

# ICW reflections on early treatment initiation

## **TO START, OR NOT TO START: A HOLISTIC APPROACH TO TREATMENT INITIATION**

The Strategic Timing of Anti Retroviral Treatment or (START) trial offers convincing scientific evidence that people living with HIV should initiate antiretroviral treatment (ART) without delay even when their CD4+ T-cell count is high, rather than waiting until their CD4+ count drops.<sup>1</sup> The START trial, a large international randomized control trial,<sup>2</sup> found that persons living with HIV have significantly lower risk of developing AIDS or other serious illnesses,<sup>3</sup> if they begin treatment earlier irrespective of symptoms and CD4 count. According to those who conducted the trial, early treatment initiation confers a double benefit by improving individual health outcomes and simultaneously lowering viral loads and thereby reducing the risk of HIV transmission.

The START trial presents a definitive and evidence-based answer to the long-asked question of whether and when it is beneficial for persons living with HIV to initiate treatment. It is clear that these compelling findings will have global implications for HIV treatment.<sup>4</sup> However, this promising evidence must be understood as only telling half the story.

Despite potential individual and public health benefits for women living with HIV, the decision to begin treatment for HIV is a deeply personal decision that reflects a variety of private, contextual and structural factors. The decision to initiate ART is a decision that should be made with full information about all the risks and benefits of initiating and staying on treatment. These risks and benefits must be more broadly defined than simply a decreased risk of AIDS or serious illness. Persistent barriers to access, quality and availability of treatment, limited treatment options, pill fatigue, stigma, discrimination and abuse in health care systems and the strength and availability of support services including peer, family and community support, mean that the decision to initiate treatment for many women is not so clear cut.

Women living with HIV have long harbored concerns about lifelong treatment and these concerns are extremely relevant for the prospects of early initiation of treatment. The International Community of Women Living with HIV's (ICW) recent qualitative research efforts<sup>5</sup> capture the perspectives of women living with HIV on the initiation of treatment for life. Our research revealed the following key concerns:

- 1 Starting antiretroviral treatment early improves outcomes for HIV-infected individuals: NIH-funded trial results likely will impact global treatment guidelines. Press Release Available at <http://www.nih.gov/news/health/may2015/niaid-27.htm>
- 2 The trial included 4,685 participants at 215 sites in 35 countries. Twenty-seven percent of those enrolled in the study were women.
- 3 "The study measured a combination of outcomes that included serious AIDS events (such as AIDS-related cancer), serious non-AIDS events (major cardiovascular, renal and liver disease and cancer), and death. Based on data from March 2015, the DSMB found 41 instances of AIDS, serious non-AIDS events or death among those enrolled in the study's early treatment group compared to 86 events in the deferred treatment group. The DSMB's interim analysis found risk of developing serious illness or death was reduced by 53 percent among those in the early treatment group, compared to those in the deferred group." Available at <http://www.who.int/hiv/pub/guidelines/arv2013/download/en/>
- 4 This represents a change from the current World Health Organization HIV treatment guidelines recommend that persons living with HIV start antiretroviral therapy when CD4+ cell counts fall to 500 cells/mm<sup>3</sup> or less. Available at <http://www.who.int/hiv/pub/guidelines/arv2013/download/en/>
- 5 The 3 qualitative research studies were conducted in partnership with the Global Network of People Living with HIV (GNP+) and can be found on the <http://www.iamicw.org> website.

## Autonomy and Human Rights

Women living with HIV consistently raise issues around autonomy in healthcare decisionmaking including when and whether to start treatment. Women also raise issues of lack of informed consent. Certain basic requirements such as options, time, and information that enable women to make informed decisions as well as the receipt of non-discriminatory care are critical considerations for the ability for all persons living with HIV to get and stay on treatment that works for them. Women in our research expressed experiences and raised concerns about hasty implementation of treatment scale-up, including rights violations, drug resistance, side effects, and increased vulnerability to gender-based violence. Programming for early treatment initiation must not become a mandate that supersedes human rights.

## Sustainable Access to Treatment, Care and Support

There are significant gaps in the HIV response infrastructure that undermine access to treatment, treatment sustainability and financing. Finding the right combinations of medicines is a very individualized process and for many people living with HIV, treatment adherence can be hampered by drug stock outs and lack of availability of certain treatment options. Upcoming changes in treatment financing at the country level also pose obstacles for people with HIV in securing consistent access to treatment under the current guidelines.

For people living with HIV, treatment is a lifetime commitment that requires a supportive environment and networks of care and support. Programs must ensure comprehensive, quality, and dignified health care for women living with HIV and recognize and support the universal right of all people living with HIV to access reliable, affordable, comprehensive, and sustainable care, treatment, and support. Given the challenges regarding availability and sustainability of treatment for those currently recommended for treatment initiation and risks of developing drug resistance, addressing these practical barriers is key for the success of any potential large treatment scale-up.

## Barriers to Treatment Adherence & Loss to Follow-Up

Women who commence lifelong ART, especially those with young children, shoulder new burdens due to the need to return for routine clinic appointments. Almost all the women in our research discussed temporal, financial (i.e. transportation costs; missing work), relational (e.g. permission from partner), and emotional costs, all of which affect their ability to seek HIV care and adhere to treatment regimens. Efforts to scale up treatment require a holistic approach to women's lives and parallel investments in community-based support to improve women's treatment literacy, preparedness, and agency to receive quality services and adhere to treatment.

## Research on the Long-term Impacts of ART for Women

Although the START trials demonstrated positive health outcomes as a result of early treatment initiation, increased focus and research is critical to examine the long-term impacts of ART, particularly for women living with HIV. There are potentially serious health risks associated with taking ARVs, including increased risk of certain diseases and cancers, the acceleration of diseases associated with aging, and harmful side effects. Women experience a variety of impacts on women's health and well-being that are not adequately studied. Because of these issues, adherence may be compromised, leading to resistance to drugs and a failure of the treatment to work.

To be certain, the START outcomes and recommendations offer a definitive and evidencebased answer to the question of whether it is beneficial for persons living with HIV to initiate treatment irrespective of symptoms and CD4 count. This evidence, however, must be understood and implemented in a way that reflects the daily realities and challenges facing women living with HIV and respects our fundamental human rights to information and autonomous decision-making about our health.

