# **POLICY**FORUM

## PUBLIC HEALTH

# Getting HIV Treatment to the Most People

Sharonann Lynch,<sup>1</sup> Nathan Ford,<sup>2</sup> Gilles van Cutsem,<sup>3</sup> Helen Bygrave,<sup>4</sup> Bart Janssens,<sup>5</sup> Tom Decroo,<sup>6</sup> Isabelle Andrieux-Meyer,<sup>7</sup> Teri Roberts,<sup>7</sup> Suna Balkan,<sup>8</sup> Esther Casas,<sup>9</sup> Cecilia Ferreyra,<sup>10</sup> Marielle Bemelmans,<sup>5</sup> Jen Cohn,<sup>11</sup> Patricia Kahn,<sup>12\*</sup> Eric Goemaere<sup>4</sup>

he new understanding that antiretroviral therapy (ART) can significantly reduce HIV transmission (1) has stimulated scientific and political leaders to claim that ending the AIDS epidemic is now a realistic goal. At the same time and despite last year's major international political commitments to put 15 million people on treatment by 2015 (2), large funding gaps threaten the gains already made and limit the potential to capitalize on the latest scientific progress. Underresourced clinics are managing ever-increasing numbers of people on treatment, even though there is attrition all along the care continuum, from testing to treatment initiation and long-term retention in care (3).

Doctors Without Borders or Médecins Sans Frontières (MSF) began offering ART in developing countries in 2000 and now supports some of the longest-running treatment cohorts; today, we support more than 220,000 people on ART in 23 countries, mainly in Africa. This article draws from our operational experience, which in turn draws partly on evidence from other providers, to present a perspective on the innovations required to deliver affordable, quality care for more people. We also compare this perspective with current realities on the ground, as assessed through a survey on HIV policies and practices, carried out in May to June 2012 by MSF teams in 16 countries where we work (see the table). Survey methodology and findings are presented online as Supplementary Materials (see table S1).

### Models of care

Distance from clinics, patient fees, transportation costs, long clinic wait times, and competing demands (such as work schedules and child care) are all associated with attrition and poor adherence to treatment (4). Programs have responded by decentralizing free ART services to local health centers, with demonstrable improvements in retention (5). For example, in rural Lesotho, 2-year outcomes of patients receiving free ART at the primary-care level showed higher retention rates than outcomes from other programs (6). Decentralization also implies placing man-

agement of ART principally in the hands of nurses and other nonphysician providers, a strategy found in randomized trials to be safe and effective (7).

Our survey shows some encouraging signs of progress on decentralization: ART is now available at more than 40% of public sector facilities in 4 countries (and >20% of facilities in 8), and 10 countries allow nurses to initiate ART. Thirteen out of 16 countries surveyed allow lay counselors to provide ART adherence counseling. However, four countries with an HIV prevalence above 1% are still below 25% facility coverage, and six countries do not allow nurses to initiate ART-restrictions that impede decentralization and integration with primary, tuberculosis (TB), and prenatal care. Mozambique is the only country with an HIV prevalence >5%that does not allow nurses to initiate ART or follow up ART patients. Shortages of nurses and lack of support for lay health workers at the primary-care level have also limited some countries' efforts to decentralize ART. Moreover, policy and practice sometimes diverge. For example, nurses and midwives can prescribe in Guinea, but only under a doctor's supervision-which reduces the impact of the task-shifting policy. In Malawi, shifts to first-line regimens with fewer side effects and to viral load monitoring for all patients on ART are included in the guidelines, but

Delivering HIV care effectively and ensuring long-term retention of patients requires innovative strategies and tools—and policies that enable their widespread use.



A community ARV group meeting (Tete, Mozambique).

full rollout has been deferred due to funding shortfalls. Uganda and Zimbabwe regularly provide up to 2 months of refills, although this is not written policy.

Looking ahead, care providers and policymakers increasingly recognize the need to move HIV/AIDS care out of the clinic entirely, i.e., to manage patients in their communities. Over the past few years, MSF and others working in a range of high HIV-burden settings have piloted community-based programs with varying degrees of peer- and selfmanagement. One successful example is the community ART groups established in rural Mozambique, where six patients per group take turns traveling to the clinic each month to receive their 6-monthly medical check-up and to pick up antiretroviral (ARV) medicines for themselves and group members. Implemented at 20 health facilities in Tete province, 1384 people formed 291 groups between February 2008 and May 2010; to date, only 0.2% of these patients have been lost to follow-up (compared with a regional average of 15% at 2 years) (8). On the basis of this success, in July 2011, Mozambique's Ministry of Health announced plans to roll out community ART groups across the country. Over the last 6 months, delegations from the ministries of health of Malawi, South Africa, Swaziland, and Zimbabwe have visited this program to assess its feasibility and

<sup>&</sup>lt;sup>1</sup>Médecins Sans Frontières (MSF) Access Campaign, New York, NY 10001, USA. <sup>2</sup>MSF, London EC1N 8QX, UK. <sup>3</sup>MSF, South Africa and Lesotho, Capetown, 7700 South Africa. <sup>4</sup>MSF, South Africa Medical Unit, Johannesburg, 2017 South Africa. <sup>5</sup>MSF, 1090 Brussels, Belgium. <sup>6</sup>MSF, Tete, Mozambique. <sup>7</sup>MSF Access Campaign, 1211 Geneva 21, Switzerland. <sup>8</sup>MSF, 75011 Paris, France. <sup>9</sup>MSF, 108 DD Amsterdam, Netherlands <sup>10</sup>MSF, 08001 Barcelona, Spain. <sup>11</sup>MSF Access Campaign, Nairobi, 00200 Kenya. <sup>12</sup>MSF, New York, NY 10001, USA.

<sup>\*</sup>Author for corrrespondence. E-mail: patricia.kahn@ newyork.msf.org

appropriateness for their own countries, and Malawi has now launched a pilot program.

Other decentralized approaches aim to relieve the burden on patients and health-care systems by providing multiple-month routine ARV refills and simplified clinic appointments. For example, patients in Zimbabwe who were given 3-month refills per visit had outcomes comparable to those receiving their pills monthly (9). However, policies in several countries limit implementation of these strategies: Only 7 of 16 countries surveyed allow multiple-month ARV refills for stable patients. A further impediment to implementation is inadequate drug supplies—when stocks (and/or funds) are low, clinics sometimes dispense as little as weekly refills (10).

Highly mobile populations require further adaptations in treatment delivery (11). In one example, MSF found that cross-border seasonal migrant farm workers in South Africa's Musina district (on the border with Zimbabwe) treated at a mobile HIV/TB clinic were more likely to start and continue ART than they were before the mobile service began. An initial screening had found lower ART coverage among farm workers than among their Zimbabwean or South African national counterparts, reflecting the former group's fear of discovery (of their undocumented status), and sometimes because clinics denied them treatment out of concern over adherence and continuity of care. To address this, in 2011, MSF and the Limpopo Department of Health launched a mobile HIV/TB service providing weekly visits to six farms (population 7500). Patients planning on returning temporarily to Zimbabwe receive a 3-month ART supply plus "tail protection" (1 week supply of two ARVs, to prevent development of resistance to nevirapine or efavirenz—longer half-life drugs in first-line ARV regimens—in case of a forced treatment disruption) and a transfer letter to another ART clinic. All patients carry a health "passport" containing records of their treatments, medications, and laboratory results (12). Given the prevalence of migration in Southern Africa, this model (or adaptations of it) could potentially benefit many regional ART programs.

#### Better tools

Viral load monitoring is an essential tool used routinely in Western countries but rarely available in low-resource settings. Regular monitoring enables care providers to distinguish patients who are poorly adherent to treatment from those who have developed drug resistance and need to switch regimens (13). Without it, patients failing treatment are

HIV POLICY AND PROGRESS INDICATORS ACROSS 16 COUNTRIES									
Parameter	Cameroon	CAR	DRC	Ethiopia	Guinea	India	Kenya	Lesotho	Malawi
Population (millions)	20.10	5.10	73.6	93.8	10.9	1210.2	43	1.9	16.3
HIV adult prevalence rate§	4.30	4.9†	2.6	1.5	1.5	0.3*	6.2	23*	10.6†
Service coverage and availability									
Percentage of people in need receiving ART	49.6	26.1	12.3	86*	56.9	33.8‡	72.1‡	61	57.70
Number (and %) of public sector facilities offering ART	108 (4.4)	76	222	743	41 (9)	1297 (3)	1242 (34.8	3) 197 (94)†	487 (80.4)
Viral load testing¶									
For confirmation of treatment failure	OPT	OPT	OPT	No	OPT	REQ	OPT	OPT	REQ
For routine monitoring of people on ART	OPT	No	No	No	No	No	No	No	No
Available	LTD	LTD	LTD	LTD	LTD	LTD	Yes	LTD	LTD
Task shifting and treatment simplication									
Nurses can initiate ART	NF	Yes	No	Yes	Yes	No	Yes	Yes	Yes
Lay workers-testing and ART adherence counseling	ART	ART	Yes	No	HIV	Yes	Yes	Yes	Yes
Routine refills at 2–3 months	No	No	No	2	No	2	2–3	No	2–3
	Mozambique	e Mya	anmar	South Africa	a Swazi	iland L	Jganda	Zambia	Zimbabwe
Population (millions)	23.5	5	4.6	48.8	1.	4	35.9	14.3	12.6
HIV adult prevalence rates	11.5*		0.5	16.6	26	‡	6.7	14.6*	13.1
Service coverage and availability									
Percentage of people in need receiving ART	45.5	33.4		52	80		54.3	77.6	79.7
Number (and %) of public sector facilities offering ART	261 (22)	100	(3.4)	2552 (68)	110 (	(42)	1424	1784 (25.4)†	590 (36)
Viral load testing¶									
For confirmation of treatment failure	OPT	OPT		REQ	01	OPT		OPT	OPT
For routine monitoring of people on ART	REQ	No		REQ	Ν	0	OPT	OPT	No
Available	No		LTD	Yes	LT	D	LTD	LTD	LTD
Task shifting and treatment simplication									
Nurses can initiate ART	No		No	Yes	Ye	25	NF	Yes	Yes
Lay workers-testing and ART adherence counseling	HIV		No	Yes	Ye	25	Yes	Yes	Yes
Routine refills at 2–3 months	No		No	3	3	3	No	3	No

**HIV Policy and Progress Indicators Across 16 Countries.** Further information and references for all data are in Supplementary Materials. HIV program and policy data are from 2011 except where indicated (\*2009; †2010, ‡2012). Population figures are as of 1 January 2012, except for India, which is from the end of 2011. There are some caveats to the data on percentage of people in need and receiving ART: In Ethiopia, need is based on CD4 <200; in India, the coverage figure is based on the number of people registered to be in need of ART; ART facilities

in Malawi include some Christian Health Association (part MOH-supported) sites, and Uganda figures include both MOH and non-MOH sites. §Age 15–49 years. ¶Included in national plan and available. OPT: Viral load testing for this purpose is recommended, but optional in the national protocol. REQ: Viral load testing for this purpose is required in the national protocol. LTD: Limited. NF: Nurses provide follow-up to patients but are not allowed to initiate ART. HIV: HIV testing administration and counseling only. ART: ART adherence counseling only. often underdetected and undertreated (14). Besides compromising individual care, treatment failure diminishes the community benefit of ART through both increased morbidity and the transmission of drug-sensitive and drug-resistant strains (15).

A study comparing outcomes of ART patients in South Africa, where routine viral load monitoring is available, to those in Malawi and Zambia, where it is not, found significant differences: In South Africa more people were appropriately switched to second-line therapies (9.8 versus 2.1%), and fewer people died (4.3 versus 6.3%) or were lost to care (9.2 versus 15.3%) (16). Another study in South Africa found that over twothirds of patients with detectable viral load reverted to undetectable levels after enhanced adherence support (17). However, not all studies have shown benefit (18), and although most care providers would agree that viral load monitoring is desirable, considerable debate remains about its feasibility given the limitations of current tools.

Recent studies found viral load monitoring to be a cost-effective strategy compared with current (clinical and CD4 cell count) monitoring. Further cost reductions can be expected as the volume of viral load testing increases (19).

Despite being recommended for a decade (20), few programs in Africa have access to routine viral load testing. Of the 16 countries surveyed, only South Africa routinely monitors viral load, and although 15 of the 16 surveyed countries recommend viral load testing for confirmation of treatment failure, in practice it is not widely available.

Until recently, access has been limited by the lack of simple, affordable viral load monitoring technologies. However, the landscape is changing: New tests appropriate to district-level laboratories, plus several point-of-care tests, will become available in 2013 (21). Sufficient funds for implementation will be essential to ensure that the best products reach the market and that multiple manufacturers are encouraged to enter the market, to create much-needed price competition. At the same time, cost-reducing strategies such as pooled viral load testing and less frequent testing of stable patients should be further explored (22). Expanded access to viral load monitoring-which provides an early warning tool and a safety net for patients-could, at the community level, facilitate greater program simplification and decentralization and help shift routine follow-up to nonmedical staff outside health facilities.

Evidence from these and other settings

suggests that increased task shifting, treatment simplification, and viral load testing will support further scale-up, improved adherence to treatment, and improved detection of treatment failure.

#### **Better policies**

Even with the most innovative strategies and tools, confronting and reversing the HIV epidemic will fail without sufficient increases in funding and decreases in drug prices. Given all the promising science and progress, this year is an opportune time for countries (particularly donors to the Global Fund) to announce increases to next year's HIV/AIDS funding. Otherwise, opportunities to implement improved policies and strategies and to reach more people will be further delayed, as will the chance to help countries struggling most, such as those in our survey where ART reaches one-third or less of those who need it (Central African Republic, Democratic Republic of Congo, India, and Myanmar).

Although efficiencies can be made in the system, more funding in the short term is needed to achieve longer-term cost savings (23). Efforts to reduce cost by adapting services should take into consideration the longer-term benefits of providing an optimized package of care, including viral load testing and accelerated access to treatment. For example, introducing viral load monitoring increases the cost of ART per person per year but is likely to save money down the road by preserving first-line (less expensive) treatment longer and by detecting and treating drug-resistant HIV strains earlier. As costing models demonstrate, scaling up faster now makes financial sense over the long term (24).

Options for making high-priced patented medicines affordable include negotiating voluntary licenses (25) or issuing a "compulsory license" to override a patent. Compulsory licenses for HIV drugs issued by Brazil and Thailand set an important precedent for access to medicines that have been priced out of reach. Countries should be encouraged to exercise this right more regularly.

At a time when donors are calling for greater efficiencies in the global AIDS response, bilateral trade agreements are being pursued that, paradoxically, seek to increase intellectual property protection and further threaten access to affordable medicines. Examples include the EU-India Free Trade Agreement and the Trans-Pacific Partnership Agreement, with the United States seeking unprecedented levels of intellectual property protection with 10 Pacific Rim nations. ingly difficult funding environment, present hurdles that must be overcome to reach the 7.6 million more people who still need treatment, to retain people in long-term care, and to move toward policies of treating earlier. Although some countries are making progress by moving HIV care closer to where people live and delivering it in ways that better fit into patients' lives, most national programs require a quantum leap forward to build community-based platforms for HIV testing and ARV delivery.

#### **References and Notes**

- 1. M. S. Cohen et al., N. Engl. J. Med. 365, 493 (2011).
- United to end AIDS: Achieving the targets of the 2011 Political Declaration: Report of the Secretary-General, United Nations General Assembly 66th Session, 2 April 2012.
- 3. S. Rosen, M. P. Fox, PLoS Med. 8, e1001056 (2011).
- 4. E. J. Mills et al., PLoS Med. 3, e438 (2006).
- 5. G. Fatti, A. Grimwood, P. Bock, *PLoS ONE* **5**, e12888 (2010).
- 6. R. Cohen et al., J. Int. AIDS Soc. 12, 23 (2009).
- 7. I. Sanne et al., Lancet **376**, 33 (2010).
- 8. T. Decroo *et al., J. Acquir. Immune Defic. Syndr.* **56**, e39 (2011).
- 9. K. Kuwenyi *et al.*, Sixth IAS Conference on HIV Pathogenesis and Treatment, abstr. no. MOPE429.
- MSF, No time to quit: HIV/AIDS treatment gap widening in Africa (May 2010; www.doctorswithoutborders.org/ publications/reports/2010/MSF-No-Time-to-Quit-HIV-AIDS.pdf).
- 11. H. Bygrave et al., PLoS ONE 5, e13198 (2010).
- T. Matambo *et al.*, presented at MSF-UK Scientific Day, 25 May 2012; http://presenter.qbrick. com/?pguid=c37366ab-d37e-4b07-a39ab0568f16c075.
- 13. K. C. Sigaloff et al., J. Acquir. Immune Defic. Syndr. 58, 23 (2011).
- World Health Organization and Joint UN Programme on HIV/AIDS (UNAIDS), Joint WHO/UNAIDS Annual Consultation with Pharmaceutical Companies: Global Forecasts of Antiretroviral Demand 2012–2013. (WHO, Geneva, 2011), pp. 1–23.
- 15. R. L. Hamers et al., Lancet Infect. Dis. 11, 750 (2011).
- 16. O. Keiser et al., AIDS 25, 1761 (2011).
- 17. A. Calmy et al., Clin. Infect. Dis. 44, 128 (2007).
- 18. P. Mugyenyi et al., Lancet 375, 123 (2010).
- 19. R. L. Hamers et al., AIDS 1 (2012).
- WHO, Scaling up antiretroviral therapy in resourcelimited settings: Guidelines for a public health approach (WHIO, Geneva, 2003).
- 21. M. M. Murtagh, HIV/AIDS diagnostic landscape. UNITAID Tech. Rep. May 2012.
- 22. G. U. van Zyl et al., Clin. Infect. Dis. 52, 264 (2011).
- 23. B. Schwartländer et al., Lancet 377, 2031 (2011).
- 24. B. Ventelou et al., PLoS ONE 7, e34101 (2012).
- 25. J. Bermudez, E. 't Hoen, Open AIDS J. 4, 37 (2010).

Acknowledgments: Our deep thanks go to the MSF staff, field teams, and Access Campaign staff for their work in gathering the national policy data presented here; the Joint United Nations Programme on AIDS (UNAIDS) for input into the survey design and support for the survey; D. Holtzman, K. Kalaris, and M. French for help with compiling and fact-checking these data; K. P. Q. Phelan and S. Shettle for their help with manuscript preparation; W. Owen for graphics work; and J. MacAllister for work on the survey table. We especially thank the mission staffs and our community counterparts who have contributed to MSF's fight against HIV over the years.

#### **Supplementary Materials**

www.sciencemag.org/cgi/content/full/1225702/DC1

Such obstacles, combined with an increas-