008, based on the fact that it is merely a syrup form of an existing medicine.¹⁴²
- Patent applications on tenofovir (TDF) have been rejected, although the patent holder (Gilead Sciences, Inc.) has filed multiple applications to patent this medicine.¹⁴³
- Patent applications on lopinavir/ritonavir (LPV/r) have been rejected and/or abandoned by Abbott Laboratories, the company that holds patents on this medicine in other countries.¹⁴⁴
- One patent application on darunavir (DRV) has been rejected, though other patent applications have been filed on this medicine.¹⁴⁵

However, as noted above, some key third-line medicines have been patented in India under the 2005 patent law. One, raltegravir (also known as MK-0518), is priced in India at \$2,500 per patient per year.¹⁴⁶ Medicines for co-infections like hepatitis C are also patented and the impact of their high prices is highlighted in Section 2.4.

Several multinational pharmaceutical companies are using litigation to remove or weaken the health safeguards in India's patent law. So far Indian courts have placed public interest over intellectual property rights and rejected attempts by multinational pharmaceutical companies to obtain TRIPS-plus¹⁴⁷ protections in India.¹⁴⁸ However, a crucial case filed by the Swiss multinational Novartis in the Indian Supreme Court threatens to overturn the crucial safeguard in the Indian law against evergreening.

140 UNDP (December 2010). "Five years into the product patent regime – India's response". Available online at: www.eatg.org/eatg/content/download/18802/145797/file/Five%20years%20into%20the%20product%20patent%20regime-India/s%20response.pdf (last accessed 8 September 2012).

141 As cited at: www.thehindubusinessline.com/todays-paper/article1743533.ece (last accessed 8 September 2012).

142 As cited at: www.msf.or.jp/info/pressreport/pdf/UTW_Jan_201001.pdf (last accessed 8 September 2012).

143 Keith Alcorn, "India rejects patents on two HIV drugs", AIDS MAP, 2 September 2009. Available online at: www.aidsmap.com/India-rejects-patents-on-two-HIV-drugs/page/1435862/ (last accessed 8 September 2012).

144 Priyanka Golikeri, "Patent office rejects Abbott Labs plea for expensive AIDS drug", DNA, 4 January 2011. Available online at: www.dnaindia.com/money/report_patent-office-rejects-abbott-labs-plea-for-expensive-aids-drug_1489973-all (last accessed 8 September 2012).

145 Keith Alcorn, "India rejects patents on two HIV drugs", AIDS MAP, 2 September 2009. Available online at: www.aidsmap.com/India-rejects-patents-on-two-HIV-drugs/page/1435862/ (last accessed 8 September 2012).

146 See "Cipla tells Merck your anti-AIDS drug too costly in India", CNBC-TV18, 4 April 2011. Available online at: www.moneycontrol.com/news/business/cipla-tells-merck-your-ant-aids-drug-too-costlyindia_533783-1.html (last accessed 8 September 2012).

147 "TRIPS-Plus" refers to efforts by some governments, including the United States, to limit other countries' use of the flexibilities specified by the TRIPS agreement.

148 Khomba Singh, "SC quashes Bayer petition to block Cipla generic drug", *Economic Times*, 2 December 2010. Available online at: http://articles.economicstimes.indiatimes.com/2010-12-02/news/27575946_1_nexavar-patent-linkage-patent-linkage (last accessed 8 September 2012).

That case was scheduled to be heard in September 2012, soon after research for this report was completed.¹⁴⁹

India is also negotiating a free trade agreement (FTA) with the European Union (EU). Leaked negotiation texts show that the EU is demanding aggressive TRIPS-plus measures of India. If India accepts those demands, the impact would be highly negative in regards to generic production and access not just in India but across the developing world. The concern over the EU-India FTA has led to statements of caution from the United Nations,¹⁵⁰ the Global Fund¹⁵¹ and UNITAID, included the following in a February 2012 statement:¹⁵²

“UNITAID has been able to create and supply markets for paediatric and second-line drugs in 50 countries largely thanks to Indian generic manufacturers,” said Denis Broun, UNITAID executive director. “They produce high-quality products and have made remarkable efforts to make them patient-friendly at guaranteed low prices. We are extremely concerned that attempts to restrict India’s ability to produce such medicines quickly and cheaply will have tragic consequences for global health programmes worldwide.”

2.4 Adapt service delivery

Integration and task-shifting of HIV services

Integration of HIV-related services with others such as those associated with STIs, mental health and drug dependence depends on where the ART centre or ICTC is located. If it is within a hospital funded by the central government, PLHIV would have access to ART but would have to go to state-funded hospitals for treatment for opportunistic infections. If the ART centre is at a major hospital, access to other hospital services such as dermatological departments is easier.

The government TB programme is run by the Revised National TB Control Programme (RNTCP). The MoH is attempting to link that programme more closely with its HIV programme, including by ensuring that anyone who tests positive for TB also tests for HIV and vice versa. ICTCs are now set up at TB centres.

The issue of integration and what form it should take is the subject of considerable discussion. For instance, NACO has been exploring ways to mainstream convergence with the National Rural Health Mission (NRHM), another flagship MoH programme. Accredited social health activists (ASHAs), which are village health workers, are at the centre of this programme. One objective identified for ASHAs is in assisting couples in getting HIV testing and then treatment.¹⁵³ However, concerns have been raised as to ASHAs’ ability to deal with marginalised populations and maintain confidentiality at the village level. Recently the Planning Commission of India announced that NACO would be merged with the NRHM,

149 Lawyers Collective HIV/AIDS Unit, Novartis case: background and update. Available online at: www.lawyerscollective.org/news/126-novartis-case-background-and-update-supreme-court-of-india-to-recommence-hearing.html (last accessed 8 September 2012).

150 See “UNAIDS/UNDP/WHO concerned over sustainability and scale-up of HIV treatment”, UNAIDS press release on 15 March 2011. Available online at: www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2011/march/20110315prtrips/ (last accessed 8 September 2012).

151 See Global Fund press release from 26 May 2011: http://www.theglobalfund.org/en/mediacenter/newsreleases/2011-05-26_Global_Fund_strategy_aims_to_help_shape_market_and_ensure_sustainability_of_AIDS_treatment/.

152 See UNITAID statement from 9 February 2012. Available online at: www.unitaid.eu/resources/news/statements/385-eu-india-fta (last accessed 8 September 2012).

153 NRHM and NACP Convergence, July 2010. Available online at: www.nacoonline.org/upload/DAPCU/DAPCU%20Related%20Orders/NACP-NRHM_Convergence_letter_to_states.pdf (last accessed 8 September 2012).

a decision greeted warily by the MoH itself.¹⁵⁴ One HCW in Delhi felt that integration could be useful if it focused on making better use of existing facilities. Often hospitals where ART centres are located are overcrowded while other hospitals have empty beds. One HCW in Delhi said the following:¹⁵⁵

We have forgotten the current healthcare system. There is no system for referral between the hospitals. Nor is there a mechanism to use the district hospitals. We should develop a good communication system and involve the current healthcare system and train more doctors and nurses. We can deal with bed deficiencies.

The response of HCWs to task-shifting was mixed. Some HCWs felt that doctors and nurses need specialised training on HIV and that specific doctors and nurses would have to be identified to ensure the quality of services. One HCW in Manipur said the following:¹⁵⁶

Not all nurses can do everything. Not all of them are trained. Take the example of the antenatal clinics. If a nurse is not trained specifically and does not know about nevirapine or other emergency interventions to prevent mother-to-child transmission during labour, how will she provide those services? There is the additional problem of sensitisation as there can be a lot of discrimination. I know; I have trained three generations of nurses. This is not a discussion to be taken lightly.

De-centralised care

In 2008, after a review of the ART programme, the government rolled out schemes for “link ART centres” or LACs. These centres were described as follows by NACO: “The concept of the link ART centres was developed taking into consideration the large distances [PLHIV] had to cover to reach ART centres. These link ART centres are being developed at ICTCs or [community care centres], whereby, stabilised patients will get their drugs within their easy reach will have to travel to main ART centre once in six months only. To qualify for a [link ART centre], there must be a minimum of 50 patients on ART in that particular district (the criteria is relaxed in difficult areas).”¹⁵⁷ As of March 2012, a total of 725 link ART centres were functioning in India.¹⁵⁸

All PLHIV in the Delhi focus group discussions said they were getting their medicines from ART centres (and not the link ART centres that have been set up). They did not note any difficulties in getting to ART centres to pick up their medicines. In contrast, PLHIV in Manipur reported numerous difficulties in travel—and as a result, disruption of treatment. The setting up of link ART centres has not eased the situation. According to one PLHIV in Manipur:¹⁵⁹

I was missing my dosages for nearly six months as I lack the financial means to travel and fetch my ARV dosages. I didn't have the courage to approach my family for travelling fares. I was holding back the secret from my family as I feared their stigmatising attitude.

154 “Health min wary of merging AIDS dept with NRHM”, Hindustan Times, 5 May 2012. Available online at: www.hindustantimes.com/India-news/NewDelhi/Health-min-wary-of-merging-AIDS-dept-with-NRHM/Article1-851028.aspx (last accessed 8 September 2012).

155 Interview with healthcare worker, Delhi, 27 April 2012.

156 Interview with healthcare worker, Imphal (Manipur), 7 April 2012.

157 Updated by NACO for the Regional Consultation and Planning Workshop on the use of TRIPS flexibilities to access affordable ARV in Asia, 29-31 May 2012 (on file with research team).

158 National AIDS Control Programme, Phase III, State Fact Sheets (March 2012). Available online at: www.nacoonline.org/upload/Publication/State%20Fact%20Sheets/State%20fact%20sheet%20March%202012%20.pdf (last accessed 8 September 2012).

159 Focus group discussion, Bishnupur (Manipur), 9 April 2012.

In addition, as reported by the HCWs in Manipur and confirmed in the focus group discussions there, most patients prefer to travel long distances to a main ART centre even if a link ART centre is closer and more convenient. They choose the more difficult option because they are assured of seeing a doctor at a main ART facility.

Hepatitis C and TB co-infection treatment

As noted previously, HIV and TB services are moving towards integration in India. However, one of the concerns for the TB programme is that PLHIV often do not present with the typical pulmonary TB. Often for them it is extra-pulmonary TB, which is difficult to test for. For example at the Delhi focus group discussion at Neb Sarai, four of the eight participants had taken treatment for TB. Of those four, one had presented with chest TB and the others with TB in the neck glands and the brain. In addition, there have been reports of multi-drug resistant TB (MDR-TB) and extensively drug resistant TB (XDR-TB) in India, both of which require more expensive TB treatment.¹⁶⁰

Treatment for MDR-TB is available from the Indian government's TB programme through the DOTS-plus initiative and for XDR-TB on a case-by-case basis.¹⁶¹ Yet unlike HIV, most people on TB treatment rely on the private sector. This is a problematic situation because the huge unregulated market supplying TB medicines in the private sector has led to increasing concern of fuelling TB resistance in India.

In the focus group discussions, a key issue that emerged regarding TB co-infection was the lack of adherence counselling. PLHIV reported simply being told to take the TB medicines with little information about side effects or the importance of adhering to the complete treatment course. PLHIV who are also outreach workers with some community networks have reported decisions by their networks to place outreach workers at TB centres because of this gap in the government programme. The outreach workers confirmed the lack of or ineffectiveness of TB treatment adherence counselling. For instance, a PLHIV outreach worker at one of the Delhi focus group discussions reported seeing patients throwing aside or spitting out their medication at TB centres because they could not deal with the large size of the pills.

While NACO is now screening for hepatitis B and C, it is not providing treatment for hepatitis C. This is a concern among PLHIV who are current or ex-IDUs, for whom the treatment of hepatitis C is a crucial priority. Of the eight current and ex-drug users at the focus group discussion in Churachandpur (in Manipur), three of the five who had been tested for hepatitis C had received a positive result. HCWs in Manipur also stated that hepatitis C prevalence was high in the province. The representatives of community groups interviewed in Manipur highlighted access to hepatitis C treatment as one of the most important priorities for PLHIV and drug users in their area. They added that the lack of government support for quality hepatitis C treatment meant that several PLHIV in need have been forced to seek medicine from the private sector at exorbitant prices.

The lack of adequate hepatitis C treatment from the government sector is linked to affordability and patent issues. The international standard of care treatment for hepatitis C is currently a combination of ribavirin and pegylated interferon. The two versions of this treatment, one sold by Hoffmann-La Roche and the other by Merck, are patented in India. Both companies have priced their medicines within the same range and a course of treatment can cost between \$7,000 and \$10,000. While some Indian generic

160 Dhar, A., "Says WHO: India has highest number of MDR-TB cases in South East Asia". The Hindu, 23 March 2012. Available online at: <http://www.thehindu.com/news/national/says-who-india-has-highest-number-of-multidrugresistant-tb-in-south-east-asia/article3156259.ece>.

161 RNTCP response to challenges of drug resistant TB in India January 2012 (update). Available online at: <http://tbcindia.nic.in/pdfs/RNTCP%20Response%20DR%20TB%20in%20India%20-%20Jan%202012%20update.pdf> (last accessed 8 September 2012).

companies are producing or planning to produce these medicines, they have been sued by the two multinational companies for patent infringement. According to an HCW interviewed in Manipur:¹⁶²

Among PLHIV I treat, the highest percentage of deaths is from hepatitis C. The plain interferon is one-fifth the price of the pegylated interferon, but the latter is better as it is a shorter course of treatment and better tolerated. But either way, both courses of treatment are expensive. Of the over 150 patients whose files I have reviewed only five percent have got treatment. We also have to manage the side effects of the medicines.

2.5 Community mobilization

Service delivery

Representatives of the community groups interviewed for this survey identified several services that they were delivering formally as part of the ART roll out or as part of their own work. Among the services were providing pre- and post-test counselling, ensuring that newly tested PLHIV register at ART centres, and providing counselling related to STIs, TB and hepatitis C. Community groups' engagement in such activities, often in close collaboration with the government's HIV programme, increased greatly following the release of NACP-III in 2006. A key guiding principle of NACP-III was the following: "Promotion of social ownership and community involvement through civil society representation and participation in planning and implementation."¹⁶³

However, all four representatives expressed considerable frustration and discomfort over what they perceive as a shift in NACO's approach and dealing with community groups in the past few years. This was best reflected in the process leading up to the drafting of NACP-IV, which many civil society respondents said was unnecessarily complicated and time-consuming. Community groups and NGOs had to create a platform;¹⁶⁴ demand regional consultations and consultations with marginalised groups on the national HIV programme;¹⁶⁵ work directly with the Planning Commission of India;¹⁶⁶ and provide written inputs on the next phase of the programme. Although the final version of NACP-IV had not been released when this research was finalized, the community group representatives expressed their apprehension about the future role of community groups and NGOs in the national HIV programme.

Advocacy

Treatment literacy and advocacy and lobbying on rights of PLHIV (and in particular on treatment access) were primary areas of work for all four community groups, according to their representatives interviewed. Community groups are also playing a crucial watchdog function regarding the government treatment programme. For instance, in response to the reluctance of the government to phase out d4T and to universalize access to second-line treatment, PLHIV groups have used the Indian Supreme Court to demand greater commitment from the government. They have succeeded in getting a commitment

162 Interview with healthcare worker, Imphal (Manipur), 6 April 2012.

163 NACO, The National AIDS Control Programme, Phase III (2006 – 2011): Strategy and Implementation Plan, 30 November 2006, available online at: [www.nacoonline.org/upload/Publication/Strategy%20and%20Implementation%20Plan%20-%20NACO%20Programme%20Phase%20III%20\(2006-2011\)%202006.pdf](http://www.nacoonline.org/upload/Publication/Strategy%20and%20Implementation%20Plan%20-%20NACO%20Programme%20Phase%20III%20(2006-2011)%202006.pdf) (last accessed 8 September 2012).

164 "NACP IV should not be a cut and paste job", *The Hindu*, 6 May 2011. Available online at: www.thehindu.com/news/national/article1988787.ece (last accessed 8 September 2012).

165 More information on the civil society consultations on NACP-IV is available at: <http://indiaco.ning.com/page/links-consultations-for> (last accessed 8 September 2012).

166 Petition of civil society organisations to the Planning Commission of India, July 2011. Available online at: <http://indiaco.ning.com/profiles/blogs/petition-of-civil-society> (last accessed 8 September 2012).

from NACO to open more centres to provide second-line treatment, to ensure access to second-line treatment to all who need it and to put in place a phase-out plan for d4T.¹⁶⁷ Stock-outs of ARVs at ART centres have been another key area of advocacy and action reported by all representatives of community groups interviewed.¹⁶⁸

Those representatives also highlighted the crucial role in continuing advocacy for the HIV/AIDS bill, a proposed anti-discrimination law drafted in consultation with civil society. Since 2007, the Indian government has been deliberating on the proposed bill, which was drafted largely from the findings of several consultations across the country.¹⁶⁹ Although Indian courts have prohibited discrimination based on HIV in the public sector, these judgments are not applicable to the private sector—where PLHIV continue to lose their jobs, are refused treatment in hospitals and where their children face barriers in attending school.¹⁷⁰ The bill is comprehensive, addressing issues of discrimination, consent, confidentiality as well as those related to harm reduction, key populations and access to courts and justice.¹⁷¹

In Manipur, the representatives of community groups interviewed highlighted their work with drug users, adding that such work is difficult for numerous social and legal reasons. Members of that population are criminalised under the current legal regime; have little support from health authorities (for instance, when they overdose); and often struggle to comply with complicated ART regimens. The value of community groups' efforts with and among drug users was reflected in the interviews with two of the HCWs in Manipur. They spoke of a close collaboration between the community groups and the ART centre, particularly in supporting current drug users on ART to adhere to their regimens. Yet they also noted that this collaboration had been stopped, even though they were reluctant to identify the reason for that development.

The representative of one of the community groups interviewed in Delhi highlighted the role of PLHIV networks—along with other health groups and legal aid organizations—in the movement for ensuring access to generic medicines in India. Their involvement includes mobilization and advocacy against the EU-India FTA and in opposing patents and patent applications on ARVs and other medicines (see Section 2.3). Indian groups have also been among the vocal critics of voluntary licences being signed between multinational companies and generic companies for generic production of patented ARVs. Although India is covered under these licences, many other countries are not—as can be seen in the 2011 license agreed to between the Medicines Patent Pool and Gilead Sciences, Inc.¹⁷² and the voluntary licences signed by Matrix Laboratories Ltd. and Emcure Pharmaceuticals Ltd. with Bristol-Myers Squibb Co. for atazanavir.¹⁷³ In both cases, although the ARVs in question are not even patented in

167 "Judiciary alleviates their pain, Times of India", 4 December 2011. Available online at: http://articles.timesofindia.indiatimes.com/2011-12-04/chandigarh/30474074_1_hiv-positive-hiv-patients-hiv-status (last accessed 8 September 2012).

168 "Pressure from AIDS activists resumes ARV supply in UP", Citizens News Service, May 2011. Available online at: www.citizen-news.org/2011/05/pressure-from-aids-activists-ensure-arv.html (last accessed 8 September 2012).

169 The HIV/AIDS Bill 2007. Available online at: www.lawyerscollective.org/files/Final%20HIV%20Bill%202007.pdf (last accessed 8 September 2012).

170 Bhardwaj, K., "Do we need a separate law on HIV/AIDS?", Infochange Agenda, 2008. Available online at: <http://infochangeindia.org/agenda/hiv/aids-big-questions/do-we-need-a-separate-law-on-hiv/aids.html> (last accessed 8 September 2012).

171 Bhardwaj, K., "Do we need a separate law on HIV/AIDS?", Infochange Agenda, 2008. Available online at: <http://infochangeindia.org/agenda/hiv/aids-big-questions/do-we-need-a-separate-law-on-hiv/aids.html> (last accessed 8 September 2012).

172 ITPC letter to Medicines Patent Pool, October 2011. Available online at: www.essentialdrugs.org/edrug/archive/201110/msg00016.php (last accessed 8 September 2012).

173 "BMS signs new agreement with Matrix Labs", *Express Pharma*, 16-31 August 2011. Available online at: www.expresspharmaonline.com/20110831/market09.shtml (last accessed 8 September 2012). Matrix Laboratories changed its name to Mylan Laboratories Ltd. in October 2011, shortly after this voluntary license was announced.

India, Indian-based generic companies have agreed to restrictions in their ability to supply generic ARVs in key developing countries.

The representatives of the community groups that were networks of people living with HIV and several of the PLHIV in the focus group discussions reported participating in protests and other actions to ensure continued supply of generic medicines¹⁷⁴. The representative of one community group in Delhi said the following:¹⁷⁵

Why do we keep going on all these protests? It's not just about us. Not just about my medicine. It is everyone else's medicine too. We have to stand up against these FTAs because the government cannot sell our lives. We remember what it was like ten years ago. We cannot go back to that situation. Already we had to fight the government to get proper access to second-line treatment. We know their main worry was the cost. What will happen if prices go even higher?

3. KEY CHALLENGES

In the course of the research, including interviews and focus group discussions, several challenges were discussed by participants. Some of these are directly related to the government programme (training, access to second-line treatment, integration, etc.), while others are related to challenges beyond the treatment programme (discrimination, trade policies, etc.). Key challenges are identified below but it should be understood that several other challenges also confront the Indian government's ART programme. All need to be addressed to ensure the successful adoption and implementation of the Treatment 2.0 framework in the future.

Stigma and discrimination

Findings from this research identified stigma and discrimination as a key reason hampering the scale-up of HIV testing as well as access to treatment. Both healthcare settings and families were identified as major sources of discrimination.

Stigma and discrimination was a cross-cutting issue reported by all PLHIV in the focus group discussions and the in-depth interviews. Family members were a key concern for several PLHIV. One noted the following, for example: "Every family member discriminates in my house except my wife and children. I do everything by myself."¹⁷⁶ For some, though, families were supportive and their stigmatizing attitudes and behaviour had changed for different reasons. In one case, a PLHIV requested his mother to get his ARVs as he was unwell; her attitude improved on seeing other people like him at the hospital when complying with his request. Others relied on the community groups or PLHIV networks to provide counselling to the family or brought their family members to meetings or events where they met other PLHIV. Some PLHIV also reported a change in attitudes after the availability of treatment.

A counsellor interviewed in Manipur also discussed the different kinds of stigma that PLHIV face. She noted that most people she counselled were more comfortable stating that they got HIV from injecting drug use than from sex.

174 The authors noted that those interviewed in Delhi wished to highlight the confusion in role of UNAIDS in relation to their governments and community support and activism. Specific reference was to the incident that took place at the regional (Asian) AIDS Conference held in Busan, Korea in August 2011, where Korean colleagues were beaten and harassed by law enforcement agents during a FTA protest within the conference settings. UNAIDS chose to refrain from making any public statements in support of community activists and against the Korean government.

175 Interview with representative of community group, Delhi, 26 April 2012.

176 Focus group discussion, Jehangirpuri (Delhi), 25 April 2012.

Although all the healthcare workers interviewed reported receiving training and sensitisation on HIV-related stigma and discrimination, several PLHIV reported being discriminated against in healthcare settings. One focus group participant provided the following account: “When my husband was ill, [the first hospital we approached] would not allow us to admit him. After a lot of pressure they admitted him but no one came to look after him. Then he was referred to [another health facility] but there also he was just left in one corner.”¹⁷⁷ In some cases PLHIV also reported stigma at the NGOs where they were working. According to a female PLHIV in one of the Manipur focus group discussions:¹⁷⁸

When I was pregnant and about to deliver my child, I overheard my colleagues whispering ‘she is HIV-positive and she will give the child HIV.’ I confronted them at a staff meeting and they apologized. I know my rights and I could stand up for my rights but there are so many women living with HIV who shy away and instead of standing up they avoid public places.

PLHIV in focus group discussions were not able, however, to identify or propose any legal redress mechanisms to address the discrimination. Most instead said they had turned to their community groups for assistance when needed.

Insufficient adaptation of government treatment programme for marginalised groups

While the Indian government’s treatment programme has scaled up significantly since 2004, the programme remains ill-equipped to respond to the needs of marginalised groups like IDUs and the transgender community. As noted in the Section 2.5, HCWs and community groups both identified as a concern the fact that many members of these groups have particular difficulty in adhering to treatment regimens.

Low levels of treatment literacy

The focus group discussions in Manipur indicated low levels of treatment literacy among marginalised groups. Two of the reasons for this may be related to i) the discrimination they face in accessing the government programme, and ii) the stigma attached to HIV and members of marginalised groups, which in turn leads to hesitation on their part to seek information. As noted previously in this report, many PLHIV in Manipur, where the epidemic is concentrated among IDUs, were unable to identify their medicines or were even unaware of their basic potential side effects. Poor treatment literacy can have a negative effect on treatment adherence and, on a broader scale, the ability of PLHIV to hold the government treatment programme accountable.

Patents on second- and third-line ARVs and co-infection medicines

As noted previously, despite the best efforts of community groups and their allies, key ARVs and medicines for hepatitis C have been patented in India. The impact of these patents is not only felt in India but across the developing world. The hesitation of the Indian government to provide universal access to second-line treatment when the generic second-line is considered too expensive is indicative of how the government generally reacts to the proposal that it supply patented ARVs and other medicines.

Free trade agreement negotiations

The proposed EU-India FTA is a critical threat facing generic ARV production in India. Despite repeated statements by the Indian government that it will not agree to the EU’s demands to increase market access for its exporters (including multinational pharmaceutical companies), the EU is continuing to

177 Focus group discussion, Jehangirpuri (Delhi), 25 April 2012.

178 Focus group discussion, Churachandpur (Manipur), 10 April 2012.

pressure India to relent. If the Indian government does not resist such pressure entirely, access to lower-priced generic ARVs and other medicines could be restricted across the developing world.

Community groups facing funding crunch

Nearly all the community groups interviewed for this research indicated that they were facing a crisis in funding and were drastically cutting back on services. It is unclear how effective the Indian treatment programme can be in the future without community level outreach workers, peer educators and groups that support the government treatment programme. Community groups provide direct support for HIV treatment and care through a range of services from counselling to follow up. Moreover, they work to reduce costs, which helps increase the scope for scale-up, by filing and supporting legal actions to ensure that key medicines are not patented.

4. RECOMMENDATIONS

The survey indicates that the Indian government's treatment programme has come a long way since it started in 2004. However several areas of concern were highlighted and several differences in the services available in Delhi and those in Manipur became evident. The nature of the epidemic being concentrated among IDUs in Manipur raised issues of unique relevance to that region.

In general, some concerns that have dogged the treatment programme from the beginning persist, including occasional stock-outs and malfunctioning of diagnostic machines as well as problems associated with access to services for marginalised groups. More recent challenges regarding availability and access to second-line ART and hepatitis C treatment are also priorities for community groups' advocacy efforts.

The recommendations below are based on responses from the survey and focus group discussions. Though the research was limited to some extent by time and other constraints, the findings pointed to critical issues that should be **addressed by the Indian government**.

- **Recommendation area 1: Immediate tabling and passing of anti-discrimination law on HIV.** As noted by focus group participants, discrimination is a critical issue PLHIV continue to face. The draft HIV/AIDS bill (in discussion since 2007) should be finalised by the health and law ministries without any dilution. The bill should then be tabled in Parliament and passed without delay.
- **Recommendation area 2: Universal access to treatment.** NACO and the MoH should commit to universal access to treatment for HIV and related priorities. As part of this effort, they should implement without delay—and in consultation with and monitoring by community groups—the phase out of d4T and the removal of procedural barriers (in the form of SACEP decisions) to alternative first-line and second-line treatment. They should also make second-line treatment available in more ART centres; initiate studies as to the need for third-line treatment and start preparing for third-line treatment roll out; and ensure access to hepatitis B and C treatment. Any integration or task-shifting should be based on consultations and in accordance with human rights principles, including consent and confidentiality.
- **Recommendation area 3: Marginalised groups and the ART roll out programme.** HIV testing and treatment for marginalised groups requires a different approach than the general approach currently employed by NACO. The government should consult with marginalised groups and implement changes in the manner in which services are provided

to them. To provide appropriate care, counselling and follow up for marginalised groups (for instance drug users who are living with HIV or the MSM/transgender community), NACO should also ensure the training and sensitisation of healthcare workers.

- **Recommendation area 4: Rejection of all TRIPS-plus measures in free trade agreements and ensure use of all TRIPS flexibilities.** The Indian government should i) immediately make public the texts of the EU-India FTA negotiations as well as of other FTA negotiations, and ii) reject all TRIPS-plus provisions in such negotiations. In addition, the government should immediately appoint its top lawyer in all cases filed by multinational companies against the government that challenge the health safeguards in the patent law. In addition, the India Parliament should ensure that no laws are amended or adopted that are TRIPS-plus or that remove or dilute the health safeguards in India's patent law.
- **Recommendation area 5: Participation of and support for PLHIV and other key populations.** NACO should continue full and open engagement and consultation with civil society and community groups and ensure that their recommendations are reflected in NACP-IV.

KENYA AND TREATMENT 2.0: CHALLENGES AND OPPORTUNITIES TO SCALE UP HIV TREATMENT

This country report is part of *Missing the Target 10 (MTT10)*, the 2012 version of a longstanding series on global access to HIV treatment coordinated by the International Treatment Preparedness Coalition (ITPC). *MTT10* focuses on challenges to the scale-up of HIV services as required to implement the Treatment 2.0 framework. As with other *Missing the Target* publications, national and local community groups conducted research based on a general template and prepared their country-specific reports. The following countries are included in *MTT10*: Cameroon, China, Côte d'Ivoire, Honduras, India, Kenya, Morocco and Russia.

The full *MTT10* report and individual country reports are available at the ITPC website: www.itpcglobal.org. Also available at that website are French versions of the Cameroon and Côte d'Ivoire reports and a Spanish version of the Honduras one.

Kenya

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ACRONYMS AND ABBREVIATIONS

ART	antiretroviral treatment
ARV	antiretroviral drug
CBO	community-based organization
FBO	faith-based organization
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HTC	HIV testing and counselling
KEMSA	Kenya Medical Supplies Agency
MARP	most-at-risk population
MoH	Ministry of Health
MSM	men having sex with men
NASCOP	National AIDS and STI Control Programme
NGO	non-governmental organization
PLHIV	people living with HIV
STI	sexually transmitted infection
UNAIDS	Joint United Nations Programme on HIV/AIDS
VCT	voluntary counselling and testing
WHO	World Health Organization

Note on text: All "\$" figures are U.S. dollar amounts. All URLs cited were valid as of 1 October 2012.

HIV drugs list

Many HIV drugs are commonly referred to in an abbreviated format. Listed below are the abbreviated names of all the drugs mentioned in the Kenya report as well as the full generic name associated with them. Where relevant, brand names of key drugs are also noted. The drugs are grouped by class.

NRTIs (nucleoside reverse-transcriptase inhibitors)	
3TC	lamivudine
AZT	zidovudine
FTC	emtricitabine
NNRTIs (non-nucleoside reverse transcriptase inhibitors)	
EFV	efavirenz
NVP	nevirapine
Protease inhibitors	
LPV/r	lopinavir/ritonavir (refers to lopinavir being “boosted” by ritonavir)

1. INTRODUCTION AND OVERVIEW

1.1 Methodology

Research for this study was conducted in two regions in Kenya: Nairobi, the capital, and Migori county in Nyanza province, in the far western part of the country. Migori was selected in part because as a mostly rural area, it offers a contrast with urban Nairobi. It is also an area where sex work is fairly common because fishermen are mobile on Lake Victoria, including into neighbouring Tanzania. High levels of poverty mean that many women exchange sex for fish. The province has Kenya’s highest HIV prevalence, estimated at nearly 15 percent, which is more than double the national rate.¹⁷⁹

Four research methods were used: i) a literature review; ii) eight focus group discussions; iii) in-depth interviews with two government officials;¹⁸⁰ and iv) questionnaires. The data collected were processed and subjected to both quantitative and qualitative analysis.

A total of 63 people participated in the focus group discussions, the majority of whom (48) were women. Thirty-one people participated in four discussions held in Nairobi, an urban setting. Thirty-two participated in four discussions groups of eight people apiece in Nyanza province. Three of those settings were rural, while one is considered suburban or semi-urban.

Separate questionnaires were prepared and distributed to respondents from the following categories: 13 people living with HIV (PLHIV), five representatives from community-based organizations (CBOs) providing services to PLHIV, and five community health workers.

179 Kenya National AIDS Control Council (2009). Kenya HIV Prevention Response and Modes of Transmission Analysis. Available online at: <http://siteresources.worldbank.org/INT/HIVAIDS/Resources/375798-1103037153392/KenyaMOT22March09Final.pdf>.

180 Both officials were district AIDS and STI control officers, one each from Nairobi and Migori.

1.2 Context

Kenya, like most other countries in sub-Saharan Africa, has been greatly affected by the HIV pandemic since the early 1980s. More than 2 million people are estimated to have died from AIDS, and about 1.4 million are currently thought to be living with HIV in the country.

Kenya is experiencing a mixed and geographically heterogeneous HIV epidemic with characteristics of both a generalized epidemic among the overall population and a concentrated one among specific most-at-risk populations (MARPs). Adult HIV prevalence topped 14 percent in the late 1990s; it has since halved to about 6.3 percent, according to data from 2009,¹⁸¹ with prevalence among women at 8 percent and among men at 4.3 percent. This female-to-male ratio of 1.9-to-1 is higher than in most population-based studies in Africa.¹⁸² Age and sex differentials are considerable, with HIV prevalence peaking among women (13.3 percent for women aged 30-34) a decade earlier than among men (10.2 percent for men aged 40-44), reflecting both historical transmission patterns and significant levels of inter-generational sex.

The epidemic is geographically diverse, with particularly high prevalence in Nyanza province (at 14.9 percent, according to a report released in 2009) and higher than national average prevalence in Nairobi and Coast province at 8.8 percent and 8.1 percent, respectively.¹⁸³ Apart from some major cities and transport corridors, HIV prevalence is lower than the national average across the rest of the country. HIV prevalence among the urban population is 8.4 percent compared with 6.7 percent for the rural population.¹⁸⁴ Yet an estimated 70 percent of PLHIV live in rural areas.

Modes of HIV transmission also vary geographically, reflecting the diverse nature of the epidemic. For example, transmission attributed to both injecting drug use and men having sex with men (MSM) is more common in Coast province and Nairobi than in Nyanza or across the nation as a whole. Modelling exercises reported in 2009, for instance, concluded that share of new infections among IDUs was 6.1 percent of the total in Coast province, a higher rate than in both Nairobi (5.8 percent) and nationally (3.8 percent).¹⁸⁵ Also notable in that report was the finding that 14.1 percent of new infections nationally were among “sex workers and clients”. The comparable share was much higher (23.1 percent) in Nyanza than in Nairobi or Coast (14.7 percent and 18.2 percent, respectively.)

2. NOTABLE FINDINGS AND OBSERVATIONS ASSOCIATED WITH TREATMENT 2.0

“Treatment 2.0” is the name of an initiative developed and launched in 2010 by the World Health Organization (WHO) and Joint United Nations Programme on HIV/AIDS (UNAIDS). It aims to simplify and improve the way HIV treatment is currently provided in order to maximize *the effect of ART and further* scale up access to HIV treatment, care and support. The initiative focuses on innovation and

181 As per results from the 2008-2009 Kenya Demographic and Health Survey (KDHS) prepared by the Kenya National Bureau of Statistics (KNBS). Available online at: www.unfpa.org/sowmy/resources/docs/library/R313_KNBS_2010_Kenya_DHS_2009_final_report.pdf.

182 As per results from the 2008-2009 Kenya Demographic and Health Survey (KDHS) prepared by the Kenya National Bureau of Statistics (KNBS). Available online at: www.unfpa.org/sowmy/resources/docs/library/R313_KNBS_2010_Kenya_DHS_2009_final_report.pdf.

183 Kenya National AIDS Control Council (2009). Kenya HIV Prevention Response and Modes of Transmission Analysis. Available online at: <http://siteresources.worldbank.org/INTHIVAIDS/Resources/375798-1103037153392/KenyaMOT22March09Final.pdf>.

184 Kenya National AIDS Control Council (2009). Kenya HIV Prevention Response and Modes of Transmission Analysis. Available online at: <http://siteresources.worldbank.org/INTHIVAIDS/Resources/375798-1103037153392/KenyaMOT22March09Final.pdf>.

185 Kenya National AIDS Control Council (2009). Kenya HIV Prevention Response and Modes of Transmission Analysis. Available online at: <http://siteresources.worldbank.org/INTHIVAIDS/Resources/375798-1103037153392/KenyaMOT22March09Final.pdf>.

efficiency in HIV programming, including the integration of important new findings such as the preventive effects of ART.¹⁸⁶

WHO and UNAIDS are currently developing various frameworks that will help countries and all stakeholders develop and implement strategies based on Treatment 2.0 principles and priorities. The frameworks will be based on the initiative's five main priority work areas, also known as "pillars":

1. Provide point-of-care and other simplified diagnostic and monitoring tools
2. Optimize drug regimens
3. Reduce costs
4. Adapt delivery systems
5. Mobilize communities

The agencies have worked closely with partners at global, regional and country level to explain the Treatment 2.0 agenda in general, and the importance of the five pillars specifically. This effort also seeks to build support for the overall approach, which can only be successful when countries' HIV programmes and strategies align with it.

Findings and observations obtained through research for this report are organized by the five Treatment 2.0 pillars (Sections 2.1 through 2.5 below). This structure is intended to highlight progress, gaps and challenges in Kenya regarding expanded and enhanced HIV treatment for all in need.

Existing awareness of Treatment 2.0 in Kenya

Participants in this research study were not specifically asked about their awareness of the Treatment 2.0 agenda. Based on data collected, it appears that PLHIV and representatives of CBOs knew little or nothing about most of the agenda's elements. Health officials appeared to be aware of some of the important elements, such as the potential benefit of treatment-as-prevention, but were not aware of any formal efforts to implement programming based on such priorities.

2.1 Provide point-of-care and other simplified diagnostic and monitoring tools

HIV testing

Both ELISA antibody and rapid tests are used in Kenya, with confirmatory tests undertaken if initial rapid tests come back positive. According to the national HIV testing guidelines (updated in 2010), the country focuses both on client-initiated HIV testing and counselling (HTC) through voluntary counselling and testing (VCT) initiatives and provider-initiated HTC.

These two are similar but vary by setting. Client-initiated testing is mostly provided in community-based settings and can be done by individuals who are not formal health workers. Community health workers and others can take a certified course and then be able to conduct tests. Similar certification policies allow non-governmental organizations (NGOs) to provide HIV testing services. The tests are mostly done through door-to-door and mobile VCT, stand alone VCT (at dedicated sites), and workplace VCT. Provider-initiated HTC is done in health facility settings by formal health workers. Most testing is "opt in", with the important exception of pregnant women who access antenatal care services and at delivery (if they have not been tested by then). "Opt out" policies also apply to TB patients in health facilities.

186 Detailed information about the Treatment 2.0 agenda may be found online at: http://data.unaids.org/pub/Outlook/2010/20100713_fs_outlook_treatment_en.pdf.

Rapid tests are available free of charge through the government-sponsored VCT programme. Also available for free are follow-up confirmatory tests (e.g., ELISA tests) as long as the client gets those tests at the comprehensive care centre to which he or she was referred. Clients must pay fees for such tests if they get them at facilities other than the one to which they were referred, including private ones. Some clients choose to do so, even though they must pay, out of concern *about stigma and confidentiality* because the referral facilities are nearly always the ones nearest their home.

HTC services in Kenya are standardized, and thus the majority of respondents to this research had similar experiences regardless of location. They were all taken through pre- and post-test counselling and referred to HIV clinics for confirmatory testing, treatment and care. The respondents who underwent diagnostic testing and counselling and those who were tested because they were pregnant had varied experiences depending on the hospital they visited. However, they were all referred for confirmatory tests and care.

Most respondents (84 percent) said they were assured test results would not be shared with anyone except clinic staff who care for them. Information provided in advance included the following: how HIV is transmitted; how the test works; the meaning of positive and negative test results; that the test does not always detect a very recent HIV infection (i.e., the meaning of the “window period”); how to prevent the spread of HIV; and that the results would be available within one hour of the test, for those who received a rapid test. Respondents noted that post-test counselling focuses on provision of risk reduction information and emotional support. Clients are also referred to i) relevant health facilities for follow-up services, and ii) community-based support and psycho-social support groups as the case may be.

It is important to note that not all respondents reported having received such extensive information and support. One focus group participant said the following about her experience:¹⁸⁷

Personally I was not given any counselling at all because when I was tested I was just told that I am positive. I did not believe because I felt like maybe they were just saying that...and I just stayed on my own, withdrawn and not talking to anyone. Later when I went to deliver my child is when I was tested again and that is when I believed. I was in denial for two years.

All HCT service providers collect routine data daily that is fed into the National Health Management Information System (HMIS), which provides the framework for monitoring and evaluation (M&E) of HTC programmes in Kenya. The national HIV/AIDS M&E framework provides both appropriate data collection and reporting instruments as well as the indicators. HTC uptake is generally increasing in Kenya. According to the Kenya HTC Report (2011), the number of sites providing HTC had reached 1,027 in 2009-2010, up from 640 in the period categorized as 2005-2008.¹⁸⁸ The number of people getting tested in the earlier period was 2.85 million; in the later period, some 7.94 million people received HTC services.

Healthcare providers surveyed for this report offered the following suggestions to improve access to testing:

Bringing the service closer to the people/community, including by increasing the number of community health workers certified to offer VCT services

187 A female participant in a focus group discussion at Muhuru Bay, Nyanza province, 10 May 2012.

188 As cited in the Kenya HTC Report 2011, prepared by the National AIDS and STI Control Programme (NAS COP). Available online at: <http://nascop.or.ke/library/HTC/HTC%20Report%202011.pdf>

- Creating more awareness on the importance of HIV testing
- Introducing mobile and home-testing services throughout the country, as they are not currently available in some areas
- Encouraging self-testing and ensuring a steady supply of testing kits and commodities
- Mobilizing communities and creating more awareness, empowerment and participation
- Improving the scope and quality of follow-up services available after testing, including in regards to information provided by counsellors during post-test counselling

Other diagnostics

For nearly two-thirds (61.6 percent) of PLHIV respondents to this research, their first CD4 counts after testing positive were below the WHO recommended level of 350 cells/mm³ for initiating antiretroviral treatment (ART). This indicates that most people are being tested relatively late in the HIV infection stage.

Most PLHIV respondents said that in addition to CD4 tests, they have access to other monitoring and diagnostic tests including viral load testing, liver tests, TB and hepatitis screening, testing for malaria, urinary tests and pregnancy tests (if deemed relevant). The majority (80 percent) said they accessed these tests for free, with the remaining 20 percent reporting that they had paid for one or more of the tests.

The monitoring and diagnostic tests as well as viral load testing are conducted in public (government) health facilities, private hospitals and non-government hospitals operated mainly by faith-based organizations (FBOs). The services are provided free of charge in all government health facilities, but some private health facilities charge minimal fees primarily for the commodities used. CD4 tests are typically carried out soon after testing positive as well as regularly thereafter (every six months or so) for patients on ART.

2.2 Optimize drug regimens

The Kenyan treatment guidelines are aligned with the updated WHO recommendations (from 2010). The guidelines specify when to initiate ART for both children and adults as well as the required procedures. In addition to public health facilities, ART services are also provided at facilities operated by FBOs and the private sector.

Kenya has decentralized HIV treatment and care services in the public sector. They now are provided at national, provincial, district and sub-district hospitals that are collectively referred to as central ART service delivery sites. The provision of services at such facilities is part of the overall organization of the government's health sector, which is structured to offer services at five levels. Level 1 is the community level, with level 2 facilities serving as dispensaries and clinics. Levels 3 and 4 refer to health centres at the sub-district and district level, respectively, with district-level facilities categorized as "primary". Level 5 refers to "secondary" facilities at provincial level. "Tertiary" refers to "national" hospitals in Nairobi and Eldoret.

In addition, ART and other HIV treatment services are provided through mobile "satellite sites" that operate below the sub-district level. These satellite sites are situated within communities and are therefore easily accessible. They are often provisioned by healthcare workers travelling to and from central sites on a regular basis.

Government health facilities in Kenya provide ARVs for free to HIV-positive clients. Most of the drugs are generic versions, with a few people taking second-line regimens that include originator-brand ARVs. A wider range of branded medicines are, however, available for people who would like to buy them; patients who visit private-sector sites for ART also must pay for their ARVs.

Listed below are among the ART regimens currently taken by PLHIV respondents to this research:

- TDF+3TC+LPV/r
- EFV+3TC+TDF
- 3TC+NVP+d4T
- 3TC+AZT+NVP

Practically all respondents said they received their medications regularly, with the majority adding that they had never missed dosages three days consecutively or more. From the analysis of the findings, it is noteworthy that a major reason advanced for missing doses is when the respondents were away from home, which implies that they forget to bring their drugs with them when they travel. (Interestingly, 15.4 percent of respondents were unaware of the names of the drugs they are taking; instead, they differentiated them based on the colour of the drugs.)

The benefits of ART are exhibited by the table below, which summarizes responses to questions about PLHIV's health status before and after starting ART:

HEALTH STATUS	BEFORE STARTING ART	AFTER STARTING ART
Excellent	8.3%	16.7%
Very good	8.3%	58.3%
Good/fair	25.0%	25%
Poor	58.3%	0%

Nevertheless, a significant share of patients abandon ART. Testimony from one participant illustrates a particularly worrying reason some people stop taking ART, in addition to other reasons such as side effects: "You see many preachers who tell people to come and be prayed for instead...this has made many people decide to stop taking their medication".¹⁸⁹

Another focus group participant gave the following account:¹⁹⁰

There are some herbal doctors who tell you that you will have to stop taking these medicines... My sister passed away because she started herbal medicines and stopped [ARVs]. She received [ARVs] but never used to take them at all because when she passed away and I went to her place, I found them in her drawer.

In addition to ARVs, PLHIV have access to other important medicines free of charge in government facilities when accessing HIV treatment. Among those are antibiotics, anti-fungal medications, medicines for fever and pain, cotrimoxazole prophylaxis, medicines to manage diarrhoea, drugs to prevent and manage malaria, and isoniazid preventive therapy to ward off TB. Often, however, facilities do not have

189 A female participant in a focus group discussion at Embakasi (Nairobi), 3 May 2012.

190 A female participant in a focus group discussion at Embakasi (Nairobi), 3 May 2012.

some or all of these medicines in stock, usually because of problems associated with procurement and logistics. In such instances, patients who want or need those medicines and others to address opportunistic infections must go to private facilities and pay for them. However, many NGOs and FBOs active in HIV-related services often do provide such services for free.

2.3 Reduce costs

In April 2012, Kenya's High Court found the Anti-Counterfeit Act of 2008 to be unconstitutional because it violates the right to life, health and human dignity. This ruling was important because the original act threatened access to generic medicines, including for HIV treatment, by potentially muddling the distinction between "generic" and substandard and fake medicines. If it had been upheld, the health and well-being of the 80 percent of Kenyans who currently take generic ARVs would have been jeopardized. Generic medicines are much cheaper than originator brands, and the purchasers of ARVs—including the government and donors such as the U.S. President's Emergency Program for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund)—would likely not be able to afford to cover a greater number of people if they could not buy the lowest-cost medicines possible.

The funding for ART and other HIV-related services is a joint collaboration between the government and bilateral and international development partners (such as PEPFAR and the Global Fund) as well as several NGOs. In the recent past, the government has enhanced funding through the Medium Term Expenditure Framework (MTEF) budgeting process in ministries and other public-sector institutions. In addition to prioritizing the purchase of generic medicines, cost-reduction strategies in Kenya include (but are not limited to) the following:

- Establishment of comprehensive care centres that provide for "one-stop" shopping, including for all forms of diagnostics and treatment
- Integrated approach to treatment and other forms of services provision, especially in national (referral), provincial, district and sub-district health facilities
- Establishment of satellite sites and mobile clinics and outreach programmes that are found within the communities, a step that makes service provision both accessible and affordable as well as appropriate
- Establishment of more HTC sites, with a projected total of 3,000 planned as part of universal access targets. Other important steps in this area include home-based HTC and self-testing for HIV
- Institutional strengthening of systems and procedures in health care and treatment facilities
- Training of more clinicians and community health workers who are able to reach more people, especially at community-based healthcare facilities and through home visits

2.4 Adapt service delivery

The majority of PLHIV respondents said they had easy and reliable access to health facilities within their communities, including for all relevant HIV services from testing to treatment. Focus group participants listed the following as among the services they find it relatively easy to access:

- Access to ART
- Referrals to health facilities where they can access treatment
- Treatment for protection from opportunistic infections and other diseases
- Guidance that heavy use of alcohol or other such substances might suppress the effectiveness of ART

PLHIV respondents said they can usually receive other services—in addition to ART and other direct care and support services—at the healthcare facilities that are easily accessible within communities. Among them are the following:

- Nutrition supplements
- Psychosocial support, especially through support groups (group therapy)
- Adherence support (for ART)
- Information, education and communication (IEC) through sessions organized by community healthcare providers
- Referrals to information about income-generating activities, often through programmes sponsored by civil society organizations and/or PLHIV groups

PLHIV respondents did raise some concerns about the quality and extent of services they currently receive. Among them were the following:

- Lack of treatment for opportunistic infections from government health facilities
- Inconsistency in the supply of cotrimoxazole from government health facilities
- Poor attitude towards PLHIV by healthcare workers, especially in the rural areas. Respondents cited instances in which workers treated them with disrespect and in some cases shared confidential information with community members
- Inconveniently long distances to healthcare facilities
- Lack of essential commodities and equipment in some facilities, such as adequate laboratory equipment. In such cases PLHIV must travel to other sites, often long distances away, for monitoring tests

The following are among the constraints and problems noted by healthcare personnel respondents regarding HIV service delivery in general:

- Failure to disseminate guidelines regarding, for example, HTC and ART provision
- Inadequate funding/budgetary provisions by the government for integrating family planning, reproductive health and HIV-related activities
- Shortage of staff, especially in public health facilities
- Limited efforts to enhance the capacity of service providers or the space in clinics to provide integrated care. This would include, for example, the provision of HIV services along with a wide range of other health services (e.g., reproductive health) at one facility and in a seamless manner

- Different reporting formats and the absence of clear monitoring and evaluation indicators to gauge healthcare workers' performance
- Existence of parallel HIV and other service supervision and logistics systems

In terms of follow-up, healthcare personnel respondents provided the following suggestions as ways to improve HIV-positive clients' ability and inclination to access comprehensive care and support:

- Enhance counselling and psychosocial support to give them "emotional" strength
- Intensify follow-ups, especially through the use of community health workers and phone calls to clients who miss appointments and seem to be falling out of care
- Use social workers to pay home visits at programme initiation to enable effective follow-up
- Encourage HIV clients to access ART at sites closer to their homes
- Increase the number of community health workers providing services both at facility and community levels

Integration of health services in Kenya is a priority of the Ministry of Health (MoH). Most comprehensive care centres (CCCs) for HIV care also offer critical services related to TB, reproductive health, and sexually transmitted infections (STIs). It is important to note, though, that clients pay additional fees for non-HIV services at CCCs, except in limited circumstances.

2.5 Community mobilization

On average, CBOs have between 22 and 50 clients, which seems reasonable given the size and resource capacities of most of them. The majority of CBOs are not officially linked to the country's national ART programme. Even so, they provide services to a variety of targeted beneficiaries, including but not limited to PLHIV, women and children, youth and most MARPs including sex workers, MSM and injecting drug users.

CBO respondents to this report said they currently provide the following services as part of their overall HIV-related work:

- Pre-test counselling: 66 percent (of respondents)
- Post-test counselling: 75 percent
- Provision of on-site testing: 66.7 percent
- Treatment literacy: 100 percent
- Legal services: 33.3 percent
- Psycho-social support emotional and spiritual support: 80 percent
- Peer counselling and support to improve drug adherence: 100 percent
- Peer advocates for prevention and general HIV care: 100 percent
- Essential treatment of opportunistic diseases: 66.7 percent
- Nutritional support: 100 percent

- TB counselling, screening and prevention: 75 percent
- Selected vaccine preventable diseases (hepatitis B, pneumococcal, influenza, yellow fever, etc.): 33.3 percent
- Home consultations: 50 percent

Most CBO respondents also indicated that they are heavily involved in “representing” PLHIV, including by lobbying and advocating on their behalf. Many, for example, said their groups advocate to increase access to ARVs and conduct information/education seminars.

However, CBOs acknowledged that they have minimal involvement in facilitating access to ART; prescribing ART on site; tracking patients’ access; and providing financial support for individuals on ART. This seems to be explained in terms of CBOs lacking technical/clinical skills as well as financial resources to engage more effectively in ART access.

As a result of non-engagement in direct ART access, CBO respondents reported and demonstrated limited knowledge, awareness, skills and experience in the management of ART. All said, though, that they would welcome training and support to enhance their capacities to provide services and support such as the following:

- Achieving desired outcomes of prevention programmes
- Developing partnerships with other community groups to enhance programme effectiveness
- Understanding the strategies necessary to deliver effective prevention programmes
- Obtaining additional and more sustainable funding
- Identifying root causes and patterns promoting and impeding prevention efforts
- Testing prevention theories and strategies, and then implementing if deemed effective
- Collecting data for evaluation and planning
- Facilitating the formation of participatory and cooperative teams, composed of CBO staff, to plan programmes and solve problems

PLHIV support groups

According to research, relatively few PLHIV (15.4 percent) have not joined a support group. Among the services provided by such groups are the following, as cited by respondents:

- Education and information sharing, especially on experiences and challenges
- Life skills training
- Income-generating activities such as making beads, bags and detergents as well as farming and poultry keeping
- Home visits and psychosocial support
- Education and referrals to health facilities
- Emotional support and disclosure
- “Merry go-round” schemes, pooling resources and micro-credit lending

The benefits of peer support groups are illustrated by this quote from a focus group participant:¹⁹¹

Personally I see it this way. When we are in a support group we will grow because there are many among us who have been educated on those things and can support others. For example, in the area of nutrition there are those who are not well educated in and when you are in a group at least you will share and somebody will get enlightened.... Somebody will say that I have to eat eggs, meat and I cannot afford these things...but in a support group when we are seated as a group like this...let me say on my side I will tell them that it is not a must you take eggs... you can eat “omena” (small fish) “skuma” (kale) and “ugali” (maize), and that is a balanced diet. You can then add even one ripe banana after eating. So I think the groups are helpful.

It is also important to note the role that PLHIV and support groups are playing in efforts to reduce HIV-related stigma and discrimination. According to respondents, PLHIV actively engage and participate in community activities such as the following, all of which help address stigma:

RESPONDENTS ENGAGING IN...	NO	YES
peer counselling	0%	100%
treatment literacy	61.5%	38.5%
activism (protests)	69.2%	30.8%
raising awareness	23.1%	76.9%

3. KEY CHALLENGES

This section summarizes some of the main challenges identified during research to an enhanced and expanded HIV response in Kenya. Improvements in such areas are considered critical for the effective adoption and implementation of the Treatment 2.0 framework in the future.

The following factors hinder people in the community from being **tested for HIV**:

- Fear of the unknown and complacency that they are not at risk for HIV
- Lack of information/myths about HIV
- Stigma and discrimination associated with HIV
- The notion that once one partner in a relationship is tested then the results reflects those of the other partner

Challenges that **healthcare staff face in providing services related to HIV** include the following:

- Lack of frequent trainings to be updated on the latest developments in the field
- Lack of steady supplies of commodities
- Lack of adequate staffing

191 A female participant in a focus group discussion in Dandora (Nairobi), 3 May 2012.

- Inadequate supply of drugs for opportunistic infections
- Inadequate defaulter tracing
- Lack of adequate space within facilities to provide services
- Stigma by clients—e.g., when PLHIV specifically state that they prefer to be attended to by a healthcare worker who is openly HIV-positive or who they believe is positive
- High demand for services
- Insufficient updated trainings for healthcare providers

The following are among the **overarching challenges** seen in regards to the provision of more effective HIV prevention, treatment and care services in Kenya:

- Clients who test positive take a long time before enrolling for treatment, usually due to stigma that might arise out of disclosure
- Lower levels of male involvement in HIV-related services and programmes. Women comprise the majority of PLHIV who have been tested, joined support groups and accessed ART.
- Lack of sufficient human resource capacity to provide services at all levels, including among health facilities and community groups. Resulting excessive workloads compromise the quality of services provided
- Inadequate training of service providers on new technologies
- Persistent HIV-related stigma and discrimination throughout society

4. RECOMMENDATIONS

Based on findings from this research, the following suggestions/recommendations are made to improve HIV-related service delivery and maximum impact.

Recommendation area 1: HIV testing and counselling (HTC)

- Establish more HTC sites as part of the overall effort to realize universal access targets
Lead responsibility: MoH, through the National AIDS and STI Control Programme (NASCO)
- Enhance the reach and effectiveness of HTC personnel by i) expanding dissemination of guidelines to healthcare workers, and ii) through training and capacity building
Lead responsibility: MoH (NASCO); development partners
- Ensure timely and adequate supply of kits and commodities
Lead responsibility: MoH (NASCO); Kenya Medical Supplies Agency
- Expand and improve advocacy for increased funding for campaigns aimed at increasing HTC uptake
Lead responsibility: Community-based entities (CBOs, NGOs, FBOs, etc.)

Recommendation area 2: Disclosure, support and stigma reduction

- Strengthen “prevention with positives” (PwP) initiatives and prevention training centres (PTCs) at community level
Lead responsibility: MoH; civil society organizations, including CBOs
- Increase community awareness as part of an effort to engage PLHIV in stigma-reduction efforts
Lead responsibility: Civil society organizations, including CBOs; mass/public media entities
- Increase access to and availability of psycho-social support among PLHIV
Lead responsibility: PLHIV support groups; civil society organizations, including CBOs

Recommendation area 3: Access to ARV services and adherence

- Continue with decentralization of health service provision facilities
Lead responsibility: MoH; development partners
- Train and strengthen the capacity of clinicians and community-health workers to provide more comprehensive ART-related services, including in regards to improving adherence
Lead responsibility: MoH (NASCOP and Kenya Medical Training College); development partners
- Ensure timely and adequate supply of commodities and drugs
Lead responsibility: MoH (NASCOP); KEMSA; development partners
- Step-up advocacy and promotion programmes on ART and adherence in HIV care and treatment
Lead responsibility: MoH (NASCOP); civil society organizations, including CBOs; PLHIV support groups

Recommendation area 4: Enhancing community participation

- Strengthen community participation in HTC and ART programmes, including through i) sensitization and capacity building, ii) community empowerment, and iii) outreach programmes and home visits
Lead responsibility: MoH (NASCOP) and the National AIDS Control Council (NACC); civil society organizations, including CBOs

MOROCCO AND TREATMENT 2.0: CHALLENGES AND OPPORTUNITIES TO SCALE UP HIV TREATMENT

This country report is part of *Missing the Target 10 (MTT10)*, the 2012 version of a longstanding series on global access to HIV treatment coordinated by the International Treatment Preparedness Coalition (ITPC). *MTT10* focuses on challenges to the scale-up of HIV services as required to implement the Treatment 2.0 framework. As with other *Missing the Target* publications, national and local community groups conducted research based on a general template and prepared their country-specific reports. The following countries are included in *MTT10*: Cameroon, China, Côte d'Ivoire, Honduras, India, Kenya, Morocco and Russia.

The full *MTT10* report and individual country reports are available at the ITPC website: www.itpcglobal.org. Also available at that website are French versions of the Cameroon and Côte d'Ivoire reports and a Spanish version of the Honduras one.

Morocco

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ACRONYMS AND ABBREVIATIONS

ALCS	Association de Lutte Contre le Sida
ART	antiretroviral treatment
ARV	antiretroviral drug
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
IDU	injecting drug user
MoH	Ministry of Health
MSM	men having sex with men
NGO	non-governmental organization
PLHIV	people living with HIV
STI	sexually transmitted infection
UNAIDS	Joint United Nations Programme on HIV/AIDS
VCT	voluntary counselling and testing
WHO	World Health Organization

Note on text: All "\$" figures are U.S. dollar amounts. All URLs cited were valid as of 1 October 2012.

HIV drugs list

Many HIV drugs are commonly referred to in an abbreviated format. Listed below are the abbreviated names of all the drugs mentioned in the Morocco report as well as the full generic name associated with them. Where relevant, brand names of key drugs are also noted. The drugs are grouped by class.

NRTIs (nucleoside reverse-transcriptase inhibitors)	
3TC	lamivudine
AZT	zidovudine
FTC	emtricitabine
NNRTIs (non-nucleoside reverse transcriptase inhibitors)	
EFV	efavirenz
NVP	nevirapine
Protease inhibitors	
LPV/r	lopinavir/ritonavir (refers to lopinavir being “boosted” by ritonavir)

1. INTRODUCTION AND OVERVIEW

1.1 Methodology

Research for this report was conducted from 3 April to 2 May 2012 mainly in two cities, Marrakech and Casablanca, which are among the places most affected by HIV in Morocco. It included three elements: i) a review of recent relevant literature (reports and articles) both in print and online; ii) individual interviews; and iii) focus group discussions.

Individual interviews were conducted with a total of 20 people. They included eight persons living with HIV (four women and four men), four from each city; four healthcare professionals, including two physicians, a nurse working in a public hospital and one physician from a non-governmental organization (NGO); four NGO representatives working mainly on HIV and sexual, reproductive and family planning; two policymakers from the Ministry of Health (MoH); and two civil society treatment experts. Individual interviews were conducted using unified research templates developed globally for this research and translated. Informed consent for each participant was obtained in a form that was translated into Arabic.

A total of 31 people participated in four focus group discussions, two of which were held in each city. The composition of the participants was as follows: six HIV-positive women, six HIV-positive men, nine men having sex with men (MSM) and 10 female sex workers. Three of the focus group discussions took place at an NGO location (two in Marrakech and one in Casablanca) while the fourth was held at a hospital in Casablanca. Although all discussions were held in urban settings, about one-third (10) of participants lived in rural areas.

1.2 Context

HIV prevalence in Morocco remains low and stable in the general population (0.14 percent¹⁹²). However, data from sentinel surveillance systems and integrated bio-behavioural studies (IBBSS) conducted in

192 As per most recent data available in July 2012, according to the Division d'épidémiologie et de lutte contre les maladies au Ministère de la santé (DELM), the main Moroccan government agency responding to HIV.

2010 and 2011 among some most-at-risk populations (MARPs)—female sex workers, MSM and injecting drug users—indicate a concentrated epidemic among high risk populations in some regions of the country. For example, the studies estimated HIV prevalence among female sex workers and MSM in the city of Agadir to be 5 percent¹⁹³ and 5.7 percent,¹⁹⁴ respectively. In Nador, prevalence among IDUs was reported to be as high as 22.5 percent.¹⁹⁵

It was estimated that some 29,000 people were living with HIV in Morocco at the end of 2011,¹⁹⁶ with the majority of them unaware of their HIV status. According to the MoH, a total of 6,453 AIDS cases had been reported by the end of that year. Of those, 71 percent of cases were among people in the 25-44 year age group. More than three-quarters (78 percent) of reported AIDS cases are among people living in urban areas. Analysis of reported AIDS cases by the MoH shows an increase in the proportion of women with HIV from 16 percent in 2000 to almost 50 percent at present. Sexual transmission is attributed to 93.5 percent of reported cases (80 percent heterosexual and 13.5 percent homosexual).

The number of people living with HIV (PLHIV) receiving antiretroviral treatment (ART) has increased significantly over the past three years. By the end of 2011,¹⁹⁷ a total of 4,047 individuals were receiving ART in Morocco, an increase from 2,647 two years earlier. Despite the increase, only about 40 percent¹⁹⁸ of those estimated to be clinically eligible for treatment are receiving it. The main obstacle to increased uptake is lack of knowledge of HIV status, which is linked to insufficient HIV testing.

In the past, the Moroccan National AIDS Programme has been generally responsive in regards to implementing new and revised guidelines and seeking to correlate with key global initiatives. It has been uncharacteristically slow regarding the Treatment 2.0 agenda, however. Findings from this report indicate that key government stakeholders are interested in the approach but want to wait for “clear and concrete” guidance from the World Health Organization (WHO) and the Joint United Nations Programme on HIV/AIDS (UNAIDS). The new 2012-16 AIDS National Strategic Plan, unveiled in April 2012,¹⁹⁹ mentions “the operationalization of the treatment approach 2.0 recently launched by WHO” as well as “the simplification and standardization of antiretroviral drug regimens and their continuous adaptation to the international recommendations.” The plan is vague, however, about how these priority steps might be implemented in Morocco.

2. NOTABLE FINDINGS AND OBSERVATIONS ASSOCIATED WITH TREATMENT 2.0

“Treatment 2.0” is the name of an initiative developed and launched in 2010 by UNAIDS and WHO. It aims to simplify and improve the way HIV treatment is currently provided in order to maximize the effect of ART and further scale up access to HIV treatment, care and support. The initiative focuses on

193 IBBS respondent-driven sampling (RDS) survey among female sex workers in Casablanca, Fes, Rabat and Agadir; MoH, 2011.

194 IBBS respondent-driven sampling (RDS) survey among MSM in Agadir and Marrakech; ALCS/INH /MoH, 2011.

195 IBBS respondent-driven sampling (RDS) survey among injecting drug users in Tangiers and Tetouan; MoH, 2010.

196 Estimation using EPP/Spectrum Model. Source: Direction de l’Epidémiologie et de Lutte contre les Maladies (DELM) of the MoH. As cited in the 2012 Morocco UNGASS Country Report, available online at: http://www.unaids.org/en/dataanalysis/knowyourresponse/countryprogressreports/2012countries/ce_MA_Narrative_Report%5B1%5D.pdf. (in French)

197 As per Boutaina El Omari, the Global Fund programme manager at the MoH, interviewed on 23 April 2012.

198 UNGASS Progress Report 2012, MoH. Available online at: http://www.unaids.org/en/dataanalysis/knowyourresponse/countryprogressreports/2012countries/ce_MA_Narrative_Report%5B1%5D.pdf (in French)

199 Plan Stratégique National de Lutte Contre le SIDA 2012-2016, MoH.

innovation and efficiency in HIV programming, including the integration of important new findings such as the preventive effects of ART.²⁰⁰

WHO and UNAIDS are currently developing various frameworks that will help countries and all stakeholders develop and implement strategies based on Treatment 2.0 principles and priorities. The frameworks will be based on the initiative's five main priority work areas, also known as "pillars":

1. Provide point-of-care and other simplified diagnostic and monitoring tools
2. Optimize drug regimens
3. Reduce costs
4. Adapt delivery systems
5. Mobilize communities

The agencies have worked closely with partners at global, regional and country level to explain the Treatment 2.0 agenda in general, and the importance of the five pillars specifically. This effort also seeks to build support for the overall approach, which can only be successful when countries' HIV programmes and strategies align with it.

Findings and observations obtained through research for this report are organized by the five Treatment 2.0 pillars (Sections 2.1 through 2.5 below). This structure is intended to highlight progress, gaps and challenges in Morocco regarding expanded and enhanced HIV treatment for all in need.

Existing awareness of Treatment 2.0 in Morocco

PLHIV and members of marginalized populations interviewed for this report, including those who participated in focus group discussions, were not aware of Treatment 2.0. Among those who might be expected to know about the initiative, the majority of NGO staff, health workers and stakeholders interviewed had indeed heard about Treatment 2.0. Few were able to explain exactly what it is and what it aims to do, however. In most cases, it was assumed that Treatment 2.0 was simply another term for treatment-as-prevention—which is only one component of a far broader approach and framework.

Members of the research team took the opportunity to explain the framework more accurately during various interviews. Most respondents were enthusiastic about the approach but agreed on the need for more information and support. The National AIDS Programme Manager, Dr. Aziza Bennani, stated the following: "WHO should provide countries with clear guidance on Treatment 2.0 and assistance to develop strategies at national level".²⁰¹ (As noted above, WHO is in the process of drafting such guidance.)

2.1 Provide point-of-care and other simplified diagnostic and monitoring tools

The MoH has strengthened the integration of voluntary testing initiated by providers in priority health areas. For example, rapid HIV tests are now routinely offered to TB patients in 49 TB centres. The overall number of people tested for HIV by NGOs in collaboration with the MoH has expanded significantly: a total of 106,816 people²⁰² were tested during the years 2010 and 2011 compared with

200 Detailed information about the Treatment 2.0 agenda may be found online at: http://data.unaids.org/pub/Outlook/2010/20100713_fs_outlook_treatment_en.pdf.

201 Interview on 25 April 2012 in Rabat.

202 As per a follow-up email sent on 23 April 2012 by Boutaina El Omari, the Global Fund programme manager at the MoH, following an interview on 18 April.

87,332 during the previous two years. NGOs currently operate more than 50 free and anonymous VCT sites in the country and eight mobile testing units.

Tests are offered confidentially and are accompanied by pre- and post-test counselling. In centres operated by NGOs (usually in collaboration with the MoH), other preventive services and commodities are available, including condoms and lubricants, assessment and treatment of sexually transmitted infections (STIs), and social and psychological support. Since the introduction of rapid tests in most facilities, a far greater share of those tested actually get their results, even though positive results require further confirmation. Another notable improvement is that referral systems and procedures have greatly improved, which means that those who test positive are directed to treatment facilities far more quickly and efficiently.

Major ongoing challenges persist despite the increase in testing uptake in recent years. Most notably, the number of facilities offering HIV counselling and testing remains inadequate. Several medium-sized cities have no facilities where HIV tests are offered and it is sometimes difficult for people to obtain a test without travelling a long distance. Awareness of existing options also remains limited, as some people interviewed were not able to identify facilities in their own neighbourhoods or cities.

Human resources dedicated to HIV testing are another concern. In Morocco, only physicians are allowed to provide HIV tests. This is a problem because the majority of voluntary HIV tests are carried out by NGOs. Yet because of regulations, those NGOs usually must rely on volunteer physicians who practice in hospitals or private clinics and are only able or willing to dedicate a few hours a week to NGOs. As noted by one NGO representative:²⁰³ “We have a fully equipped VCT centre but it works only two days a week as we lack physicians....We could perform more HIV tests if we had a full-time physician or if trained non-medical NGO staff were authorized to do the test.”

Such barriers, coupled with a general lack of awareness about HIV and risks, are among the main reasons that early detection of HIV status remains a real challenge. According to healthcare workers, diagnosis often occurs at a late stage and people continue to be hospitalized at advanced stage of AIDS and/or die within days of admission to hospitals. For example, clinical data from 2010 from the Department of Infectious Diseases in Marrakech showed that out of 235 patients, more than 60 percent were classified upon admission as Category C, the most advanced stage of HIV where a patient presents with AIDS-indicator conditions. Among the eight PLHIV interviewed for this research, only one person (a man) had taken the initiative to get an HIV test; the others had only been tested following the suggestion of their doctor in a hospital because they were already ill.²⁰⁴

Individuals interviewed were generally positive about their experiences after diagnosis in regards to access to key monitoring and diagnostic tests, including CD4 testing to determine whether a person is eligible for treatment. Treatment is initiated according to national recommendations at a CD4 count below 350 cells/mm³ or AIDS clinical symptoms. CD4 and viral load tests are provided free of charge in public hospitals every six months, although their availability can sometimes be limited due to stock-outs of reagents or problems with machines. Even though viral load assessment is done at only a single site (the National Laboratory of Reference in the capital), patients do not need to travel there for testing—their blood samples are sent to the laboratory. Recent efforts have focused on making CD4 testing available in some cities that still lack it.

203 Dr. Mohamed En Khammas, HIV counseling and testing national coordinator at ALCS, 1 April 2012 (email correspondence).

204 Admou B et al. “Clinical and immunological status of a newly diagnosed HIV positive population, in Marrakech, Morocco. *African Health Sciences*, Vol 10, No 4, December 2010.

Genotyping is only available at one site intermittently. Some important additional tests, especially in complicated cases—such as therapeutic drug monitoring, eye examinations, etc.—are only provided if patients are able to pay for them themselves or through the NGOs supporting them. The majority of such support is provided by one HIV-focused NGO, Association de Lutte Contre le Sida (ALCS).

2.2 Optimize drug regimens

National HIV treatment recommendations are regularly updated and comply with the 2010 WHO guidelines: the criteria for starting treatment include a CD4 count less than 350, while symptomatic patients or those co-infected with active hepatitis (B or C) can initiate regardless of CD4 count. A new version of the guidelines was being finalized while research for this report was conducted.

Of the 4,047 PLHIV on ART as of 31 December 2011,²⁰⁵ about 80 percent were on a first-line regimen with nearly all the others on a second-line. (Just 20 persons were on a third-line regimen.) Ninety percent of all people on a first-line regimen were on one of three regimens: TDF+FTC+EFV, AZT+3TC+NVP or AZT+3TV+EFV. A similar share of those on second-line regimens were on one of three different ones as well, with all three commonly used second-line regimens using LPV/r instead of the third drug in each of the first-line regimens specified above. Priority is given to procuring generic formulations whenever possible.

According to the person responsible for the antiretroviral drug (ARV) supply system, the consolidation into a handful of treatment regimens—which is a key objective of the Treatment 2.0 agenda’s focus on “optimizing” drug regimens—is the result of a “huge effort” made over the past year to standardize prescriptions. She said, “Before, we had about 20 different therapeutic schemes. Physicians prescribed according to their own volition or upon availability, making it difficult to track inventory of available ARVs and stock-outs became more frequent.”²⁰⁶ In discussing the benefits of the change, the official added, “Alongside this harmonization a computer system was implemented for real-time tracking of stocks. Since the adoption of [this new system] stock-outs have decreased significantly and in addition, by introducing fixed-dose combinations, we gained in regards to adherence to ART regimens.” (Both physicians and PLHIV interviewed during this research reported that even though the situation was improving, stock-outs still occur on occasion. Little progress reportedly has been made in limiting stock-outs for paediatric formulations, however.)

This move to standardization reportedly has not been accompanied by additional steps to make treatment easier for patients. All PLHIV interviewed said they would prefer fixed-dose combinations that would only need to be taken once a day, which is another key goal of Treatment 2.0 optimization efforts. With one exception, all of those interviewed were taking more than one pill for each dose; moreover, all had to take HIV medicines at least two different times a day. Such complexity hinders adherence and thus the effectiveness of treatment for many patients. Yet according to the procurement unit person interviewed, caregivers are resisting the move to fixed-dose combinations. He said that “physicians ask for separate drugs to have more flexibility to switch the regimens for side effects management.”²⁰⁷

Treatment is provided free of charge, but with significant restrictions. ARVs are not available in pharmacies and treatment is not provided in private clinics. ART can only be prescribed, dispensed and

205 As per a follow-up email sent on 23 April 2012 by Boutaina El Omari, the Global Fund programme manager at the MoH, following an interview on 18 April

206 Interview with Boutaina El Omari, the Global Fund programme manager at the MoH, on 18 April 2012.

207 Nouredine Sakhri, pharmacist at the MoH (response to questions by email, 18 April 2012).

monitored by infectious-disease specialists and internists at one of 10 public health facilities across the country, all of which are affiliated with hospitals in cities. Many patients therefore live far from treatment facilities and face substantial personal expenses for transportation, accommodation, etc. Most HIV-positive participants of focus group discussions said that in the past year they had delayed going to a treatment facility to obtain medicines at least once because they could not afford transportation costs.

Officially, discrimination is prohibited in regards to treatment access and availability. However, most focus group participants from marginalized populations (i.e., MSM and female sex workers) stressed the high level of stigma and discrimination against them in public health settings, from health workers as well as from members of the public using health facilities. Some suggested that ART for people in those populations should be provided through NGOs, as is currently possible in regards to HIV testing, treatment for STIs and other prevention services. As noted by one participant, NGOs are “less judgmental and less bureaucratic than public hospitals.”²⁰⁸

2.3 Reduce costs

First-line ART regimens cost the government around \$273 per person per year, while second-line regimens average about \$478.²⁰⁹ (As noted previously, only about 20 people are currently on third-line regimens, which cost about \$18,600 per person.). Treatment is funded mainly through the national budget and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). In 2003, the government’s contribution represented 30 percent of the budget allocated to purchasing ARVs against 70 percent for the Global Fund. Those shares are expected to be reversed by the end of 2012, with the government covering 70 percent of ARV purchasing costs from the national budget.²¹⁰

The introduction of generic drugs in 2003 has resulted in a 10-fold decrease of ARV prices. The MoH is committed to going further by “pursuing price reductions to reach an annual first-line treatment cost of \$150-\$160.”²¹¹ This effort may be feasible as most first- and second-line ARVs have not been patented in Morocco and thus continue to be easily accessible in generic versions (almost exclusively from India).

It should be noted, though, that the lack of generic options for third-line drugs means that the costs of ART for the 20 individuals currently on third-line regimens equals the amount needed to provide treatment to more than 1,600 people on first-line ones.²¹² This massive cost gap could be a major problem if and when more people are put on treatment and the number of those needing second- and third-line options grows. Many of the ARVs used in those regimens are already, or likely to be, patented in Morocco as originator-brand companies seek greater control over access and pricing for newer products. Flexibility to cut costs was further limited after Morocco signed a free trade agreement with the United States in 2004 that required it to strengthen its intellectual property law. According to treatment activist Hakima Himmich,²¹³ the Moroccan law on intellectual property protection is “one of the most restrictive in the developing world...It includes several TRIPS-plus provisions, including

208 Female sex worker at a focus group discussion in Casablanca, 28 April 2012.

209 As per exchange-rate calculations from May 2012.

210 Sakhri N et al, “Évolution de la contribution de l’État dans le financement des antirétroviraux (ARV) depuis 2003. DELM/Ministère de la santé, Poster, Francophone Conference on AIDS 2012, Geneva.

211 Interview with Boutaina El Omari, MoH’s Global Fund Programme Management unit, Rabat (18 April 2012).

212 Noureddine Sakhri, pharmacist at the MoH (response to questions by email, 18 April 2012).

213 Chair of ALCS, interviewed by telephone on 30 April 2012.

restrictions on the use of compulsory licenses, prohibition on parallel imports, patents on new use and new formulations, data exclusivity, etc”.²¹⁴

In another step that could limit the scope to cut drug-purchasing costs, Morocco in October 2011 signed the Anti-Counterfeiting Trade Agreement (ACTA), a multinational treaty that aims to establish an international legal framework for targeting counterfeit goods and products. Many observers believe the ACTA could undermine access to generic medicines, including ARVs, by muddling the clear distinction between counterfeit/fake products and generic ones. One consequence of this confusion could be seizures of generic medicines by customs officials, a situation that has already happened on at least one occasion elsewhere in the world.

2.4 Adapt service delivery

HIV treatment and care services have for some time integrated a wide range of non-HIV services including sexual and reproductive health, TB diagnosis and treatment, etc. However, as indicated in interviews with care providers, reciprocity is less common: HIV-specific services are not as frequently provided as part of care related primarily to sexual and reproductive health, TB and antenatal care.

Some important exceptions and positive steps should be noted. For example, the Global Fund mechanism (especially the Round 6 grant) has played an important role in facilitating the integration of HIV services with those focusing on TB and maternal and child health. Particular improvement has been seen in the provision of vertical transmission services, which had been one of the weakest points of HIV prevention. (Integration with sexual and reproductive health has been less easy for “political and bureaucratic reasons,” according to a key informant from the MoH.²¹⁵)

Also, currently being implemented is a protocol of HIV counselling and testing initiated by providers for TB patients at specialized facilities. The programmatic objective is to enable a significant proportion of TB patients to be aware of their HIV status and, if HIV-positive and clinically eligible, to start ART at an early stage. Screening with HIV rapid tests is now available in 49 TB facilities nationwide. TB tests are available at HIV clinics as well.

Little integration has occurred in regards to hepatitis care and treatment, however. This lack of progress is increasingly worrying given the rapid growth of drug injection, especially in the north of the country, and the lack of testing and treatment services for people living with hepatitis B and C. According to a treatment educator from ALCS interviewed for this research,²¹⁶ PLHIV more often die from hepatitis co-morbidity than from HIV. Morocco in early 2012 launched an insurance programme for poor people called RAMED (Regime d'Assistance Medicale). NGOs and health workers have great hope that this insurance scheme will help improve availability of and access to services such as those for viral hepatitis, but it is not clear whether such hopes will be realized.

When it comes to prevention, in addition to awareness-raising campaigns among the general population, outreach programmes targeting most-at-risk and marginalized populations have been undertaken since the mid-1990s. These programmes are mainly implemented by NGOs in partnership with the National

214 TRIPS refers to the Agreement on Trade-Related Aspects of Intellectual Property Rights, an agreement negotiated through the World Trade Organization (WTO) in the 1990s to introduce intellectual property rules into the multilateral trading system. The TRIPS agreement included several “flexibilities” that signatories could use to ensure access to essential products such as HIV drugs without issuing patents. “TRIPS-Plus” refers to subsequent efforts by some governments, including the United States, to limit other countries’ use of these flexibilities.

215 Respondent who requested confidentiality; interviewed by telephone (26 April 2012).

216 Leila Hangal, who helped organize focus groups with PLHIV in Marrakech. Interviewed on 16 April 2012.

AIDS Programme. Most of them focus primarily on HIV and STIs, leaving unaddressed other health needs of marginalized communities.

Recently, ALCS launched a sexual and reproductive health clinic in Marrakech for MSM that provides services in addition to HIV, including in regards to mental health, substance use, violence, dermatology and proctology. MSM focus group participants in Marrakech expressed satisfaction with this initiative and suggested that similar projects should be launched in other cities and targeting other populations. With that aim in mind, ALCS is seeking to open a similar clinic for IDUs in Tetouan; as of August 2012, though, it had been unable to proceed because the MoH has been slow to respond to the request.

2.5 Mobilize communities

In general, civil society in Morocco is relatively free and operates independently from the government. The MoH works in real partnership with civil society organizations (CSOs) and community groups without the kind of pressure or control that frequently exists in other countries in the Middle East and North Africa region.

Yet despite such relative openness, few CSOs in Morocco are involved in HIV treatment issues—e.g., advocacy, treatment literacy and education, and care delivery. This is due to the fact that for a long time there has been a *de facto* separation of fields of action, with the government focusing on treatment and NGOs focusing on prevention and support to PLHIV. With the exception of a small number of organizations that address both treatment and prevention issues to some extent (including ALCS and Association Soleil), there has been no investment in developing capacities of HIV organizations, including the main PLHIV organization (Association du Jour), on issues related to treatment. Few therefore have the skills and capacity to advocate effectively and to provide a wider range of services—including direct provision of treatment, care and support for PLHIV and members of marginalized populations—should such options be made available. (One hopeful sign is that ITPC North Africa recently initiated a capacity-building programme for North African NGOs on treatment. Several Moroccan NGOs are included in this programme.)

The lack of extensive community engagement and mobilization is one reason that most PLHIV interviewed during this research either in focus groups or in personal interviews had insufficient knowledge on treatment. For example, among the eight PLHIV interviewed, none was able to identify his or her CD4 count—which is the most basic information about the status of infection. One HIV-positive woman said the following:²¹⁷

I don't know my CD4 account. All I know is that it is high and good. Once I asked the nurse to tell me my exact account. She said they don't have time to seek the information. She explained that they only keep record of bad results to investigate treatment failure. As long as the result is fine, I don't need to know.

According to PLHIV respondents to this research, treatment education in health facilities seems more to be focused on how to correctly take the medications given, than on the best treatment options available. An MoH respondent noted that “treatment education is based on ARVs delivered [rather] than on the individual.”²¹⁸ To date, there are no adapted brochures or documents available in Arabic for PLHIV explaining treatment in basic and clear terms.

217 Focus group discussion with HIV-positive women in Marrakech, 10 April 2012.

218 Interviewed in Rabat by phone on 18 April 2012.

Many of the issues noted in the comments and observations above are those that would likely be addressed by a stronger and more engaged community presence. In such an improved environment, patients would be empowered to demand more extensive information from their caregivers and healthcare workers would be more likely to tailor care to an individual's specific needs.

The importance of greater community engagement in the future, especially if Treatment 2.0 is to be fully realized, is underscored by many clients' clear desire for the type of support and information that community groups are best placed to provide. One focus group participant noted the following, for example:²¹⁹

The doctor rarely has time to give us information about the disease or the medicines we are taking. This is done mainly by the treatment educators. However, I am comfortable with this. I feel more comfortable speaking with the educators than with the doctor. They are more available, friendly and I don't need to hide my sexual orientation as I know that they won't judge me.

3. KEY CHALLENGES

This section summarizes some of the main challenges identified during research to an enhanced and expanded HIV response in Morocco. Improvements in such areas are considered critical for the effective adoption and implementation of the Treatment 2.0 framework in the future.

Inadequate access to HIV testing and counselling

Only about 20 percent of PLHIV in Morocco are thought to be aware of their HIV status. Most may not be aware that they could or should be tested; for those who might consider the possibility, lack of easy access to VCT facilities (which are mostly in large cities) is a deterrent. Insufficient effort has been made by the government to increase interest in and uptake of testing.

While the policy of the MoH to subcontract HIV testing to NGOs has been effective in reaching most-at-risk populations, the policy has limits because NGOs (unlike government health facilities) do not cover all of the country. Some of these problems may be addressed by the plan to offer HIV testing in hundreds of primary health centres across Morocco.

The other main challenge is related to human resources. As noted previously, current regulations stipulate that only physicians can offer HIV testing and counselling. Far too few doctors are able and willing to provide such services, which are usually offered in VCT centres run by NGOs, due to their heavy workloads. There is no doubt that these VCT centres could offer more HIV tests if they were open more frequently because physicians were available. According to the physician working at the ALCS VCT facility in Marrakech, "Many people come to the VCT when there is no doctor. They are invited to come back during opening hours, and some do...but some never show up again."²²⁰

Centralization of care and restrictions on provision of treatment

As noted in Section 2.2, only infectious-disease specialists and internists are authorized to prescribe and dispense ARVs. And at the same time, HIV treatment provision remains highly centralized in specialized public health facilities despite recent tentative steps to decentralize. The result is that many patients find it difficult to access services reliably, and those that do often find caregivers overwhelmed and unable to spend more than a few minutes with them during each visit.

219 Focus group discussion with MSM in Marrakech, April 2012.

220 Interview with Dr. Nadia Amine, 16 April 2012.

One chief physician at the Casablanca treatment centre agreed that the current situation makes little sense and is inefficient.²²¹ He said, “Infectiology is a discipline that needs a long training (four years) and it is not very popular among doctors....We need to extend simplified treatment combinations that could be used by [doctors who are not infectious-disease specialists].” He added that the majority of people on first-line regimens do not need to be seen regularly by an infectious-disease specialist; instead, in his opinion those specialists should focus on complicated or difficult cases such as those involving resistance to ARVs.

Limitation of care to infectious-disease departments is also seen by PLHIV who participated in the focus group discussions as stigmatizing. As one participant noted,²²² “Once you set foot in the Department of Infectious Diseases, everybody knows that you [have HIV]....In people’s heads, these departments are for the service of AIDS.”

Several respondents said that some of the current challenges could be overcome by allowing the private sector to monitor PLHIV and provide treatment. Such a step would help reduce pressure on the public sector and could, in some instances, address concerns regarding discrimination and stigmatization in service delivery. According to research for this report, private clinics are considered more discreet and less stigmatizing than public facilities and their opening hours are also more flexible.

Potential restrictions on access to generics in the future

Because it is a middle-income country with a relatively low HIV prevalence, Morocco is unlikely to receive substantial support in the future from donors such as the Global Fund. Its income classification also restricts its eligibility to receive preferential status for lower-priced ARVs in the future. For example, Gilead Sciences, Inc. has excluded Morocco from a license granted to the Medicines Patent Pool for generic production of four HIV medicines that could be useful in the coming years. In December 2011, Johnson & Johnson announced similar licenses (and restrictions that exclude Morocco) on three drugs used for second- and third-line treatment.

Such developments raise additional concerns about future access to lower-priced ARVs, including generic products. Also worrying are the country’s new intellectual property rights law and its provisions restricting Morocco’s ability to exercise key flexibilities in world trade agreements. Over the past few years, many civil society organizations in Morocco have sought to sensitize public opinion, media and different stakeholders to issues regarding intellectual property rights and access to medicines. Such efforts have had little impact, however. The new law and a free trade agreement with the United States, agreed to in 2004, could greatly limit access to generic HIV drugs in the future, including those needed for second- and third-line regimens. The high costs of purchasing more or only branded medicines could lead to quotas and restrictions on treatment access for PLHIV in need.

HIV-related stigma and discrimination

All persons interviewed for this report agreed that HIV-related stigma and discrimination remain a major obstacle to effective and comprehensive access to HIV prevention, care and treatment services in Morocco. Stigma and discrimination are encountered at all levels of society, including in the media, in laws and among caregivers. Apart from sporadic and inconsistent efforts, no thoughtful strategy has been developed to address it.

221 Interview with Prof. Marhoum Kamal from Hospital Ibn Rochd Casablanca, 2 April 2012.

222 Focus group discussion in Casablanca, 26 April 2012.

In a study carried out by ALCS in 2010 among 133 PLHIV in five cities, 40 percent of respondents reported having experienced stigma or discrimination by medical staff because of their HIV status.²²³ Women reported greater levels: half of the women surveyed said they had faced HIV-related stigma compared with 28 percent of men. Of all surveyed, 21 percent reported being refused treatment, medical consultation or care because of their HIV status; 15 percent said they experienced delays in access to care; and 50 percent said their HIV status had been improperly disclosed by healthcare providers. Dental units, gynaecological and ophthalmologic services were considered among the most stigmatizing services.

In focus group discussions with PLHIV for this report, two women said they had been denied delivery in a public hospital; one added that her child had been refused circumcision, an important cultural practice in Morocco.²²⁴ One participant said he had experienced refusal of dental care because of his HIV status. For them, efforts to educate and raise awareness of medical staff must be pursued, but it is not enough. One HIV-positive focus group participant said the following:²²⁵

Awareness is important, but we also need to punish discriminatory behaviour when it happens to set an example....Hospitals should set up an office or a telephone number for people who experience these behaviours to collect their complaints that should be considered seriously and those responsible must be punished. This is the only way to change the situation.

Stigma and discrimination have also been identified by PLHIV as a major obstacle to adherence. Several people interviewed agreed that taking medications regularly and on time in an environment where nobody around is aware of one's HIV status—usually because of concerns about stigmatization—is a real challenge. Many said they hide taking their medicines from family members or at the workplace. At one hospital visited during research, a nurse pointed out the large amount of packaging materials in which ARVs are distributed in the trash bins at the exit of the health services. Many PLHIV discard the packaging immediately after getting their medicines to avoid attracting the curiosity of those around them, to whom many have said only that they are dealing with a “blood disease” or hepatitis—anything but HIV infection.

4. RECOMMENDATIONS

Research indicates that in some respects, concrete steps have been taken in Morocco in response to the Treatment 2.0 agenda. In most cases, however, such steps have not been conceptualized as part of this framework. Ongoing and future developments should be consolidated and coordinated as per the key Treatment 2.0 principles and objectives.

One overarching need is for WHO and/or other relevant normative agencies developing the Treatment 2.0 framework to provide guidance and assistance as soon as possible so that countries can create and implement national strategies linked with its priorities and principles. The following other recommendations aim to advance the framework in Morocco.

- **The MoH should organize a national consultation on Treatment 2.0** with the participation of all stakeholders: caregivers, civil society, PLHIV, and representatives of

223 Raff N, et al. “Stigmatisation et discriminations des personnes vivant avec le VIH (PVVIH) dans le milieu des soins: Leçons d’une enquête auprès de 133 PVVIH marocains. Oral présentation, Francophone Conference on AIDS 2010, Casablanca.

224 Focus group discussion in Marrakech, 11 April 2012.

225 Focus group discussion in Marrakech, 11 April 2012.

most-at-risk populations. Representatives from WHO and UNAIDS should be invited to discuss the framework in-depth and explain what it could and should mean in practice.

- **The MoH should revise regulations to allow nurses, pharmacists and trained NGO staff to provide HIV tests (including counselling).** The impact of this change should be monitored regularly and evaluated, with the potential goal of expanding access even further to qualified individuals and organizations.
- **The MoH should increase the number and location of facilities where ART services can be provided by allowing a far greater range of physicians (not just infectious-disease specialists) to treat HIV cases.** This broadening step could be undertaken by developing a training curriculum on management of HIV infection that all physicians are required to take. It need not be overly extensive or time-consuming, and would certainly be less complicated than similar curricula for infectious-diseases specialists. To the fullest extent possible, newly trained physicians should be located in cities and regions currently lacking treatment centres. The direct engagement of infectious-disease specialists could be reserved for situations such as when patients exhibit signs of resistance or are unable to adhere to regimens.
- **The MoH should prioritize the purchase and prescribing of simplified ART regimens, with a particular focus on using fixed-dose combinations only.** Simplified regimens are a key goal of Treatment 2.0. Using few, simpler regimens with limited side effects can help rationalize HIV treatment efforts and improve adherence. One likely result would be less drug resistance, thereby helping limit the need to change regimens and risk further treatment failure. Improved adherence can also have a preventive effect as evidenced in findings showing the benefits of treatment-as-prevention.

Morocco has already made important strides in this area, including in regards to reducing the number of different regimens available. The one major challenge is the lack of fixed-dose combinations among the treatment regimens currently prescribed.

- **Key international institutions and mechanisms should help ensure access to affordable generic medicines.** In particular, institutions involved in drug procurement and supply such as the Global Fund, UNITAID and the Medicines Patent Pool should resist and confront efforts to restrict the ability of middle-income countries with low prevalence, such as Morocco, to purchase and provide generic HIV medicines now and in the future. Morocco will be unable to scale up treatment affordably and effectively as part of the Treatment 2.0 framework if second- and third-line ARVs are not available at affordable and reasonable prices.
- **The government should harmonize all policies, including those of the Ministries of Health, Trade and Industry and Foreign Affairs, to ensure that trade agreements and provisions do not restrict access to affordable, generic medicines.** This priority, like the recommendation immediately above, is essential for the country's ability to overcome trade-related obstacles and utilize flexibilities in existing trade agreements to benefit public health programmes. In practice, it requires consistent, coordinated positions by all government ministries, departments and personnel on international bodies (such as the Global Fund, UNAIDS, the World Trade Organization and the World Intellectual Property Organization).

One important initial step should be to revise the recent intellectual property law, which is far too accepting of restrictive patent demands. Also useful would be the creation of a common working group among the different relevant government agencies as well as civil society representatives to explore how best to exploit TRIPS flexibilities. The government should also withdraw from the Anti-Counterfeiting Trade Agreement (ACTA).

- **Reducing stigma and discrimination in health facilities should be a priority of the new 2012-2016 AIDS National Strategic Plan** with concrete action in partnership with PLHIV. More training for health workers is needed and a mechanism to receive complaints of PLHIV should be put in place.

RUSSIA AND TREATMENT 2.0: CHALLENGES AND OPPORTUNITIES TO SCALE UP HIV TREATMENT

This country report is part of *Missing the Target 10 (MTT10)*, the 2012 version of a longstanding series on global access to HIV treatment coordinated by the International Treatment Preparedness Coalition (ITPC). *MTT10* focuses on challenges to the scale-up of HIV services as required to implement the Treatment 2.0 framework. As with other *Missing the Target* publications, national and local community groups conducted research based on a general template and prepared their country-specific reports. The following countries are included in *MTT10*: Cameroon, China, Côte d'Ivoire, Honduras, India, Kenya, Morocco and Russia.

The full *MTT10* report and individual country reports are available at the ITPC website: www.itpcglobal.org. Also available at that website are French versions of the Cameroon and Côte d'Ivoire reports and a Spanish version of the Honduras one.

Russia

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ACRONYMS AND ABBREVIATIONS

ART	antiretroviral treatment
ARV	antiretroviral drug
CBO	community-based organization
IDU	injecting drug user
MoH	Ministry of Health
MSM	men having sex with men
NGO	non-governmental organization
PLHIV	people living with HIV
STI	sexually transmitted infection
TB	tuberculosis
WHO	World Health Organization

Note on text: All "\$" figures are U.S. dollar amounts. All URLs cited were valid as of 1 October 2012.

HIV drugs list

Many HIV drugs are commonly referred to in an abbreviated format. Listed below are the abbreviated names of all the drugs mentioned in the Russia report as well as the full generic name associated with them. Where relevant, brand names of key drugs are also noted. The drugs are grouped by class.

NRTIs (nucleoside reverse-transcriptase inhibitors)	
3TC	lamivudine
ABC	abacavir
AZT	zidovudine
d4T	stavudine
TDF	tenofovir
NNRTIs (non-nucleoside reverse transcriptase inhibitors)	
EFV	efavirenz
Protease inhibitors	
LPV/r	lopinavir/ritonavir (refers to lopinavir being “boosted” by ritonavir)

1. INTRODUCTION AND OVERVIEW

1.2 Methodology

Research for this report included a documentation review, four focus group discussions, personal interviews and an online questionnaire. The focus groups were conducted in the city of St. Petersburg and in the Leningrad region, which is a separate administrative unit of Russia with St. Petersburg as its main city. The focus groups consisted of the following: i) one group of HIV-positive women on antiretroviral treatment (ART) from St. Petersburg; ii) one group of men having sex with men (MSM) on ART from St. Petersburg; iii) one group of injecting drug users (IDUs) living in the Leningrad region; and iv) one group of social activists on ART registered in the Leningrad region. The total number of focus group participants was 22.

Seven personal interviews were conducted with people living with HIV (PLHIV). Others interviewed were three medical service providers, including two doctors and one peer counsellor; representatives from three community-based organizations (CBOs); and two healthcare administrators working in the field of HIV, including the head of one of the major HIV clinics and a senior specialist at one of the government ministries that focuses on HIV issues.²²⁶ The interviews covered four areas: universal access to treatment and the Treatment 2.0 agenda; the regulatory framework in the field of HIV; funding for the HIV response in Russia; and community involvement in the HIV response.

A total of 87 people responded to an online questionnaire developed and made available by ITPCru, the regional branch of the International Treatment Preparedness Coalition, using the SurveyMonkey tool. All respondents identified themselves as PLHIV. Information about the survey was distributed using the ITPCru listserv. The questions were the same as those in the structured forms used for in-person interviews with PLHIV.

226 To safeguard confidentiality, specific information is not provided about these two individuals' titles or workplaces.

1.2 Context

Russia is at the centre of the region with the world's fastest-growing HIV epidemic. From 2001 to 2010, there was a 250 percent increase in the number of people living with HIV in Eastern Europe and Central Asia, according to UNAIDS. Russia and Ukraine account for almost 90 percent of those cases²²⁷ As of 31 March 2012, a total of 665,590 HIV-positive people were officially registered people in Russia, including 5,968 children younger than age 15²²⁸ In 2011, a total of 62,385 new cases of HIV infection were reported, as compared with 58,187 in the previous year. UNAIDS and other sources estimate the actual number of PLHIV in Russia to be much larger, perhaps as many as 1.5 million, than the number of officially registered cases.²²⁹ That would correspond to HIV prevalence exceeding 1 percent.

Injecting drug use remains the main cause of HIV infection in Russia and the region as a whole, although considerable transmission also occurs among sexual partners of people who inject drugs.²³⁰ The HIV epidemic in Russia is relatively young, with approximately two-thirds of HIV-positive people being diagnosed below the age of 30. Also notable is a trend towards feminization of the epidemic. Since 2002, a steady increase in the proportion of HIV cases among women has been observed; as of 31 December 2011, some 232,500 women in Russia were registered as HIV-positive, accounting for about 35.8 percent of the total registered HIV cases.²³¹

Diverse claims and assumptions have been expressed in regards to access to treatment in Russia in general. According to some officials, Russia has achieved universal access to HIV treatment—100 percent of patients in need of treatment are receiving it, which constituted approximately 100,000 patients in 2011.²³² However, according to independent monitoring carried out by non-governmental organizations (NGOs), the number of ART regimens purchased by the government in 2011 would cover only 81,000 patients.²³³ No information is available regarding the gap of some 19,000 people in need.

More importantly, the officials' claims to have achieved universal access are suspect because no reliable estimates exist as to the number of people in need of ART. Some specialists say the number of HIV-positive patients who are eligible for treatment today is as high as 200,000.²³⁴ Many people who may currently be in need of ART may not even know they have HIV because they have not been tested. The claims also seem unverifiable given the absence of mandatory treatment protocols regulating the initiation of therapy.

What seems indisputable is that the need for ART will only rise considerably. It is projected that by 2015, given current trends, the number of officially registered HIV cases will increase to nearly 940,000 and more than 350,000 of those people will need treatment. Covering all of them would cost the Russian

227 UNAIDS World AIDS Day Report 2011. See http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2216_WorldAIDSday_report_2011_en.pdf.

228 As per data from the Russian Federal AIDS Centre, www.hivrussia.ru (accessed 22 June 2012).

229 Cited at *Rossiyskaya Gazeta*, www.rg.ru/2011/11/21/vich-site.html (accessed 22 June 2012).

230 UNAIDS World AIDS Day Report 2011. See www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/JC2216_WorldAIDSday_report_2011_en.pdf.

231 As per data from the Russian Federal AIDS Centre, www.hivrussia.ru (accessed 22 June 2012).

232 Interview with A. Mazus, chief of the Moscow AIDS Centre, in *RiaNovosti* on 30 November 2011. Available online at: <http://ria.ru/interview/20111130/502514901.html> (accessed 10 May 2011).

233 "To treat or not to treat". Report on government procurement and provision of ARV based on community research. Available online at: http://itpcru.org/netcat_files/10/196/To_treat_or_not_to_treat_0.pdf

234 Presentation of Aza Rakhmanova, chief infectious disease specialist of St. Petersburg, at the conference "Screening and treatment of TB among drug users, including HIV-positive drug users". Delivered 21 May 2012 in St. Petersburg.

government about 63 billion rubles (\$1.93 billion), based on prices paid for antiretroviral drugs (ARVs) in 2010.²³⁵

2. NOTABLE FINDINGS AND OBSERVATIONS ASSOCIATED WITH TREATMENT 2.0

“Treatment 2.0” is the name of an initiative developed and launched in 2010 by the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the World Health Organization (WHO). It aims to simplify and improve the way HIV treatment is currently provided in order to maximize the effect of ART and further scale up access to HIV treatment, care and support. The initiative focuses on innovation and efficiency in HIV programming, including the integration of important new findings such as the preventive effects of ART.²³⁶

WHO and UNAIDS are currently developing various frameworks that will help countries and all stakeholders develop and implement strategies based on Treatment 2.0 principles and priorities. The frameworks will be based on the initiative’s five main priority work areas, also known as “pillars”:

1. Provide point-of-care and other simplified diagnostic and monitoring tools
2. Optimize drug regimens
3. Reduce costs
4. Adapt delivery systems
5. Mobilize communities

The agencies have worked closely with partners at global, regional and country level to explain the Treatment 2.0 agenda in general, and the importance of the five pillars specifically. This effort also seeks to build support for the overall approach, which can only be successful when countries’ HIV programmes and strategies align with it.

Findings and observations obtained through research for this report are organized by the five Treatment 2.0 pillars (Sections 2.1 through 2.5 below). This structure is intended to highlight progress, gaps and challenges in Russia regarding expanded and enhanced HIV treatment for all in need.

Existing awareness of Treatment 2.0 in Russia

Awareness of the Treatment 2.0 agenda overall was quite low among individuals contacted during research for this report. Few interviewees were aware of certain key principles guiding the agenda, such as the concept of treatment-as-prevention. One of the healthcare officials interviewed was familiar with the framework but was unsure whether it could be realized fully in Russian given the current environment; the other official was not aware of the concept at all.

None of the focus group participants or respondents to the questionnaire mentioned the overall agenda—although it must be noted that there were no direct questions regarding Treatment 2.0 specifically. Several participants did have opinions about different aspects of the Treatment 2.0 pillars, and many of their observations and comments are integrated throughout this report.

235 Estimates of the Federal AIDS Centre, www.hivrussia.ru/pub/2011/01.shtml (accessed 22 June 2012).

236 Detailed information about the Treatment 2.0 agenda may be found online at: http://data.unaids.org/pub/Outlook/2010/20100713_fs_outlook_treatment_en.pdf.

2.1 Provide point-of-care and other simplified diagnostic and monitoring tools

HIV testing is generally available free of charge in special AIDS clinics (called AIDS centres); at infectious-disease clinics with specialized departments for HIV; at outpatient clinics with relevant specialists; and at antenatal clinics (for pregnant women). Tests can also be obtained for a fee in private clinics. General awareness about the options for and availability of HIV testing seems to be rather high, judging by the answers of the focus group participants: they named a range of clinics offering HIV testing and counselling.

The extent and quality of pre-test counselling and post-test counselling—both of which are required by current federal policies—were not considered satisfactory by focus group participants and PLHIV interviewed for this research. Only a few said they had received any information at all before being tested, including that they had a right to refuse a test. The information dispensed reportedly was mostly negative and fatalistic as healthcare workers emphasized the “limited lifetime” of PLHIV. As a result, some people did not return to the healthcare system for treatment for a long time—for up to 10 years, based on the input from focus group participants. The general impression was, as quoted by a focus group participant, that doctors as a rule “are busy and give very limited information”. Only 13 percent of respondents said they were referred to support groups at the time of their diagnosis; one person was referred to a hotline. (Note: Most of the responses from PLHIV pertained to pre- and post-test counselling experiences they had several years ago, when they tested positive. Yet most also said that what they heard from others more recently indicates that little has changed regarding the quality of such counselling.)

Healthcare providers interviewed said they consistently provide pre-test and post-test counselling. Yet although this indicates some improvement in the provision of such services, some respondents who had been tested for HIV in recent years said problems persist. Informed consent appears to be inconsistently prioritized, and several participants noted that they were essentially forced to be tested because of a longstanding law, which advocates have long opposed, requiring workers in some professions to be tested regularly for HIV.

Provider-initiated testing, which is considered a potentially important element of Treatment 2.0, is rarely available today in Russia. Respondents had mixed feelings about it. Some thought it would be a useful option assuming two conditions are met: i) there are clinical indications that would prompt the offering of a test, and ii) the negative attitudes to PLHIV throughout society on the whole improved, as this might mean people would not fear the social consequences of being HIV-positive. All participants liked the idea of offering testing in a variety of different settings and suggested options including the use of special buses, tents put up during special testing campaigns, and providing tests at a range of public places (airports, train stations, hypermarkets, etc). It is worth noting that all respondents specifically excluded workplaces as sites where HIV testing should be offered.

Government policies mandate that key monitoring tests, including CD4, viral load and resistance testing, are provided free of charge. Most individuals surveyed said they had been offered a CD4 test soon after being diagnosed, but all of these critical tests are not always offered or made available on a regular or timely basis. For example, according to the Simona+ monitoring project carried out in 2011-2012 by community organizations, only 5 percent of respondents included in the survey were offered resistance testing.²³⁷ That low rate seems especially problematic given that 32.5 percent of respondents

237 A.Volgina, S. Golovin, D. Godlevskiy. “Roles and principles of organizing public control as an instrument of raising effectiveness of the governmental spending for HIV response”. Presentation at the annual conference of Rospotrebnadzor in Suzdal, December 2011.

reported having changed their ART regimens—thus raising concerns that caregivers switched their medicines without knowing which ARVs or drug classes the patients were resistant to, if any.

Availability of important monitoring tests also is plagued by continued problems with procurement and distribution. In 2011, for example, numerous cases of stock-outs of viral load and CD4 tests were identified in several regions of the country.²³⁸

2.2 Optimize drug regimens

ART in Russia is provided free of charge through government-run clinics (AIDS centres) that have special licenses to dispense such drugs. Patients are not required to pay for all other related treatment services at public facilities, including appointments with doctors. Focus group participants all said they had never had to pay for HIV medicines or other services; one noted that “the only cost is the cost of transportation”.

The ARVs provided in Russia are approved by the Ministry of Health and Social Development (MoH) through a special decree that covers both HIV drugs and those used to treat hepatitis C and B, as well as diagnostics. As a rule, the drugs provided must also be included in the List of Essential Medicines revised by the MoH on an annual basis.

New national HIV treatment guidelines were implemented at the end of 2011, and they generally conform to updated WHO guidelines released in 2010. One concern is that the new guidelines themselves are not presented as mandatory but as “recommendations”. This is perceived as a disadvantage in Russia because patients therefore may find it difficult if not impossible to use the guidelines as a basis for filing complaints if their rights to treatment are violated.

Also of note is that there are some discrepancies between the new guidelines and current clinical practice. The main one is the absence of tenofovir (TDF) in the List of Essential Medicines—which means it is not procured and used as part of ART—although TDF is included in the new guidelines as one of the recommended drugs for a first-line regimen. CBO representatives interviewed said the most commonly prescribed treatment regimens are AZT+3TC+EFV; ABC+3TC+EFV; and AZT+3TC+LPV/r. Their observations were confirmed by subsequent monitoring of federal ARV procurement carried out by community groups.²³⁹ Most of the ARVs currently provided as part of these regimens and all other regimens are originator-brand versions, not generic ones. As a result, as noted in Section 2.3, ART costs in Russia are higher than in some other countries with comparable per capita incomes and fairly large HIV epidemics (e.g., Brazil).

According to the interviewees and focus group participants, transportation costs and inconveniently lengthy distance from AIDS centres are not major concerns—although some said it could take them up to two hours to get to an AIDS centre. Most respondents were more concerned about limited access to treatment for certain most-at-risk populations, including prisoners, migrants and IDUs. Barriers cited for prisoners’ access included the following: lack of qualified medical staff in prisons; lack of monitoring tests (CD4, viral load, etc.); and stock-outs. The main challenges for migrants, both from within Russia and abroad, is the difficulty in being accepted as patients at local AIDS centres when not officially registered as a resident of the municipality or region. Key obstacles for IDUs include stigma among

238 Articles about stock-outs of CD4 and viral load tests have been published in several Russian newspapers, including *Novaya Gazeta* and *Kommersant*. See for example: www.kommersant.ru/doc-y/1760557.

239 “To treat or not to treat”. Report on government procurement and provision of ARV based on community research. Available online at: http://itpcru.org/netcat_files/10/196/To_treat_or_not_to_treat_0.pdf.

healthcare workers; the absence of harm reduction and opioid substitution treatment services; punitive drug-use policies and laws; and stereotypes that they cannot be adherent to ART regimens.

Access to treatment for major co-infections, namely tuberculosis (TB) and hepatitis C, is far more limited across Russia. Standard of care treatment (ribavirin+pegylated interferon) for hepatitis C is rarely provided at public-sector facilities due to its high cost. Patients can obtain standard of care treatment by paying the full cost at pharmacies, but few can afford the \$15,000 or even more needed to cover a course of treatment. (One exception should be noted: treatment for both HIV and hepatitis C is provided free of charge to patients co-infected with both viruses on a preferable basis at AIDS centres and infectious-disease clinics. Access nevertheless remains highly restricted. Results from recent monitoring of the hepatitis C treatment government procurement show that fewer than 4,000 people can be covered by the national hepatitis C treatment programme each year.)

The problems regarding TB treatment are more about execution than cost. The country's health policy stipulates the provision of TB treatment free of charge because TB is considered a "socially significant disease". In practice, though, regular stock-outs and the high cost of the second-line medications limit availability. The most recent stock-out was of drugs used to treat multi-drug resistant TB (MDR-TB), which is a growing problem in Russia.

The current Russian drug-procurement system relies on open electronic auctions and various calculations and estimates as to need for the upcoming year. The system has often worked poorly. In 2010, delays in auctions and improper calculations of ARVs required and patients in need of treatment caused numerous stock-outs of ARVs; a similar situation occurred in 2011 with respect to viral load and CD4 tests. MoH officials have consistently denied that these stock-outs happened, but they were confirmed by healthcare officials interviewed for this research. In acknowledging the problems, one added, "We would prefer [the process] to be more systematic, and the instruments inside to be more developed and functional."

2.3 Reduce costs

As noted in Section 2.2, ARVs in Russia are purchased centrally by the government and provided free of charge to PLHIV—and thus the cost of the medicines is not a direct concern of patients in need. The government's current level of funding for the HIV response, including treatment, is generally adequate. However, there are concerns that it may not be sufficient in the future given the high cost of ARVs and the ever-rising epidemic, which in turn means sharply escalating numbers of people in need of treatment in the country.

A major component of the high cost of treatment, as referenced in Section 2.2, is the fact that the Russian ARV market is dominated by originator-brand producers. The government can use the auction system to attempt to bring down the prices of both branded and generic medicines, but such efforts have not proved to be particularly successful. For example, the overall level of price reduction as a result of the auction was only 1.45 percent in 2010 and 1.52 percent in 2011,²⁴⁰ a fact that raises significant doubts about the effectiveness of the auction procedure and the government's efforts in the field of price reductions.

Patents for most first- and second-line drugs have not yet expired in Russia; therefore, despite the emergence of generic producers in the country, the opportunities for introducing lower-cost generic drugs remain limited. In 2011, the MoH centrally purchased generic versions of four drugs: AZT (100

240 "To treat or not to treat". Report on government procurement and provision of ARV based on community research. Available online at: http://itpcru.org/netcat_files/10/196/To_treat_or_not_to_treat_0.pdf.

mg and 300 mg), d4T (30 mg and 40 mg), NVP (200 mg) and ritonavir. Listed below are costs per patient per year of commonly prescribed ARVs in Russia as per data from 2011. Each cost is followed by a figure indicating the lowest cost generic version sold elsewhere, according to data from Médecins Sans Frontières (MSF) updated in July 2012.²⁴¹ Of note is the fact that even the price for generic ritonavir in Russia is considerably higher than the lowest generic price for ritonavir in the world:

- 3TC+AZT: \$1,356 per patient per year in Russia (generic version elsewhere, according to MSF: \$95²⁴²)
- LPV/r: \$2,578 (generic version elsewhere, according to MSF: \$371²⁴³)
- EFV: \$308 (generic version elsewhere, according to MSF: \$44²⁴⁴)
- Ritonavir: \$669 (generic version elsewhere, according to MSF: \$83²⁴⁵)

Russia's August 2012 accession to the World Trade Organization (WTO) will likely have an impact on access to more affordable generics and the future costs of ART. As part of its accession, Russia must bring its national laws into compliance with WTO standards. Among the most notable in regards to medicines is the WTO's Agreement on Trade-Related Intellectual Property Rights (TRIPS), which covers issues regarding intellectual property. Many of the legal changes required under TRIPS strengthen patents and thereby often restrict countries' ability to manufacture or purchase generic drugs. Among them is a requirement that WTO members prohibit third parties from using the data of pre-clinical and clinical trials of medicines submitted by the applicant for the registration of the medicine without the applicant's consent for six years after the registration. At the time research for this report was conducted, it was anticipated that this "data exclusivity" rule could become effective as early as September 2012 in Russia. If and when that rule is written into law, it could significantly inhibit efforts to bring more affordable generic medicines to the market.

Amendments to the TRIPS agreement included several "flexibilities" that signatories can use to ensure access to essential products such as HIV drugs without issuing patents. However, it is not yet clear if, or how, TRIPS flexibilities will be used by the Russian government to ensure possibilities for generic competition. The lack of clarity in this regard is relevant not only for HIV medicines, but for those used to treat TB, hepatitis C and other conditions.

2.4 Adapt service delivery

Some degree of integration of HIV care and services with other healthcare services has occurred. Focus group participants noted that many AIDS centres and infectious-disease clinics also offer consultations by gynaecologists and psychologists as well as access to specialists for sexually transmitted infections (STIs) and skin care. In certain centres and clinics, treatment of opportunistic infections and hepatitis C is also available.

Also, there are infectious-disease specialists in ordinary outpatient clinics who can provide services for HIV-positive patients. However, many focus group participants said they were reluctant to visit these

241 The data below are based on findings from a government procurement monitoring project carried out by ITPCru in 2012. The figures are taken from the publically available tender documentation at the official website: <http://zakupki.gov.ru>.

242 As cited at <http://utw.msfacecess.org/drugs/4fe29eb2850dfc2ba8000023>.

243 As cited at <http://utw.msfacecess.org/drugs/4fe29e91850dfc2ba8000019>.

244 As cited at <http://utw.msfacecess.org/drugs/4fe29e6f850dfc2ba800000f>.

245 As cited at <http://utw.msfacecess.org/drugs/4fe29e61850dfc2ba8000009>.

outpatient clinics. Among the disincentives cited were long queues, fear of HIV status disclosure and the fact infectious-disease specialists do not prescribe ART.²⁴⁶ (As asked rhetorically by an HIV-positive woman in a focus group on 3 April 2012, “So why go two times to two different places?”).

Since TB remains the major cause of death among HIV-positive patients, integration of HIV and TB services is of particular significance for an effective HIV response. There are specialized departments for HIV/TB co-infected patients in certain clinics. Some AIDS centres offer TB screening services; however, the level of integration generally is far from ideal, and there is no established system for bringing together HIV and TB services. A study carried out in 2011-2012 among patients receiving ART revealed that less than half of respondents were tested for TB before initiation of HIV treatment.²⁴⁷ Lack of integration and follow-through is a particular problem for patients with triple diagnosis of HIV/TB/drug use. One healthcare worker observed to researchers that many patients fall out of or are forced to leave TB treatment programmes because of poor adherence and “regimen violation” in TB clinics.²⁴⁸

Effective service delivery is also hampered by limitations associated with current HIV prevention policy. Both healthcare officials interviewed for this research agreed that the budget for prevention is far too small and thus cannot meet the country’s needs. Also of note is that current prevention efforts are not oriented towards vulnerable groups who pose the greatest risk for HIV infection. For instance, in 2011 only 17 percent of the total budget for prevention efforts was allocated for activities involving most-at-risk populations such as IDUs, MSM and sex workers. Current government prevention efforts instead focus on promoting a “healthy” way of life, which is a rather vague way to address the huge threat of HIV. In general, the poor quality of prevention efforts represents a major failure to improve the overall HIV response by more effectively halting the spread of the epidemic.

Hostility toward drug users is a main reason harm reduction strategies are still neither financed nor even supported in principle by the government. Condoms, according to several surveys, remain largely unavailable for most groups, especially most-at-risk populations. Russia clearly needs a well-funded long-term prevention programme taking into account the specific characteristics of its current epidemic. In the absence of such a change, comprehensive and effective HIV service delivery will be impossible to achieve.

2.5 Mobilize communities

CBOs in Russia play a vital role in the broader HIV response. Among the services provided by civil society groups are pre- and post-test counselling, counselling on STI and reproductive health, TB-related services, counselling at clinics and at home, emotional and psychological support, case management services and peer advocacy activities. Many NGOs are also active in terms of advocacy and lobbying; among the three CBOs interviewed (through their representatives), two said they undertook advocacy work. Other activities mentioned by respondents included mutual aid groups; distribution of condoms; hotline counselling; maintaining ARV emergency reserves; employment support; services in prisons; and work with organizations servicing lesbian, gay and transgender communities.

246 It should be noted that the situation is starting to improve in regards to those challenges, according to some interviewees. Yet it is not clear the extent to which such improvements are occurring.

247 The findings are from the Simona+ Project and were presented at the meeting “Role of the community in ensuring universal and uninterrupted access to HIV treatment in the Russian Federation”. The meeting was held in St. Petersburg from 23-25 May 2012.

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Yet although many organizations (including all of respondents) are in some way engaged in activities aimed at increasing access to HIV treatment for their clients, none dispense ART. That is because they are not allowed to do so under existing laws. The only way NGOs are currently engaged in the distribution of ARVs is unofficially, by providing medicines to those in need because of stock-outs or who have run out of medicines due to other reasons. These ARVs are donated by other patients who have extra pills.

The possibility of expanded community involvement was perceived positively by both healthcare officials interviewed for this research. Among the opportunities they and other respondents noted were the following: participation in prevention programmes (very important, especially in regards to IDUs in particular, and with marginalized groups in general); work and support in public-sector outpatient clinics; support for patients in terms of adherence; advocacy on behalf of PLHIV; and monitoring and evaluation of government programmes. One respondent suggested establishing “patient advisory boards” in AIDS centres and infectious-disease clinics. (Note: Several NGOs in Russia already offer some or all of these services. Participants in this research project said, however, that the sector should be more involved in providing them in general.)

All participants agreed that greater community involvement and engagement is critical to improve the HIV response in Russia. Several noted, though, that community mobilization continues to be hindered by suspicion on the part of government institutions and a general decrease in the level of funding for NGOs.

3. KEY CHALLENGES

This section summarizes some of the main challenges identified during research to an enhanced and expanded HIV response in Russia. Improvements in such areas are considered critical for the effective adoption and implementation of the Treatment 2.0 framework in the future.

Absence of an integrated strategic approach to HIV treatment, prevention and care

Russia still lacks a national strategy for counteracting HIV; the strategy developed by the MoH several years ago was severely criticized by the community and was never implemented.²⁴⁹ An effective strategy would include i) mandatory HIV treatment guidelines; ii) a unified database of HIV-positive patients; iii) a clear strategy for optimizing quality and costs of treatment, as well as creating opportunities for introducing quality generic drugs; iv) a robust HIV prevention programme based on the real risks and needs; and v) a programme for improving treatment adherence among patients.

Insufficient and inadequate efforts are undertaken by the government to work with most-at-risk populations, especially migrants, prisoners and IDUs

Studies in several countries with concentrated epidemics have proven the effectiveness of targeting most-at-risk populations,²⁵⁰ especially IDUs, in terms of improving their access to treatment and prevention. Yet members of those groups have been and continue to be disproportionately ignored and discriminated against in Russia.

For instance, the percentage of IDUs among those tested for HIV was only 1.1 percent in 2010,²⁵¹ despite the fact that injecting drug use remains the main HIV transmission vector in the country. In 2011, just 17 percent (85.6 million roubles, or \$2.6 million) of the total prevention budget was allocated

249 For more information see http://esvero.ru/z_news_2012_04_02.shtml (in Russian only).

250 Long EF, et al (2006). “Effectiveness and cost-effectiveness of strategies to expand antiretroviral therapy in St. Petersburg, Russia”. *AIDS*, 2006 Nov 14;20(17):2207-15.

251 *Integrated Prevention and Treatment Programme for Socially Significant Diseases Among IDUs*, Moscow 2011. See <http://esvero.ru/files/Concept.pdf> (in Russian only).

to healthcare institutions to focus on vulnerable groups. Not only was the project underfunded, but it was severely criticized by experts both from the community and from governmental institutions for lacking transparency and useful impact.

Migrants encounter problems with receiving treatment because most do not have residence permits. Penal institutions, meanwhile, are under the jurisdiction of the Ministry of Justice—and due to their closed nature it is almost impossible to monitor availability of treatment. Several cases have been reported in the media of HIV-positive inmates dying due to lack of treatment.

Overall, a clear strategy for working with vulnerable groups is needed from the government, including screening and prevention efforts, equal access to treatment, and programmes for improving adherence. Failure to implement such changes will make it almost impossible to effectively respond to the surging epidemic and integrate the Treatment 2.0 agenda. Some glimmers of hope for radical change have been seen. In a report about the Russian HIV epidemic prepared in 2011, the Federal AIDS Centre stated that the primary objective of the HIV response is to “ensure effective work in the field of HIV prevention, especially among women, young people and vulnerable groups.”²⁵² It is not yet clear whether action will follow these words.

Limited integration of HIV services with services related to the main co-infections, especially TB

Although TB remains the main cause of death among PLHIV, TB-associated services are not provided to patients with HIV in the full scope and quality needed. Based on data from 2011, nearly half (43 percent) of HIV-positive patients registered in AIDS centres were not tested for TB. Among those who have undergone in-patient treatment, only 81 percent were tested for TB.²⁵³ The high cost and lack of medicines to treat MDR-TB and lack of drug treatment services limit access to comprehensive services for drug-dependent patients co-infected with HIV and TB. Treatment for hepatitis C—another common co-infection, especially among HIV-positive IDUs—is also available only for a limited number of patients. Moreover, there are no officially approved guidelines for treating HIV/TB and HIV/hepatitis C co-infection.

Lack of community involvement in the HIV response on a national level

The most common current methods of involving the community in the national HIV response programmes include i) consultations with NGOs organized by the relevant ministries, such as the MoH and Rospotrebnadzor (the Russian Federal Consumer Rights Protection and Human Health Control Service); ii) inclusion of NGO representatives on various commissions at the national and regional level; and iii) participation of NGO representatives in relevant hearings of the Public Chamber, an institution that monitors the activities of the federal government and parliament (Duma) and is responsible for facilitating dialogue between the state authorities and Russian citizens. However, the effectiveness of all these mechanisms seems to be relatively low, as the concerns raised by community organizations are rarely taken seriously or responded to quickly or effectively (if at all) by government officials. Examples of such concerns that have been addressed unsatisfactorily include stock-outs of medicines and test kits; the absence of mandatory treatment protocols; and the failure to include a critical ARV, TDF, on the List of Essential Medicines.

Moreover, the community involvement mechanisms themselves lack transparency. Consultations with the MoH, for instance, are announced rarely or at the last minute—e.g., just one or two days before the date of the consultations—thus making it virtually impossible for representatives from remote regions to

252 As cited at www.hivrussia.ru/files/stat/2011/spravka1.docx.

253 Presentation of Gennady Onishchenko, head of Rospotrebnadzor (the Russian Federal Consumer Rights Protection and Human Health Control Service), at its annual conference in Suzdal in 2011.

reach Moscow in time. The overall lack of respect for the critical input of the community sector, especially among government officials, represents a lost opportunity to enhance and improve the HIV response with minimal financial or programmatic effort. Community members' experience and in-depth knowledge of the issues related to HIV epidemic in Russia deserve to be integrated into the official HIV response programme in a much more effective and transparent way.

4. RECOMMENDATIONS

The following recommendations aim to help Russia move closer to being able and willing to develop and implement programmes and policies to promote the Treatment 2.0 agenda in the future. The bulk are geared toward the government, which is the most powerful and important stakeholder in Russia in terms of the HIV response. **The MoH should prioritize the following**, in collaboration (where relevant) with other agencies including Rospotrebnadzor and the Federal Penal Service:

- Develop and ensure mechanisms for the implementation of a **long-term national strategy for counteracting HIV epidemic** based on best international practices.
- Undertake a range of **measures aimed at improving access to treatment**, including the following:
 - officially adopt mandatory treatment guidelines in compliance with updated WHO protocols and ensure mechanisms for their implementation by medical service providers;
 - develop and implement a confidential database of HIV-positive patients, which would be used for effective planning to procure and dispense the required volume of ARVs;
 - update the List of Essential Medicines and ensure mechanisms for including new drugs with duly proven efficacy and safety as quickly as possible, and then work to hasten their registration in Russia; and
 - reform and improve drug procurement processes to eliminate the risk of stock-outs of medicines and diagnostics.
- Carry out systematic work aimed at **reducing prices for ARVs and test kits**, including the development of in-country manufacturing of ARV drugs and providing mechanisms for generic companies to enter the market on the condition that quality standards are duly met. Such efforts will also require working with trade officials to utilize all legal options such as TRIPS flexibilities in order to lower the cost of drug procurement.
- Develop an **appropriate HIV prevention programme** based on the evidence-based experience. This programme should include indicators allowing for easy monitoring of its effectiveness, and particular focus should be placed on reached most-at-risk populations.
- Ensure more transparent, effective and meaningful **involvement of the civil society sector** in the national HIV response.

Recommendations for the patient community and civil society groups:

- Conduct targeted advocacy aimed at prompting the MoH to update HIV treatment guidelines and create a comprehensive database of HIV-positive patients. Community groups should seek opportunities to work with the MoH to achieve these goals and then monitor their implementation.

- Work with local and regional authorities to promote integration of services for IDUs, and people living with HIV, TB and viral hepatitis
- At the national level, advocate for harm reduction strategies as an HIV prevention tool from a health and human rights perspective
- Identify coordinated and effective ways to exert pressure on pharmaceutical companies to reduce prices for HIV, TB and hepatitis C medications. Similar efforts should be undertaken to hasten the registration of new drugs, an effort that will also require targeting relevant government agencies
- Through more comprehensive education efforts, seek to reduce stigma and discrimination related to HIV and drug use. Another priority should be to confront and expose the claims of AIDS “denialists”.



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