



Consultation on WHO ART Guidelines

Defining Standards of Treatment and Care
E-consultation

Global Network of People Living with HIV

27 July 2009 – 16 August 2009

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Executive Summary

This report presents the key points and recommendations that emerged during the e-consultation on the forthcoming revision of the WHO's Recommendations for Antiretroviral Therapy (ART) for HIV Infection in Adults and Adolescents (ART Guidelines), held between July 27th and August 16th, 2009. The e-consultation was organised by the Global Network of People Living with HIV (GNP+) and hosted by NAM. It aimed to gather the perspectives and values of people living with HIV (PLHIV) related to the upcoming revision to the ART Guidelines.

Each week the e-consultation focused on a different topic area with three broad questions that covered different aspects of the guidelines:

- **Week 1 (July 27th - August 2nd)** Personal perspectives: how do we feel about treatment and what do we expect from ART?
- **Week 2 (August 3rd - 9th)** Advocate perspectives: balancing the tension between quality and equity of HIV care.
- **Week 3 (August 10th - 16th)** Positive Health, Dignity and Prevention: how important is a human rights-based approach to treatment when used as a prevention tool?

A total of 317 advocates and activists living with HIV were invited to participate via email (300 were invited and 17 requested participation), of whom 128 registered, and 66 posted comments: a 21% response rate. Participants came from 36 countries representing all six WHO regions: Americas (13 countries), Africa (9), Western Pacific (5), Europe (4), Eastern Mediterranean (3), and South-East Asia (2). Participants were extremely well informed about treatment issues and most had personal experience of ART.

One of most important points to emerge from this e-consultation was the broad consensus that PLHIV must be educated and empowered about their options – whatever they may be – in order to make a joint decision with their clinician, and that treatment should begin:

- When the individual is ready;
- Based on the individual's overall health rather than focusing solely CD4 count criteria;
- And that the individual, rather than the virus, should be the focus of treatment and care.

CD4 count criteria for starting treatment should be in line with current scientific knowledge of best outcomes, at 350 cells/mm³. A minority of PLHIV advocated for starting treatment at 500 cells/mm³ and/or immediately following an HIV diagnosis in areas of high TB prevalence.

There was also broad consensus that d4T (stavudine) be removed from the list of recommended drugs due to its toxicity profile, and that tenofovir be recommended in its place. It was agreed that PLHIV require a broader choice of first- and second-line therapies with a focus on drugs that are easier to tolerate than currently recommended regimens. In addition participants highlighted the following concerns:

- The potential for NNRTI-associated toxicity;
- The difficulties of trading side-effects for potency;
- The realities of unnecessary drug switches due to stock-outs;
- Drug resistance issues, requiring third-line and salvage therapies;
- And improved patient education about the availability of second-line therapies – where they are available.

PLHIV feel very strongly that CD4 counts and viral load tests must be considered standard monitoring tools regardless of setting. Many also argued that resistance testing prior to starting treatment and following

treatment failure was both necessary and cost-effective, and that if the WHO ART guidelines recommend them, this will help advocates fight for their funding on a local level.

Understandably, advocates are both optimistic and pragmatic regarding the benefits and tradeoffs if WHO recommends starting ART earlier and recommends using more expensive regimens. However, PLHIV feel that it is important to save lives now and worry about paying for it tomorrow. Although participants from sub-Saharan Africa, especially, were concerned about current and future levels of funding on drug access issues, many advocates argued that the guidelines could be used as a tool for PLHIV activism, and it that it was up to PLHIV and civil society to ensure that governments and funders see the long-term cost-effectiveness of starting treatment earlier with better drugs.

Consequently, PLHIV are not prepared to give up anything in return for guidelines that recommend earlier treatment with a greater choice of better-tolerated drugs. Nevertheless, participants appreciated that, in reality, the question of what PLHIV are prepared to give up was moot since "this is not a choice that is ours to make."

Those participants who had seen the results of the DART study recently presented to IAS 2009 were ready to consider a compromise on monitoring frequency if that meant earlier treatment with better drugs could be made affordable. Concerns were raised, however, regarding the interpretation of the DART study with some advocates noting that this could result in problems if task-shifted healthcare workers are not properly trained.

Regardless of the situation in their own country, participants were unanimous that the guidelines should reflect the best, current scientific knowledge and standards. Participants were of one voice that "the WHO guidelines should be a standard of care that all countries should strive to achieve, regardless of resources." Anything else "permits a differential set of standards which cannot be acceptable."

PLHIV understand that the link between treatment and prevention is extremely important and believe that the two "should be seen as a continuum and not a dichotomy." They noted treatment's effect on:

- Infectiousness, on both a population and individual level;
- Incentives to test, since untested people play an important role in new infections;
- And improved safer sex skills and safer behaviours of PLHIV accessing treatment and care.

Participants also highlighted that personal knowledge regarding the effect of treatment on transmission:

- Can be an incentive for better adherence for people on treatment and therefore better health;
- And makes it easier for PLHIV to start and maintain relationships.

Participants strongly advocated for WHO to highlight and clarify the role of treatment on prevention based on these reasons and, in particular, to:

- Ensure universal sustainable access to timely ART in order to prevent illness and promote wellness;
- Encourage undiagnosed individuals to know their status;
- And to reduce infectiousness on an individual, as well as a population, level.

However, they also agreed that 'treatment as prevention' should not take away the focus from a broader approach to prevention, and whilst calling for WHO to acknowledge and to clarify ART's role in reducing infectiousness, participants also agreed that WHO should state that treatment alone can only be part of an overall prevention strategy that must address those without, as well as those living with, HIV.

Finally, participants unanimously agreed that, "a human rights-based approach to health-related issues is of the upmost importance" and the "universal foundation of the response to the epidemic."

Recommendations

- 1. WHO guidelines should be based on the best, current scientific knowledge, focusing on a standard of care that all countries should strive to achieve, regardless of resources.*
- 2. WHO should be aware that if their treatment guidelines are not harmonised with those in well-resourced countries, they run the danger of being seen to promote global inequalities.*
- 3. The WHO ART guidelines should state that individuals begin treatment when CD4 counts reach 350 cells/mm³. However, although CD4 count is an important indicator of when to start treatment, just as important is making sure that the approach to treatment is holistic, and that the individual is educated about treatment and ready to commit to lifelong therapy.*
- 4. The WHO ART guidelines should no longer recommend d4T (stavudine) and recommend tenofovir in its place. More choice of first- and second-line therapies is required, with a focus on drugs that are easier to tolerate than currently recommended regimens with enough alternatives to allow for choice based on toxicity profile. Guidance on third-line therapies and beyond is required.*
- 5. The WHO ART guidelines should recommend that all PLHIV have regular CD4 counts and periodic viral load tests. Most PLHIV are not prepared to give up anything in return for better, earlier treatment. A minority, however, concede that reduced lab monitoring frequency may be a compromise that is acceptable. monitoring frequency is to be reduced whilst on treatment to save costs, then the guidelines must recommend that adequately trained healthcare workers are made available in order to assess toxicity and treatment failure. WHO should also consider recommending resistance testing prior to starting treatment and following treatment failure.*
- 6. WHO should be aware that PLHIV will rise to the challenges faced in their own countries should guidelines recommend earlier treatment with more choice of better-tolerated drugs. WHO should argue strongly that such recommendations would be cost-effective, and take the lead in persuading governments to find the funding for drugs, personnel and healthcare infrastructures to deliver such treatment and care.*
- 7. WHO should be aware that PLHIV in every setting appreciate and understand the link between treatment and prevention, and in particular the potential effect of ART on infectiousness, on both a population and individual level. WHO should highlight that access to treatment will result in population-wide prevention benefits, through reduced individual and population infectiousness; increased incentives to test; and improved safer sex skills and safer behaviours of those PLHIV accessing treatment and care.*
- 8. WHO should clarify ART's role in reducing infectiousness on an individual as well as a population level in order to ensure universal sustainable access to timely ART; encourage undiagnosed individuals to know their status; reduce stigma; and to help individuals understand their personal risk.*
- 9. WHO should also make it clear that treatment alone can only be part of an overall prevention strategy that must address those without, as well as those living with, HIV. Biomedical approaches, and prevention focused solely on diagnosed individuals, must be seen as part of a broader prevention strategy that highlights structural power imbalances in society, such as gender inequities, gender violence and poverty.*
- 10. WHO should ensure that a human rights framework forms the foundation of their approach to 'treatment as prevention' as a way of attempting to achieve universal access, and that a study on the feasibility, acceptability and sustainability of such an approach is necessary.*

Methodology

The e-consultation took place over three weeks, from Monday July 27th to Monday August 17th 2009 inclusive. It was hosted by NAM, a community-based HIV information provider. A total of 300 advocates and activists living with HIV were invited to participate via email. Invitees included PLHIV who had attended previous GNP+ consultations: HIV+ Monaco, 2007; LIVING 2008, Mexico City; the International Technical Consultation on Positive Prevention, Tunis, 2009; IAS 2009, Cape Town; as well as partners from other GNP+ programmes.

Participants were informed that their perspectives and values would directly influence discussions for the revised WHO ART guidelines, and that this e-consultation was closed and limited to people living with HIV. In the first week, participants were encouraged to suggest other people living with HIV who might like to take part: a further seventeen individuals joined the e-consultation this way.

Each week of the e-consultation, on Mondays and Thursdays, participants received emails inviting them to share their experiences and opinions on specific topic areas. Each topic area included three broad questions that covered different aspects of the guidelines:

- **Week 1 (July 27th - August 2nd)** Personal perspectives: how do we feel about treatment and what do we expect from ART?
- **Week 2 (August 3rd - 9th)** Advocate perspectives: balancing the tension between quality and equity of HIV care.
- **Week 3 (August 10th - 16th)** Positive Health, Dignity and Prevention: how important is a human rights-based approach to treatment when used as a prevention tool?

All six emails included the link to the e-consultation website (<http://www.aidsmap.com/gnp+>) as well as a personal password linked to the individual's email address. Participants were invited to fill in a short user profile and were given the option to choose a user name and to upload a photo. Name, sex, organisation and country data were provided for GNP+ internal use only.

The e-consultation was conducted in English and moderated by a GNP+ consultant living with HIV (who also authored this report – Edwin Bernard). The moderator regularly monitored the discussions to ensure that the posts were applicable to the subject; to answer any specific questions; and to suggest further areas of discussion within each question.

Participants from Algeria, Bolivia, Morocco and Peru posted in their native tongue, namely French or Spanish: the moderator provided a rough English translation following their post. Several participants contributed via email: the moderator posted their comments on their behalf.

Each discussion lasted a week, and comments were closed at 12.00 GMT each Monday. Due to several participants contacting GNP+ with technical issues during the first week of the e-consultation, the first discussion was left open until the following Thursday at 12.00 GMT. Once the discussion was closed, participants were no longer able to post new comments but were able to read previous discussions.

Links were provided to the WHO website for further information on the revision process and access to current guidelines; to news reports by NAM from the 2009 International AIDS Society (IAS) Conference held in Cape Town; and to in-depth articles about a range of relevant issues from NAM's email newsletter, HIV and Treatment in Practice (HATIP).

Participants

Of the 317 individuals emailed, a total of 128 registered, and 66 posted comments: a 21% response rate. Twenty-four participants were female. Three individuals posted anonymously without identifying their country. In all, 36 countries from all six WHO regions were represented:

Americas (18 individuals from 13 countries): Argentina; Bahamas; Bolivia; Brazil; Canada (3 individuals); Colombia; Jamaica (2); Mexico; Panama; Peru; Trinidad & Tobago; US (3); and Venezuela.

Africa (18 individuals from 9 countries): Algeria, Kenya (5); Ivory Coast; Malawi; Namibia; South Africa (3); Swaziland; Uganda (3); and Zambia (2).

Europe (13 individuals from 4 countries): France; Netherlands (4); Russian Federation; and the UK (7).

Western Pacific (7 individuals from 5 countries): Australia (3); Cambodia; China; Malaysia; and Papua New Guinea.

Eastern Mediterranean (5 individuals from 3 countries): Iran; Lebanon (3); and Morocco.

South-East Asia (2 individuals from 2 countries): Indonesia and Thailand.

Participants were extremely well informed about treatment issues and most had personal experience of antiretroviral therapy (ART). The 19 individuals from well-resourced countries had previous, personal experience of treatment issues in a low- or middle-income country and/or were working for international organisation that assisted and/or advocated for PLHIV in low- and middle-countries.

Week 1: Personal perspectives: how do we feel about treatment and what do we expect from ART?

Current WHO guidelines *suggest* starting treatment once CD4 counts have reached 350 cells/mm³, but *recommend* starting treatment before CD4 counts reach 200 cells/mm³. In practice, people tend to have much lower CD4s when they start ART, and most people only start once they are very sick. In addition, many people do not take treatment even when they are eligible, and some drop out of treatment once they've begun.

It is likely that the revised guidelines will recommend starting treatment earlier, at 350 cells/mm³, which is already the recommendation of guidelines from experts in the North America, Europe and Australia as well as those of the South African HIV Clinicians' Society.

The guidelines will also discuss the benefits and tradeoffs of:

- Using AZT (zidovudine) versus d4T (stavudine) versus TDF (tenofovir) as a preferred first line therapy drug;
- Non-nucleoside- versus protease inhibitor-based first line regimens; and
- The role of triple nucleoside regimens.

Participants were asked to discuss three broad treatment-related areas but were encouraged to discuss specific issues within each discussion area:

1. When should we start and change treatment? (32 posts by 29 individuals)
2. What drugs should be recommended for first- and second-line therapy? (22 posts by 20 individuals)
3. What kind of monitoring is necessary to help inform our treatment decisions? (20 posts by 18 individuals).

A total of 41 individuals participated in Week 1 discussions around antiretroviral therapy (ART) from a personal perspective. Although the aim was to discuss personal experiences and share opinions on what PLHIV would like the WHO guidelines to say to make sure their treatment and care needs are met, broader issues of access inevitably came into play.

1. When should we start and change treatment?

Most participants focused on the issue of starting rather than changing treatment, which was discussed more thoroughly during the question 3. The most important points to emerge from this discussion was the broad consensus that PLHIV must be educated and empowered about their options (whatever they may be) in order to make a joint decision with their clinician, and that treatment should begin:

- When the individual is ready;
- Based on the individual's overall health rather than focusing solely CD4 count criteria;
- And that the individual, rather than the virus, should be the focus of treatment and care.

If CD4 count criteria are used, they should be in line with current scientific knowledge of best outcomes: at 350 cells/mm³, with a minority advocating for 500 cells/mm³ and/or immediately following an HIV diagnosis in areas of high TB prevalence.

Patient literacy

Participants were unanimous that PLHIV must be partners in their treatment and care in order to achieve the best health outcomes. This, noted an advocate from the Netherlands, is about "putting the 'patient' in charge of their treatment and treatment options so that they (alongside peer educators from a community) are coming to an informed choice that is good for them."

"More often than not we don't have the luxury to even ask this question [i.e. 'when should we start and change treatment?'] of health care providers whose opinion and advice in many instances remains unquestionable," wrote an advocate from Thailand. "We are just supposed to do as we are told: basically it's take it or leave it and doctor knows best. I think this is really the way that treatment roll-out is made available in developing countries in Asia and the Pacific. This top down approach to dealing with clients making us just recipients of services with no voice is why treatment education and literacy is so vital among PLHIV and communities, and the need to ensure we are sufficiently empowered to question when we are given the wrong kind of treatment."

An advocate from Bolivia who has been on treatment for over four years says he only managed to access treatment because he was an activist who knew his rights and was not afraid to ask for treatment, but that many people still die untreated in his home country. *"Estoy con tratamiento por mas de 4 años, y empece cuando tenía 120 CD4, ahora solo he suvido 175 CD4, los riesgos que se vive son complejo, mi persona porque es un activista ha podido exigir y hacer cumplir mis derechos y no tengo miedo de dar la cara, es que ahora estoy vivo, pero en mi ciudad la mortalidad por cuestiones clínicas de SIDA es la mas alta de mi país (Bolivia)."*

"I think education is the most important part of taking your treatment," concurred an advocate from the Bahamas. "Persons who do not understand how the medication works and what are the side-effects need to sit down with their physician and discuss what the medications are for; what the side-effects are; what can be done to reduce side-effects; and what can be done if the meds are not working."

"Before asking PLHIV to start their treatment," added an advocate from Indonesia, "we should give them awareness and information on the effect of ARVs. Otherwise taking ARVs without willingness from ourselves will be nothing, because ART is long-term, and adherence will be the most important factor for successful ARV treatment."

When the individual is ready

Continuing the theme of patient literacy, participants also argued strongly that, "a positive patient has to be ready to start drugs. If a person is not ready," wrote an advocate from the US, "no doctor can make them start."

"I started my treatment from a CD4 of 42, because of not knowing when and what to take," wrote an advocate from South Africa. "I strongly feel that information is still needed for people to make informed decisions about the benefits of taking treatment earlier as well as the benefits of delaying it. ...personal readiness and psychological support is needed; we need to address fears of drug toxicity while considering access to treatment."

Individual health

Participants also agreed that although the WHO ART guidelines are "needed to guide practice and to help forecast appropriately financial, human resources and medical goods needs," they "do not allow for a personalised approach." (French advocate).

It was argued strongly that a public health approach to ART should not preclude treating individuals living with HIV rather than simply the virus itself. "Many physicians only see the virus and not the person who is carrying it," noted an advocate from Canada.

An advocate from Russia wrote: "My CD4 was between 350 and 500 during 13 years and I never felt sick - only few times. I finished hep C treatment one month ago with good results and my CD4 is 200 now. Taking into account strong health condition during 13 years, I think that each person's health condition has to be the criteria for starting ARVs. It is not appropriate to say that a person has to start treatment immediately if CD4 is 350 because of the WHO guidelines. Some people need treatment on 500 CD4 and some need on 350 or 200."

"Personally, I would have preferred to be on treatment before the required stage and the same can be said about the many friends and relatives that I have lost, while they were waiting for treatment," wrote an advocate from an unnamed African country. "I have recently lost my best friend that died due to incompetence and inefficiency. He was completely exposed and the waiting worsened his situation. While on the other hand, my CD4 count was below 50, and I managed to qualify for the treatment at a very dangerous stage, I nevertheless, managed to overcome the worse. I therefore believe that an individual approach should be adopted, taking into the individual's circumstances."

CD4 count criteria

Most participants agreed that the criteria for initiating therapy based on CD4 count should be when it reaches 350 cells/mm³. "In many developed countries, national guidelines recommend to start when CD4 count drops to 350," wrote an advocate from France. "There is no scientific, medical reason not to have the same recommendation for people living with HIV in developing countries."

"As many have commented I think it is high time treatment should start a bit earlier, say when CD4 count is between 300 and 400," wrote an advocate from Malawi, "because it is when the treatment can work well. I live in a sub-Saharan developing country where a lot of people start treatment when the CD4 count is low which is very dangerous: many people die and they think the medicine is killing people. So there should be a standard set to say that even when someone is not feeling sick they should start treatment [based on CD4 criteria]."

Advocates from Argentina and Lebanon advocated starting treatment earlier, at 500 cells/mm³. "I read many articles on the best practice of beginning therapy," wrote the Lebanese advocate, "and I think PLHIV have the right to start taking their medicines when their CD4 count is lower than 500...but on the other hand, they have the right to know exactly what kind of medicines they need, what are their side-effects, why they should start, if they are able to wait and until when."

An advocate from Uganda argued that in settings with a high prevalence of TB, pegging initiation to CD4 counts "is becoming irrelevant" and that people should start treatment as soon as they are ready, soon after a positive HIV test result. "I think that as long as one tests positive and physically and clinically feels s/he needs the treatment, the person should be allowed to start rather than waiting for the person to be bed-ridden and become an issue for their dependants (children)."

Finally, an advocate from the US notes that his "view on this issue has changed in the past year. Before, I would have said to wait until CD4 count is low or there is symptomatic disease. I thought that once we start, we would have to take pills for our lifetime, so why not delay until necessary. Recent discussions on Positive Prevention have caused me to realign my thinking since it appears that people on medications with an undetectable viral load are far less infectious (or possibly not infectious at all). So, by starting effective treatment at diagnosis, people with HIV/AIDS will be contributing to AIDS prevention. Additional studies have shown that the earlier that people with HIV/AIDS start therapy, the better their health outcomes. So, this appears to be a win-win situation."

Treat holistically

"I think it would be good for WHO to be taking a holistic approach to treatment," writes an advocate from the UK, "which reflects not only the importance of drugs themselves but the much wider context of care, respect, solidarity and support which we all know to be so important to our well-being, our adherence and our capacity to cope with the virus and its consequences in our bodies. The WHO definition of health is a very holistic definition, but sadly this holistic definition often gets forgotten about in its day-to-day work, and the word 'treatment' often gets very narrowly defined - and interpreted - as just something just referring to ARVs."

Recommendation

The WHO ART guidelines should state that individuals begin treatment when CD4 counts reach 350 cells/mm³. However, although CD4 count is an important indicator of when to start treatment, just as important is making sure that the approach to treatment is holistic, and that the individual is educated about treatment and ready to commit to lifelong therapy.

2. What drugs should be recommended for first- and second-line therapy?

There was broad consensus that d4T (stavudine) be removed from the list of recommended drugs due to its toxicity profile, and that tenofovir be recommended in its place. It was also agreed that a broader choice of first- and second-line therapies should be made available with a focus on drugs that are easier to tolerate than currently recommended regimens.

In addition participants highlighted the following concerns:

- The potential for NNRTI-associated toxicity;
- The difficulties of trading side-effects for potency;
- The realities of unnecessary drug switches due to stock-outs;
- Drug resistance issues, requiring third-line and salvage therapies;
- And improved patient education about the availability of second-line therapies – where they are available.

Remove d4T from list of recommended drugs

This issue dominated the discussion, with many advocates having had personal or professional experience of the impact of d4T's toxicities. "I for one experienced a lot of side-effects with stavudine during first-line therapy," wrote an advocate from Malawi. "I had prolonged neuropathy which lasted almost a year and a half. My legs were completely dead with no feelings at all. Thankfully I am responding well to second-line therapy."

An advocate from Zambia compared his experience of treatment in the UK with that in his home country. "Where it all seems to have fallen apart is the prescription of stavudine (D4T) as the medicine of first choice by clinicians. As a treatment support counsellor, it was always a depressing time as one after another patient told of harrowing tales of having to cope with difficult, unbearable side-effects; in most cases resulting in a terribly diminished quality of life. I admire the African Spirit. I can't imagine what the outcome might have been like if similar treatment were meted out at, say, Kings College, London where I was a patient for at least two of my four year ARV treatment in the UK."

A French advocate with extensive support experience in Africa amplifies these points: "Regarding access to first-line regimens, there is an absolute emergency: ban d4T!"

Nevertheless, an advocate from Iran wrote: "As for myself, D4T worked very well for 10 years although for many it is not an easy drug to use."

NNRTI toxicity

Several participants highlighted issues around the potential toxicities of efavirenz (notably central nervous system side-effects) and nevirapine (notably rash and liver toxicity). "It is imperative that clinicians fully disclose the side-effects of *Stocrin (Sustiva)* and not downplay them (as is now customary)," wrote an advocate from the US.

"I think nevirapine is over-prescribed," wrote an advocate from Zambia. "The high levels of hypersensitivity observed at my treatment centre demands treatment advocacy to mobilise resources to lower prices of new non-nucleoside reverse transcriptase inhibitor(s), along with expanding second-line regimens."

Trading side-effects for potency

An advocate from Trinidad & Tobago illustrated the conundrum of wanting better-tolerated drugs when resources (and options) are limited when he stated: "I would say we need drugs with less side-effects, especially lipodystrophy. Although I suffer with that side-effect, I maintain my present meds, since they work very well for me."

"Suffice to say, regardless of how the patient feels," noted an advocate from Zambia, "if CD4 counts tell a good story, one is forced to endure these side-effects. People are known to have lost use of once-healthy limbs prior to ARV treatment due to the uncompromising practitioner stances regularly taken."

Stock-outs

Participants from Cambodia and Jamaica highlighted experiences of having to switch successful drug combinations due to stock-outs. "In my country," writes the Cambodian advocate, "sometimes physicians change people to D4T from AZT and from D4T 30mg to D4T 40mg" due to stock-outs. "The WHO guidelines should not allow a change from AZT to D4T when there is no AZT in stock." In the case of the Jamaican advocate, however, his enforced switch from *Combivir* to *Truvada* occurred with no problems.

Drug resistance issues

An advocate from Swaziland highlighted issues of drug resistance due to a variety of issues, many of which – such as stock-outs – are outside of the control of the individual. "People are initiated on treatment at a very compromised immune system of 200 but they are defaulting due to economic status, some due to fatigue, other due to treatment failure and many other reasons. The guidelines need to be concerned about drug resistance because over the years as you are taking the treatment even if you are complying and adhering in the long run you will end up with drug resistance and you will need to be changed to the second-line expensive regimen. So my question is: are the guidelines going to come up with third-, forth-, fifth-line and so on regimens since we will be in need of new drugs to tackle the resistance challenges that will come up?"

Patient education

Finally, an advocate from the UK working in Africa also highlighted the need for patient information on the availability of second-line therapy. "Ministries of Health in Southern African countries are dumping second-line therapies because the uptake is so bad," she wrote. "I cannot believe that the need is not there - it is just people do not know about second-, third- and fourth-line therapies."

Recommendation

The WHO ART guidelines should no longer recommend d4T (stavudine) and recommend tenofovir in its place. More choice of first- and second-line therapies is required, with a focus on drugs that are easier to tolerate than currently recommended regimens with enough alternatives to allow for choice based on toxicity profile. Guidance on third-line therapies and beyond is required.

3. What kind of monitoring is necessary to help inform our treatment decisions?

Participants argued strongly that CD4 counts and viral load tests must be considered standard monitoring tools regardless of setting.

Many also argued that resistance testing prior to starting treatment and following treatment failure was both necessary and cost-effective, and that if the WHO ART guidelines recommend them, this will help advocates fight for their funding on a local level.

Concerns were also raised regarding the interpretation of the recent DART study and frequency of monitoring.

CD4 and viral load

Participants highlighted the difficult situation they currently find themselves in: knowing that CD4 counts and viral load tests are necessary, but being unable to access them. "A combination of CD4 and VL count is necessary for treatment decisions like starting and changing treatment," wrote a Kenyan advocate. "We demand CD4 count machines and we demand access to quality laboratories with VL count machines. This is currently lacking in Kenya." A South African advocate concurred: "CD4 count is important with the staging of HIV and treatment of OIs. Viral load also should be used, but it is often used too late, putting most of our lives in danger."

Expectations were high amongst some participants that the WHO ART guidelines could 'fix' this problem. "Viral load is very important to monitor the treatment together with the CD4 count," wrote an advocate from Malawi. "But unfortunately in our country we do not have enough equipments for these services. For someone who is on treatment I think doctors or health personnel can know well if the medication is working properly if there are regular tests on VL and CD4 counts. Now, because we are poor we just receive the medicine without proper check-ups; you end up with liver, kidney problems because of lack of equipment. So WHO has to look into this matter, especially in poor developing countries where access is a problem to health centres."

Some advocates argued that information regarding the personal risks of infectiousness based on knowledge of viral load was an extremely important part of deciding if and when to start treatment. "If you are in a sero-discordant relationship," wrote an advocate from Australia, "and for whatever reason you do not want to use condoms, then you might want to go onto meds whatever the counts are as a prevention measure, weighing up whether you fit the criteria they define in the 'Swiss Statement'."

Resistance testing

An Iranian participant reiterated the power of the WHO guidelines when advocating for resistance testing in his country. "In a country like mine," he wrote, "these guidelines have an important role in the mind of health decision-makers and they presume if WHO does not require it therefore it is not that important. Drug resistance testing before starting ARVs is of utmost importance, but unfortunately is not included in WHO recommended guidelines. Please note that ARVs are costly, and if not prescribed properly does more harm than benefit, therefore I believe a 200-300 dollar drug resistance test can be cost-effective."

Participants also highlighted the utility of resistance testing when deciding when to switch to second- and third-line therapy. However, one advocate pointed out that this is moot where access to drugs beyond the second-line is non-existent. "Phenotype resistance testing is not available at all except for those who have money to pay for private health care," noted a South African advocate. "For people like me who depend on the public health care system in South Africa it's not done purely because if I become resistant to my second-line drugs (AZT/DDI/*Kaletra*) there is no other option as we don't have third-line regimens."

Monitoring frequency

An advocate from Argentina highlighted that annual CD4 monitoring, which is common in Latin America, is not frequent enough. "You know the situation in countries in Latin American, access to health systems is so difficult, especially for poor people. Healthcare visits are few, often a year apart, and this is too late to catch people before they get sick."

Advocates who had seen the results of the DART study recently presented to the IAS Conference were torn between welcoming the possibility of reduced monitoring frequency freeing up funds for more drugs with the concern that this could result in problems if task-shifted healthcare workers are not properly trained. "The DART study that was conducted in Uganda and Zimbabwe showed that if healthcare workers are trained to clinically assess PLHIV compared to those who rely on lab monitoring there really wasn't a big difference in outcome," noted a South African advocate. "But we met with the investigators because I was concerned about their conclusion, that it may be misunderstood as saying lab monitoring is not needed at all. They said, 'No, their recommendation is that the frequency of lab monitoring pushes the clinic budget high and this can be reduced by maybe doing viral load at three months rather than at baseline and then maybe yearly or six months after that.' I think this can be explored and it seems cost-effective, but PLHIV cannot accept no lab monitoring at all because in areas where healthcare workers are task shifting, they need to be confident when they are making decisions about treatment changes and side-effect issues."

Concerns over frequency of monitoring were placed in sharp focus when advocates highlighted co-infection issues. "Currently I think there is a lot of uncertainty in developing countries as to how, why and when people are put on treatment and what are the minimum standards for effective monitoring," wrote an advocate from Thailand. "How long between CD4 and VL tests and when to start treatment. For those who are IDU and co-infected with HCV this is another complexity to the issue that is hardly raised by healthcare workers."

The importance of regular monitoring for pregnant and nursing mothers was also highlighted. "On a recent visit to Zimbabwe," wrote a UK advocate, "a colleague told me about a positive woman not on medication who was breastfeeding her three-month-old baby. We heard today that that baby died. Why oh why is this happening? None of the women in her support group were regularly accessing a medical practitioner or had an in-depth knowledge of their HIV. I can't imagine where I would be now if I was solely relying on the medical visit I had when I was diagnosed. So much about treatment is education and being on top of our own conditions and being empowered to make those decisions ourselves and not have them imposed by clinicians. So what kind of monitoring? Every kind. From the personal holistic monitoring to the global monitoring, and most importantly dialogue between health care providers and support services and positive people's organisations."

Recommendation

The WHO ART guidelines should recommend that all PLHIV have regular CD4 counts and periodic viral load tests. If monitoring frequency is to be reduced whilst on treatment to save costs, then the guidelines must recommend that adequately trained healthcare workers are made available in order to assess toxicity and treatment failure. WHO should also consider recommending resistance testing prior to starting treatment and following treatment failure.

Week 2: Advocate perspectives: balancing the tension between quality and equity of HIV care.

The aim of Week 2's discussions was for advocates to appreciate the difficult task faced by the WHO ART guidelines writing committee and to weigh up the desire for the best possible quality of care against making sure as many people as possible get access to ART.

Governments, healthcare managers and advocates in low- and middle-income countries with large unmet treatment needs face an unenviable dilemma: attempt to treat more people by continuing to use cheaper drugs and increase (or maintain) CD4 count, viral load and resistance tests and toxicity monitoring or use more expensive, better-tolerated drugs but reduce (or eliminate) some monitoring.

As Keith Alcorn of NAM writes in his coverage of the DART study at the recent IAS conference: "The results of the DART study are likely to stoke the growing controversy over the best way to monitor HIV treatment in resource-limited settings. In the past year, there have been growing calls to incorporate viral load monitoring into treatment programmes, both in order to detect failure of first-line treatment early and in order to determine whether patients apparently failing treatment on the basis of recent declines in CD4 count are genuine cases of treatment failure. However, trial investigator Professor James Hakim of the University of Zimbabwe told delegates that it would be possible to treat up to one-third more patients with antiretroviral drugs if laboratory monitoring were limited to the use of CD4 counts after the second year of treatment."

Drug costs aside, there are also concerns about the availability of certain drugs and drug monitoring equipment as well as concerns about the additional personnel required to deliver treatment and care as the numbers of people eligible for ART increase, with an increased focus on task shifting.

Again, participants were asked three broad questions and encouraged to debate the issues:

1. What are the benefits and tradeoffs if WHO recommends starting ART earlier and recommends using more expensive regimens?
2. What, if anything, are we prepared to give up in return for earlier treatment, more drug choice and/or better monitoring?
3. Should the WHO guidelines reflect only what is thought possible given the many resource issues, or state the acceptable minimum based on the best and current scientific knowledge and standards?

Although there were fewer participants during the second week of discussion – possibly due to the extremely difficult questions being asked – out of the 20 participants who took part, ten were new to the discussion.

1. What are the benefits and tradeoffs if WHO recommends starting ART earlier and recommends using more expensive regimens?

Responses to this question ranged between optimism and pragmatism. Participants from sub-Saharan Africa were particularly concerned about funding and drug access issues. "The point is that although it is great to get people on treatment earlier, we are having drug stock-outs even for those with CD4 counts of below 200," wrote an advocate from Uganda. "I'm worried that a person having a CD4 count of 100 will not get drugs while we have put on treatment a person with a CD4 count of 300. The inconsistent supply of antiretroviral drugs in our Government's health system is causing us to not do what is right for our people. Three of our major US-funded sites are no receiving more funding and no new patients will be recruited. Our country can't afford those expensive regimes."

"The benefits of earlier initiation have been scientifically proven to help prevent the onset of opportunistic infections," wrote an advocate from Swaziland. "However, in my country only 32,000 of the 68,000 who require treatment based on current WHO ART guidelines are on treatment – a clear indication that as a

country we are failing when it comes to delivering ART services to people. This early initiation would now increase the number of people who are suppose to be on ART and will overwhelm our ARV programme. Already we are told that the Global Fund will reduce funding of our ARV programme by 10%, so how will we manage to put people on treatment early when we are expected to cut by 10%?"

"We in Africa have not even managed to put half of all the people infected with HIV on ART, which clearly improves the lives of PLHIV, with the available 'cheap' regimens, so we cannot start asking for more expensive ones," argued an advocate from Uganda. "It is like asking someone who has failed to get a share of the main course of a meal what they want to have for a desert!"

"Using expensive regimens can't work", added a Malawi advocate. "The expensive regimens are a non-starter."

And yet, many advocates argued that PLHIV activism following the revision of the WHO ART guidelines could make a difference, as it has in the past. "Is it really reasonable to now change our goals?" asked an advocate from France. "Certainly not, and that's why we should do it [i.e. have earlier treatment with more choice of drugs]. From the very beginning of the history of our common fight, we have accomplished mainly unreasonable things." Although, noted an advocate from Thailand, "the pressure on systems in terms of cost and how it could effectively be managed and rolled-out - is kind of a scary thought, yet we see that to address H1N1, for example, money does flow when necessary."

Some argued strongly that it was important to save lives now and worry about paying for it tomorrow. "Definitely earlier treatment is the right approach as it keeps the person healthy," wrote an advocate from Lebanon. "The challenge is to have more generic versions of the new meds at a reasonable price."

"This will cost at the beginning," wrote an advocate from South Africa, "because it will force funding to be found for earlier treatment for more people, but in the long term it will reduce the cost of hospitalisation, reduce TB – especially in sub-Saharan Africa, and reduce maternal and child mortality related to HIV."

"Starting ART earlier is the right choice," wrote an advocate from China. "It keep people living with HIV healthy and ensures our quality and length of life. But this needs support and commitment from the local government and healthcare sectors."

"Starting at 350 can increase attention of governments to HIV in countries with limited resources," noted an advocate from Russia. An advocate from Papua New Guinea concurred: "We need to start people earlier on drugs in order for them to contribute to the countries growth."

Some argued that governments and funders would see the long-term cost-effectiveness of starting treatment earlier with better drugs. "People will live longer and healthier lives, and due to decreased viral load, more infections will be prevented," argued an advocate from the US. "In the long run, this will actually save money. Using this line of reasoning we may motivate countries and more private funders to invest in treatment today, in order to save funding tomorrow."

Recommendation

WHO should be aware that PLHIV will rise to the challenges faced in their own countries should guidelines recommend earlier treatment with more choice of better-tolerated drugs. WHO should argue strongly that such recommendations would be cost-effective, and take the lead in persuading governments to find the funding for drugs, personnel and healthcare infrastructures to deliver such treatment and care.

2. What, if anything, are we prepared to give up in return for earlier treatment, more drug choice and/or better monitoring?

Participants appreciated that, in reality, the question was moot since "this is not a choice that is ours to make." Consequently, many responses were uncompromising. "I am not prepared to give up anything," wrote a Canadian advocate. "Treatment and monitoring to me are one and the same when it comes to improving the health of an individual."

"In a world of limited funding, this is a very hard question," wrote an advocate from the US. "I always think it is best to ask for the moon and be grateful for all that comes our way. If we ask for less, we will receive less."

"Basically, being asked to give something up in favour of something else is asking us to be complicit in 'bigger' political processes that promote global differentials, economic and otherwise. As a global community we should be demanding the moon and demanding it for everyone," added a UK advocate.

It wasn't just advocates from well-resourced countries who felt this way, however. "Not ready to give up anything in return for earlier treatment," wrote an advocate from Malawi. "The drugs, along with better drug choice and monitoring, should be available to all so that our friends that need to start the treatment can have their lives prolonged."

An advocate from China pointed out that PLHIV should not suffer due to the inefficiencies of their governments. "Too much money has been abused. In some countries we need to demand for better relocation of HIV/AIDS grants to support free ART and earlier treatment with better monitoring and more drug choice."

However, those participants who had seen the results of the DART study recently presented to IAS 2009 were ready to consider a compromise on monitoring frequency, if that meant earlier treatment with better drugs could be made affordable. As an advocate from Lebanon noted this often happens anyway: "The patient is often responsible for paying for CD4 and viral load tests anyway, and since it's expensive, most people do it once a year instead of every six months.

"Lab monitoring prices are very high," concurred an advocate from South Africa, "and this results in too few people accessing ART, but it's not the only reason why we will not meet universal access to treatment. This discussion [about monitoring frequency] will help countries to reduce cost to treat more people but maintain quality standard of care."

Recommendation

WHO should be aware that if their treatment guidelines are not harmonised with those in well-resourced countries, they run the danger of being seen to promote global inequalities. Most PLHIV are not prepared to give up anything in return for better, earlier treatment. A minority, however, concede that reduced lab monitoring frequency may be a compromise that is acceptable.

3. Should the WHO guidelines reflect only what is thought possible given the many resource issues, or state the acceptable minimum based on the best and current scientific knowledge and standards?

Participants were of one voice that "the WHO guidelines should be a standard of care that all countries should strive to achieve, regardless of resources." Anything else "permits a differential set of standards which cannot be acceptable."

Regardless of the situation in their own country, participants were unanimous that the guidelines should reflect the best, current scientific knowledge and standards. "Coming from a resource-poor community," wrote an advocate from Kenya, "I feel that issues of care and treatment should not be negotiable. Equal standards should be set for all governments. Aiming at this goal would be a good assignment for such governments." An advocate from Lebanon added: "WHO guidelines should reflect the best rather than simply reflecting what is thought possible, provided it also helps our governments change their perceptions."

"Clinical need of what is best for the 'patient' should always take precedence over a notional economic scarcity argument," stated an advocate from the Netherlands. "I say notional because I seriously do think that if there is the political will then the money can always be found. To accept sub-optimal treatment regimes does not make good economic sense and does not serve the public health: if we give too little, too late, then people will continue to opt out of testing, thinking that they don't need treatment, and continue to think (with some justification perhaps) that it is the ARV's that are causing people to get sick."

Recommendation

WHO guidelines should be based on the best, current scientific knowledge, focusing on a standard of care that all countries should strive to achieve, regardless of resources.

Week 3: Positive Health, Dignity and Prevention: how important is a human rights-based approach to treatment when used as a prevention tool?

The aim of Week 3's discussions was to discuss what PLHIV thought about the use of treatment as prevention. Participants were informed that WHO is currently examining the impact of antiretroviral treatment (ART) on prevention, since it is known that ART significantly reduces (but does not completely eliminate) the amount of virus in our bodies, and so reduces the possibility that we are infectious to others. They were aware of the concept that reducing the viral load of a country's population could help with prevention, and so making sure that everyone who needs ART gets it might go a long way towards preventing new infections. However, they were also aware that WHO does not currently support providing this information to people living with HIV to prevent transmission on an individual level primarily because knowledge about individual risks is still incomplete.

One of the stated relevant outcomes of the WHO treatment guidelines is the reduction of HIV transmission although 'treatment as prevention' is not currently WHO policy. Nevertheless, more radical ideas about how ART might be used for prevention, such as universal testing and starting ART immediately at diagnosis, are currently being explored by the research community and by WHO.

At the recent GNP+/UNAIDS technical consultation on Positive Health, Dignity and Prevention HIV advocates discussed how this more radical approach could have a major impact on people living with HIV. On the one hand, a policy of 'treatment as prevention' might allow many millions more to obtain earlier access to treatment and care, and even get close to eliminating new infections. However, undertaking such an approach could be problematic from a human rights standpoint: could universal testing and treatment threaten our right to choose if, and when, we want to start treatment? Is it also a human right to know your HIV status and to be able to access treatment?

Given these issues, participants were asked to consider whether a policy of 'treatment as prevention' is in our best interests, and specifically the following three questions:

1. How important is the link between treatment and prevention?
2. What should the WHO guidelines say about treatment and its role in prevention?
3. How relevant are human rights concerns in settings where there is no universal access to treatment?

Week 3's theme proved to be popular, with 31 participants taking part in the discussions, of whom 15 had not previously posted in Weeks 1 or 2.

1. How important is the link between treatment and prevention?

Participants strongly agreed that the link between treatment and prevention is extremely important and that the two "should be seen as a continuum and not a dichotomy."

They noted treatment's effect on:

- Infectiousness, on both a population and individual level;
- Incentives to test, since untested people play an important role in new infections;
- And improved safer sex skills and safer behaviours of PLHIV accessing treatment and care.

Participants also highlighted that personal knowledge regarding the effect of treatment on transmission:

- Can be an incentive for better adherence for people on treatment and therefore better health;
- And makes it easier for PLHIV to start and maintain relationships.

However, they also agreed that 'treatment as prevention' should not take away the focus from a broader approach to prevention. "Since prevention is not just a scientific or technological intervention, prevention must also address structural power imbalances in society, such as gender inequities, gender violence and poverty." (UK advocate)

Continuum, not dichotomy

"Treatment is an important element that makes our prevention efforts work. If there is no treatment, prevention is not realistic," wrote an advocate from China.

Treatment and prevention "are as linked as the two sides of a coin," noted an advocate from UK. "They must never be disassociated," concurred an advocate from Brazil. "Treatment cannot be thought about without prevention and vice-versa."

"Separating prevention from treatment leads to a fictitious polarisation between those who have HIV and those who don't: the villains and the victims," wrote an advocate from the Netherlands. "Integrating prevention and treatment will better reach the great majority of people living with HIV: those who do not know they have it! Indeed by integrating budgets on prevention and treatment both programmes in one will be more effective."

"I believe that there should not be one without the other," wrote an advocate from Jamaica, "and I strongly believe that one should not be treated less than the other. In my country the National AIDS Programme concentrated so much on prevention for people who were not yet infected that people who were already infected were left out and pushed to the back burner. A multi-disciplinary approach is required when working out treatment and prevention for both infected and uninfected persons."

Effect of treatment on infectiousness

"I see a great link between prevention and treatment," wrote an advocate from Algeria. "If one is undetectable there is a chance the treated person does not infect others, and women could not have a child without prevention and treatment, so they are the same thing for me." *Moi, je vois qu'il ya un grand lien entre la prévention et le traitement ci en as dépisté plus tout en la chance de se traité et ne pas contaminé les autres et pour la femme encante pour quelle peura avoir un enfant san la prévention et le traitmant si parce que la même choue pour moi.*

Participants cited studies and statements from global experts regarding the effect of treatment on infectiousness and transmission. "Professor Montaner, the President of the International AIDS Society, stated that there is enough scientific evidence to tell policymakers that 100% ART will decrease infection rates, and this has been shown in countries like Taiwan, for example, where infection rates fell by more than 50% after ART was introduced," noted an advocate from the US.

The recent paper published by WHO members of staff in *The Lancet* exploring the potential impact of universal voluntary HIV testing followed by immediate ART irrespective of clinical stage of CD4 count was endorsed by some participants, including an advocate from Kenya. "Universal treatment is paramount if prevention strategies are to be successful. PLHIV should be in the forefront demanding for universal access to treatment." "In my mind treatment has to be seen as a tool in prevention," added a South African advocate. "Given that we are unlikely to ever get 100% behaviour change then this is an invaluable asset in the prevention toolbox."

Not everyone was convinced about ART's role on infectiousness, however. "I don't personally associate being on treatment as being linked to prevention," wrote an advocate from Canada. "As long as you are HIV-positive, you are still infectious!" And an advocate from Panama added, "I am really concerned about the spread and poorly understood fact that a low [viral load] means automatically there is no possibility of infection. I think there are alternatives to consider before you determine without doubt that this is so."

Others argued that one cannot rely on treatment alone as prevention and that it would be better to treat based on clinical need than for public health reasons. "We can't rely on treatment alone to stop this epidemic, but need both treatment and population-wide prevention," wrote an advocate from the UK. "People who have

been recently exposed and are at their most infectious will in most cases not be aware of their infection and so universal treatment will have no impact on this transmission dynamic - which becomes more important as more people who know they have HIV get tested and treated. We also must take into account that up to 75% of those with HIV don't know, or have no means of knowing, their status, let alone getting access to reliable treatment with a second-line back up. So, we need to continue with prevention activities, and offer *treatment as prevention* on the basis of need. There will be an effect on transmissibility, and that's terrific, but the primary reason for rolling out treatment should be the health promotion needs of PLHIV. If we had the choice of just enough money to pay for first-line regimens for all (irrespective of CD4 count); or first-line plus second-line back up for all those with a CD4 count below 350, which is the ethical choice? In my view, it's the latter, backed up with good, effective, community-led prevention and anti-stigma activities."

Treatment as an incentive to test

"Treatment is key in prevention because in communities where PLHIV are on treatment and their quality of life has improved, many other people will seek to be tested knowing there something that can be done for them if they are found to be HIV-positive," writes an advocate from Uganda.

Ensuring good access to treatment is a key element to prevention, noted an advocate from Lebanon.

"Treatment and prevention are dependable on each other. You can't have good prevention unless the treatment is good. In countries where shortage of medicines is a chronic problem and treatment is barely available then prevention measures will fail."

Treatment as prevention of illness

Advocates also argued strongly that 'prevention' is far more than simply prevention of HIV transmission.

"Treatment is not to just about avoiding infection but, to avoid two developing HIV sickness and death," wrote an advocate from the Ivory Coast. "So we live normally, have sexual partners, have children – have a normal life."

An advocate from the Netherlands continued this theme. "The link between treatment and prevention is an obvious element of the dynamics of prevention for and by people living with HIV. Irrespective of the term used, the building blocks of a 'positive prevention' approach (promotion of human rights, involvement of people living with HIV, embracing shared ownership and responsibility, and recognition of diversity) aim to proactively address the sexual and health needs of people living with HIV."

Recommendation

WHO should be aware that PLHIV in every setting appreciate and understand the link between treatment and prevention, and in particular the potential effect of ART on infectiousness, on both a population and individual level. WHO should highlight that access to treatment will result in population-wide prevention benefits, through reduced individual and population infectiousness; increased incentives to test; and improved safer sex skills and safer behaviours of those PLHIV accessing treatment and care. Biomedical approaches, and prevention focused solely on diagnosed individuals, must be seen as part of a broader prevention strategy that highlights structural power imbalances in society, such as gender inequities, gender violence and poverty.

2. What should the WHO guidelines say about treatment and its role in prevention?

Participants strongly advocated for WHO to highlight and clarify the role of treatment on prevention based on many of the reasons discussed above, and, in particular, to:

- Ensure universal sustainable access to timely ART in order to prevent illness and promote wellness;
- Encourage undiagnosed individuals to know their status;

- And to reduce infectiousness on an individual, as well as a population, level.

"The recent indications that antiretroviral treatment might be used as prevention should encourage WHO guidelines authors to expand access to ART because the more you treat now, less virus will be circulating, fewer people will be infectious and then you would reduce the need for treatment later," stated a French advocate. "Monitored, successful treatment prevents HIV," noted a Kenyan advocate.

However, whilst calling for WHO to acknowledge and to clarify ART's role in reducing infectiousness, participants also agreed that WHO should state that treatment alone can only be part of an overall prevention strategy that must address those without, as well as those living with, HIV.

"WHO should make clear that prevention must be viewed at all its levels – primary, secondary and tertiary. This will help policymakers at various national co-ordinating committees to create candid and solid prevention guidelines that address prevention issues and challenges at each level," wrote an advocate from Kenya.

Treatment to prevent illness

An advocate from Peru wrote that the guidelines should use the principle of 'treatment as prevention' to achieve the best possible outcome - to allow more countries to gain access to ARVs. He added that the guidelines should also talk about ensuring access to lower priced drugs through restricting patents or trademarks to allow for generics, and push for policies that provide incentives for research into new drugs or vaccines and clinical studies that help define appropriate care regimes in order to improve patient quality of life, such as reduced side-effects. *"Referente a las directrices que tenga a bien emitir sobre Tratamiento como prevención, creo que lograr que mas paises logren el acceso a los ARV será nuestro mejor logro, y es sobre este tema creo yo el principal. Otras directrices podrian ser acerca de lograr que se accedan a precios menores los medicamentos de marcas o con patentes que tengan restricciones para obtener copias (medicamentos Genericos). Que se impartan politicas para incntivar la investigación de nuevos medicamentos o vacunas y su vez tambien estudios clinicos para un adecuado regimen de atención de aplicacion en los pacientes sobre medicamentos ARV (efectos secundarios)."*

"The guidelines should stress the need for universal access to treatment as a key driver for prevention and the need to ensure universal access for all in all communities," wrote an advocate from Kenya. "WHO should give treatment first priority because it's the base for everything," concurred an advocate from Lebanon. "You can't build a building without a good foundation or base. Universal treatment is crucial."

"Sustainability of treatment when someone has begun ART must be ensured because one of the commonest causes of poor adherence to drugs is stock-outs of all or some of the drugs," argued an advocate from Uganda. "In many of our communities where treatment literacy is low PLHIV may be forced to take half doses or miss some doses in order to 'stretch' the drugs over a longer period. This will certainly lead to resistance and drug failure and should such people pass on the virus to others through whatever means, ARVs will not work on them. At the moment, PEPFAR and Global Fund moneys that are running most of the ART programmes in poor countries have levelled off. With no increase in funding, sustainability for those already on ART is hanging in the balance and yet at the same time no new PLHIV can be put on ARVs! The new treatment guidelines should address this and help or make all governments to have sustainability plans."

Treatment to promote wellness

"If there is a more holistic approach to treatment, there will be more general recognition that HIV is not just a bio-medical problem, but has to be addressed across many different sectors and levels of societies," wrote an advocate from the UK. "If treatment is approached holistically – rather than simply being about providing ART – then this will be promoting prevention. Studies have found that increased care and support increase both ART adherence and condom use, and therefore our bodies become less able to transfer the virus to others. If our mental health is adequately supported, more of us will be able to stand up in public and talk about what has happened to us and more people who are currently negative will be able to learn from meeting

us and feel more ready to try to remain negative And if treatment and care also provided good access to sexual and reproductive health (SRH) information, care support and supplies, then there would be fewer positive women finding themselves pregnant without wanting to be, and being able to access more choice over when they want to have a child, and feeling confident and happy that they can have their children in safety and with full support of all around them - better for them and for their - HIV-negative - children."

ART as prevention

"WHO needs to reinforce the fact that ART is effective and that it can help reduce the risk of transmission," stated an advocate from South Africa.

An advocate from Australia argued that WHO should recommend viral load testing in order to ensure that individuals know when they have undetectable viral loads. "If 'treatment as prevention' initiatives go ahead, then it seems to me even more important that access to VL testing becomes standard, otherwise there will be significant gaps in knowledge of personal risk," he wrote.

An advocate from the UK argued that WHO should trumpet ART's effect on transmission. "If there was wider knowledge by the general public that PLHIV on treatment are much less infectious that can play an important role in challenging stigma," he wrote. "Less stigma would increase capacity for prevention by allowing PLHIV to be more open about their status within sexual relationships and negotiate safer sex."

An advocate from Canada, where there are many criminal prosecutions for HIV exposure following non-disclosure of HIV status, suggested that WHO is both clear about the role of ART on infectiousness, and about the equal responsibility of both parties for the prevention of transmission. "WHO guidelines in terms of treatment and prevention should be well-balanced, clear and precise to ensure that there is no room for misinterpretation, especially with so many criminal charges being brought against people living with HIV/AIDS," he wrote.

Treatment as part of a wider prevention strategy

"WHO must acknowledge and make a strong statement that treatment alone is not a prevention tool but only one piece of the overall strategy that one must undertake in preventing the spread of HIV," wrote an advocate from Canada. "I believe that WHO can make the statement that treatment and prevention go hand in hand provided that all other elements are in place to support it."

"There is evidence to suggest that early and widespread treatment coverage will have a very cost effective and direct correlation in reduction of infection rates," wrote an advocate from the US. "But guidelines should also note caution that while treatment may reduce infection rates, it isn't 100%, there are still questions and debates going on about this, and that any policies and statements should be framed in a way so that people aren't given the impression they don't need to continue with other prevention practices (e.g, condoms)".

Recommendation

WHO should clarify ART's role in reducing infectiousness on an individual as well as a population level in order to ensure universal sustainable access to timely ART; encourage undiagnosed individuals to know their status; reduce stigma; and to help individuals understand their personal risk. WHO should also make it clear that treatment alone can only be part of an overall prevention strategy that must address those without, as well as those living with, HIV.

3. How relevant are human rights concerns in settings where there is no universal access to treatment?

Participants unanimously agreed that, "a human rights-based approach to health-related issues is of the utmost importance" and the "universal foundation of the response to the epidemic."

"The importance of human rights in the response to the epidemic is not just a 'moral' issue," wrote an advocate from the UK. "There are numerous evidence-based studies which show that programmes rooted in a human rights approach give better results. Human rights are particularly crucial when supporting marginalised populations, such as people who use drugs, people in prison, people who sell sex and men who have sex with men. Those groups experience several barriers to access treatment and prevention because they are discriminated on several grounds. A human rights approach can also ensure that those of us who belong to such groups have access to appropriate treatment and prevention programmes."

Another advocate from the UK highlighted that "the only potential problem is that some commentators in low- and middle-income countries have rejected the notion of human rights on the alleged grounds that human rights are a Western conceptualisation (and hence to be resisted)." He noted, however "that human rights do not necessarily look the same everywhere, but take on a local inflexion."

Regardless of setting, participants from Algeria, Brazil, China, Kenya, Ivory Coast, Iran, Lebanon, Malawi, Panama, Uganda and Venezuela agreed with a South African advocate who wrote that, "'treatment as prevention' has the potential to restore the human dignity and health of people living with HIV because it will give us an opportunity to be treated as early as possible – as long as all countries respect the International Human Rights Declaration as a framework to change the conditional or environmental barriers that prevent people accessing health services due to coercion, or being forced to test, or their being criminalised."

"Testing and treatment should always been done with the consent of the person involved and a human rights approach can ensure this," concurred an advocate from the UK.

Finally, participants agreed with the suggestion from a South African advocate that WHO should plan "a feasibility and acceptability study" into the concept of 'treatment as prevention' as a way of scaling-up universal access to treatment "to check how this tool could be sustainable given the current human rights abuses of PLHIV."

Recommendation

WHO should ensure that a human rights framework forms the foundation of their approach to 'treatment as prevention' as a way of attempting to achieve universal access, and that a study on the feasibility, acceptability and sustainability of such an approach is necessary.