Deadly Rationing: G8/G20 Leaders Must Continue to Fund AIDS Response
Dignitas International's Experience with Drug Stockouts

DIGNITAS INTERNATIONAL: BRIEFING DOCUMENT, G8/G20 SUMMITS 2010

Take Action:
Governments must keep their commitments to fund the global AIDS response and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). We must leverage the gains being made in resource-limited countries and not undermine advances that have taken 23 years[1] and over $10 billion to achieve.[2] It is inhumane to reduce or withdraw HIV/AIDS funding when four million people are on treatment, and at least 9.5 million are still in need of treatment.[3] Funding cutbacks and withdrawals have created waiting lists for people requiring antiretroviral (ARV) treatment, and compromised adherence among those receiving treatment; this will lead to drug resistance and premature death. The UN estimated a need of $25.1 billion in AIDS funding for 2010 with a funding gap of $11.4 billion,[4] including a shortfall of up to $5 billion for the Global Fund for 2010.[5]

Like other high HIV-prevalence countries, Malawi has been experiencing stockouts of life-saving ARVs. Dignitas International has worked in partnership with the Malawi Ministry of Health since October 2004, together starting more than 13,000 adults and children on HIV treatment in Zomba District. Dignitas treats HIV/TB patients, supports the integration of HIV services within primary care, strengthens health systems, and conducts research to make care more efficient and effective. Amid ARV drug shortages, Dignitas's medical team is working hard to ensure that no one currently on treatment runs out of their medication. To do this, we've been forced to ration access to care, initiating treatment for only the very sickest and most vulnerable patients. Each month, hundreds of people who qualify for immediate treatment are placed on waiting lists, significantly reducing their chance of survival.

We are witnessing the abandonment of a decade-old global commitment to ensure universal access to HIV/AIDS treatment. Dignitas's experience in Malawi illustrates the threat posed by global systemic drug stockouts. HIV funding shortfalls due to reneged commitments by donor countries and their impact on drug availability is intolerable, particularly at a time when the AIDS response has achieved such a positive impact on millions of lives. Gains made are being rapidly undermined. The global economic recession is a poor excuse for letting millions of people die unnecessarily – it is morally objectionable and shortsighted given its broad implications for public health and human development. Without a robust response to HIV/AIDS, attempts to improve other priority areas in global health – including maternal and child health – will falter.

The global response to HIV/AIDS is being quietly eroded. Urgent and sustained effort is required to prevent the legitimization of this trend. Dignitas joins other organizations and individuals deeply concerned about the human impact of AIDS funding shortfalls, and calls on governments to meet existing financial obligations, to firmly entrench commitments made to prioritize the global AIDS response and universal access to treatment, and to ensure the successful replenishment of the Global Fund for Round 10 grants.

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[1] "The Global HIV/AIDS Epidemic Fact Sheet," Kaiser Family Foundation, November 2009, http://www.kff.org/hivaids/upload/3030-14.pdf (accessed June 10, 2010).
[2] "The Global Fund to Fight AIDS, Tuberculosis and Malaria," AVERT, http://www.avert.org/global-fund.htm.
[3] "Universal access to AIDS treatment: targets and challenges," AVERT, http://www.avert.org/universal-access.htm.
[4] "Missing the target: Rationing Funds, Risking Lives," International Treatment Preparedness Coalition, April 2010, p.10, http://www.aidsportal.org/Article_Details.aspx?ID=13373.
[5] "The Global AIDS Crisis: 5 Steps Canada Should Take – A Civil Society Platform for Action," The Global Treatment Access Group (GTAG), April 2010.

The Human Impact of Dangerous Shortfalls and Drug Stockouts: The Experience of Malawi
Current ARV medication stockouts experienced in Malawi are related to disbursement delays from the Global Fund (publically stated by the Malawi government in March 2009).[6] The Global Fund is the sole donor of ARVs to the government of Malawi.

-**Patients' health is compromised.** To keep patients on treatment, Dignitas's medical team is forced to substitute equivalent ARVs when the recommended drugs are out of stock. The inconsistent supply of antiretroviral medications affects treatment adherence and can lead to confusion, new side effects, pill sharing, and an increase in drug resistance and viral load, resulting in the need for more expensive drug regimens and the danger of drug-resistant HIV among the general population.

-**Access is being reduced.** The gains made over the last five years in Zomba District are being compromised. Dignitas and the Zomba District Health Office have decentralized treatment from Zomba Central Hospital to health centres in rural and outlying communities – closer to where many of Malawi's poorest people live and work. Patients already on treatment who are being monitored at these clinics are only being given a one-month supply of medications, instead of the usual three-month supply, if they can afford to travel to health centres with the medications. Patients tell us that transport costs make it difficult to access treatment and attend appointments. We have had to stop enrollment at the decentralized rural clinics supported by Dignitas throughout Zomba District.

-**Treatment is delayed.** Since April 2009, the initiation of new patients on ARVs in Zomba District has been reduced or delayed due to lack of medications, even though these patients are eligible and in need of treatment, and despite Dignitas and the Malawi Ministry of Health having developed adequate personnel and infrastructure. Beginning in March 2010, due to ARV stockouts, enrollment was reduced from an average of 350 patients per month to 250 patients per month at Zomba Central Hospital. Dignitas's medical team is prioritizing treatment for all pregnant women and children, and for patients who are the sickest and most immunocompromised.

-**The waiting list grows.** Dignitas currently has 680 patients on a waiting list for antiretroviral treatment at Zomba Central Hospital. Over a year ago, there was not a single person on a waiting list. Up to 100 additional patients per month would have been initiated on treatment were it not for the stockouts. With each passing day, it will take longer to clear the list; people with advanced AIDS are starting treatment first, and more people may die unnecessarily while waiting.

-**People die.** People who start ARVs when they are not gravely ill have better outcomes on HIV treatment. The new World Health Organization guidelines have set higher standards for early initiation of treatment, but we have been forced to adjust guidelines for enrollment to criteria that initiates patients even later than previously advised by WHO guidelines.[7]

[6] Bright Sonani, "AIDS Funding Stalls," March 8, 2009, The Nation, http://www.nationmw.net/newsdetail.asp?article_id=3044 (accessed June 3, 2010).
[7] New WHO guidelines call for the enrollment of patients on treatment when their CD4 count is <350 cells/mm. Currently, in Zomba, Malawi, non-pregnant adult patients with a CD4 count of <100 cells/mm are initiated on treatment first (rather than <250 cells/mm, the standard for initiation of treatment in Malawi). All non-pregnant adult patients with a CD4 cell count of >100 cells/mm are put on a waiting list. All Stage IV non-pregnant adult patients are initiated on ART.

What Can Be Done:
-Governments of the G8/G20 countries must not only maintain, but also increase and entrench their commitment to HIV funding, including treatment, without restrictions, particularly through the Global Fund. As more people access treatment, and at an earlier stage, more lives will be saved, resulting in more people remaining on treatment for longer periods of time. The resources allocated to the response must continue to correspond to the scale of the need or we will be faced with a greater social and economic cost due to HIV-related deaths and morbidity.

-To date, based on confirmed pledges, there are no funds available to fund the Global Fund's Round 10 proposals.[8] Governments must commit the necessary resources at the replenishment meetings in October 2010. We ask citizens of G8/G20 countries to pressure their governments to make funding for the global AIDS response an ongoing priority and to honour the commitments already made.

-Canada must contribute its fair share to the Global Fund, which is equivalent to 5% of the total resources needed by the Global Fund.[9] The amount required for 2011-2013 is USD 20 billion, which will allow for progress towards universal access through the continuation of existing programs and the significant scale up of well-performing programs.[10] This has not yet been achieved for the 2008-2010 period, nor has it been committed for Round 10.

-PEPFAR must continue to fund HIV care and treatment: its funding was flatlined in 2009 and 2010, and its budget for ARVs was reduced by 17% in 2009. As part of the new $63 billion Global Health Initiative aimed to provide an integrated approach to global health, PEPFAR budget allocations will now cover six instead of five years, reducing annual budget allocations for 2009–2014 from the initial reauthorization plans.[11]

-Disruptions of treatment, drug supply management and medication stockouts due to funding gaps or delays in disbursements must stop. They threaten the long-term survival of people living with HIV/AIDS and threaten to increase resistance to antiretrovirals and vulnerability to other infectious diseases such as TB.

Voices For Malawi:
"All of the gains made in the past decade with improved scale up of antiretrovirals are threatened by the drug supply question, and it fills me with both rage and sorrow thinking about what might happen to the 13,000 patients we have started on treatment in our program in Zomba – and the 200,000 currently on treatment in Malawi – if their stock were to be disrupted. This is not just an issue of cost-effectiveness in the setting of a financial crisis, but it is a crisis in morality. Not giving treatment when funds should be available is wrong."
- **Dr. Adrienne Chan, Dignitas Medical Coordinator, Malawi Country Program, 2007-2010**

"Dignitas is building a set of tools for countries like Malawi to build a highly effective system of care at the frontline, in the most remote clinics, in a practical, sustainable way. This is an argument for continuing to provide HIV care, especially including ARVs, and doing it in a way that uses the most urgent problem as a gateway to improve care for other infectious diseases, mental health, maternal health, TB. These are themselves vital, but it is simply criminal to set up a duality in which it is falsely suggested that only one or the other can be provided – AIDS versus everything else. In fact, Dignitas is showing that it can most easily and sustainably be done by doing HIV *and* everything else."
-Dr. Merrick Zwarenstein, Dignitas Board Member, Senior Scientist, Sunnybrook Research Institute, University of Toronto

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[8] "Resources Forecast," The Global Fund, http://www.theglobalfund.org/en/applicantsimplementers/resources/ (accessed June 10, 2010).
[9] "The Global AIDS Crisis: 5 Steps Canada Should Take – A Civil Society Platform for Action," The Global Treatment Access Group (GTAG), April 2010.
[10] Resource Scenarios 2011-2013: Funding the Global Fight Against HIV/AIDS, Tuberculosis and Malaria, The Global Fund, March 2010, p.5.
[11] No Time to Quit: HIV/AIDS Treatment Gap Widening in Africa, MSF, May 2010, p.16-17.

"The prospect of treating AIDS with ART in Africa was nearly impossible to consider before about the year 2000. An important obstacle to discussion, apart from technical concerns, was the cost of such an intervention because there were no low-cost generic fixed-dose combination ARVs, and not yet any global mechanisms (such as the Global Fund and PEPFAR) for provision of ARVs. This had the effect of shutting down real discussion about what should happen (on a moral level) and what could happen (on a technical level). Fortunately, but only years later, ART has become widely available in Africa, but the lesson regarding the relationship between financial capacity and what we should attempt to do should not be forgotten."
-Dr. Richard Bedell, Dignitas Medical Advisor

"When I recently joined Dignitas International, I was very excited because I had a chance to be part of this organization, which pioneered, in collaboration with the District Health Office, access to antiretroviral therapy in Zomba, Malawi, by putting thousands of AIDS patients on treatment… But within a short span my excitement turned into dismay when I witnessed the vibrant program facing the risk of coming to a stand-still and being forced to limit the initiation of new patients who are eligible for ART, and a long waiting list of sick patients, some of them staring death in the face, jostling to jump the queues, and healthcare providers left alone with no options to give hope to their patients, who were previously seen as professionals who gave them back life… The effects of the current ART stockout are demonstrating a worrying trend, where treatment interruptions predispose patients to the development of drug resistance, hence leading to a big proportion of patients failing the simplest and low-cost first-line drugs… However, I strongly believe this unfortunate situation is not inevitable as long as timely action is taken."
-Dr. Belete Assefa, Dignitas Medical Coordinator in Zomba, Malawi

"A number of concerned nurses have said, 'This is a first sign that one day these ARV patients in Malawi will leave without tablets to swallow for weeks or months. Yet we tell them that they must take their drugs without missing doses for the drugs to work effectively.' One clinician said, 'You rolled out the program of ART initiation to health centres in order to reduce the burden of patients travelling 42 kilometres to access ARVs at the main site. Now the waiting list for ART initiation is long, and patients complain that they cannot afford to get transport money for themselves and their guardians and their worry is how long shall we wait for the drugs?' … One clinician and two nurses from some health centres reported that their patients had not taken their drugs for almost a week because they could not get any transport money to get their drugs at the main site. When they were asked if they know they can develop resistance to treatment because of missing their doses they said, 'Yes, we know, but what can we do if we do not have money.'"
-Gabriel Mateyu, Clinical Officer, Dignitas Health Centre Coordinator in Zomba, Malawi

"This is casting a dark shadow on the vision of universal access to ARVs in the country… [There has been a] shift of energy and attention to drug stock management at the expense of other priority program activities. A lot of time and energy is spent troubleshooting and following up with the HIV Unit and other partners on drug supplies… [There is an] increased patient load due to the return of clients from decentralized sites, and a holding up of decentralization activities. [This has lead to] low staff morale as drug stockout issues become a daily challenge … [and] anxiety for patients who are not sure what the future of ARVs holds for them."
-Edson Mwinjiwa, Clinical Officer, Dignitas HIV Clinic Coordinator in Zomba, Malawi

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