Discussion forum on option B+ with civil society leaders
Report of a conference call
30 November 2012

Chair: Kate Thomson (UNAIDS)
Facilitator: Georgina Caswell (GNP+)
Participants: Anna Zakowicz (GNP+); Teresia Otieno (ICW Kenya); Lillian Mworeko (ICW East Africa); Joyce Kamwana (COWHLA); Alice Welbourn (Salamander Trust); Lucy Ghati (NEPHAK), Beri Hull (ICW Global)
With input from: Silvia Petretti (Positively UK), Angelina Namiba (Positively UK), Olive Edwards (Jamaican Network of Women Living with HIV), Susan Paxton (Living Positive Victoria; Asia-Pacific Network of People Living with HIV)
Note takers: Amy Medley (CDC), Sonia Haerizadeh (ICW)

Overview of purpose of call

The World Health Organization (WHO) approached the IATT PMTCT’s Community Engagement Working Group to document the various viewpoints among women living with HIV on option B+ so these views can help inform the development of their consolidated ARV guidelines. Both ICW and GNP+ sit on the IATT Community Engagement Working Group and see this as an important opportunity to influence the ARV guidelines process. Although there are other consultations currently taking place around the consolidated ARV guidelines, some of which touch on option B+, this teleconference was a real opportunity to document the various viewpoints of women living with HIV in one place.

1. In your view, what are the main benefits and advantages of option B+?

(1) Health of mother and child

- Mothers’ and babies’ health has improved. Before, mothers used to give birth to sick babies, which led to high infant and maternal mortality. With treatment, infant and maternal mortality due to untreated HIV infection will be reduced (Malawi).

(2) More accessible and easier to implement than options A and B

- Women are able to access B+ very easily because, with other options, they need to test for CD4 count. In remote settings, this is difficult because they may not have a CD4 machine or they have to wait for results from the central laboratory. This causes a delay in initiating women on treatment. This delay can be eliminated by allowing providers to start women on treatment upon diagnosis. It also means that ART can be initiated at lower-level health facilities, which may be more accessible to women. Option B+ can be administered in all of the centres (Kenya).
- In terms of operational issues and health care systems, B+ is easier in terms of initiation and task shifting to lower levels (Denmark).
(3) Less fear of resistance
- Some women were afraid that they would develop resistance if they started and stopped treatment like they did with other PMTCT options. Women no longer fear resistance from intermittent treatment because, with B+, women are put on treatment for life (Kenya).

(4) Psychological benefits
- Psychologically, internalizing the whole idea of when to start treatment is easier when you know the course – that you will be on treatment for life if you are HIV-positive and pregnant (Denmark).

(5) Better for women in communities where they have a lot of children
- When a woman has more children (4, 5 or 6), getting on and off drugs is more difficult then staying on ART, especially when the time between children is short (Denmark).

(6) Reduction in stigma and discrimination
- Because women are put on treatment while their CD4 is fairly normal, they do not get to a point where they look sickly and people cannot tell that they are HIV positive. This reduces stigma and discrimination, because it is very hard to tell just by looking at someone that they have HIV. Before, when we went by CD4 count, one would be put on treatment only after their health had deteriorated (Malawi).
- This is also true because tenofovir regimens, which used to create a lot of side effects including physical deformities, have been replaced with drugs that have fewer side effects. They are putting women on 5A with option B+, which doesn’t cause physical deformities so it’s harder for people to tell you are HIV-positive. This also reduces stigma and discrimination because you can’t tell that women have HIV by observing deformities attributable to HIV treatment medications (Malawi).

(7) Reduction in the MTCT infection rate
- In Malawi, the MTCT infection rate has decreased by 73% (Malawi).

(8) Treatment as prevention in discordant relationships
- B+ is basically treatment as prevention so it minimizes the risk of transmission to partners, especially for women in serodiscordant relationships (Denmark).
- There may also be a psychological benefit for women to knowing that their risk of passing HIV on to their sex partners and infants is greatly reduced. It may lift a burden for them (Switzerland).

(9) Women are happy to be taking action to protect their baby from HIV
- While standing in the immigration line in Jamaica, I saw a group of doctors on the way to a HPV conference in Puerto Rico. I had a chat with one and she said her clinic was using option B. The women were taking up the option and there was a group that even had T-shirts that said “I am HIV positive but did not pass it on to my baby”. She said the guidelines are useful so that when countries were not doing what was needed there was some reference to hold government to and that the women could always refuse to take up the offer (Jamaica).

2. In your view, what are the main risks and disadvantages of B+?

(1) Human rights violations: involuntariness and lack of confidentiality
• Mixed feelings about option B+ from people who look at it from a human rights perspective; they see option B+ as a potential violation of a woman’s right to make voluntary decisions about her own health care if HIV testing and ART initiation become mandatory for pregnant women (Uganda).

• Women aren’t given many choices to say whether they want option B+ or not. It is just being imposed on them. If you are pregnant, you go to get tested, and if you are positive you are put on treatment for life (Malawi).

• It is not an option. Call it a regimen, because for so many women it is not an option. It is mandatory testing. It is not voluntary. There is no confidentiality. To call it an option is rubbing salt into the wound (United Kingdom).

(2) Lack of information to beneficiaries of B+
• Women are not given much information on what option B+ means and are not given much choice around whether to test for HIV, and if positive, whether to start ART. You need proper information to make an informed choice on whether to start treatment for life. Women are not always given this information (Malawi).

(3) Risks relating to sustainability and equity in countries with ART waiting lists
• Policy-makers have expressed concerns about the sustainability of option B+ given current resources. Others can’t be on treatment because there are not enough ARVs to go around, but we have women with CD4 counts of 1000 going on treatment. How are we going to sustain option B+ in countries where we already have long waiting lists for ART initiation? How will we balance the need to start all pregnant women regardless of CD4 count on ART with the need to offer ART to people who need it for their own health (Kenya)?

(4) Inequity in treatment access between couple members
• You are talking about a family – a man and a woman – and you are promoting male involvement. The concern is that a woman has a high CD4 count and a man’s CD4 is low and the man is waiting for any opportunity to be enrolled on treatment and the woman is enrolled on treatment just because she is pregnant. This is discrimination against the man and reduces his ability to access services that he is longing to access. We bring our partners to antenatal care and the woman is enrolled on treatment and the man is not. This may cause the woman to feel guilty that she is receiving ART while her husband and children, who may be sicker, are not receiving ART. How will this affect their relationship (Uganda)?

• Option B+ may cause conflict within women’s relationships. What effect will this have on the woman’s safety (United Kingdom)?

(5) May cause ethical dilemma for health care providers
• B+ forces health care providers to make tough decisions on whom to initiate on ART. One person needs treatment based on their CD4 count and the other person doesn’t need treatment because of a high CD4 count. But because of the policy, they will have to enrol the pregnant woman on treatment and not others (including her husband) who may have a lower CD4 count (Uganda and United Kingdom).
(6) Food security
- People need good food to eat before they can start taking ARVs. Right now so many are too ill and sick to start taking them. Some people don’t even need ARVs to raise their CD4 counts; they just need good nutrition. We are always trying to find biomedical magic bullets, but none of the conversation is about what is going on with basic rights to food security and its links to intimate partner violence. This isn’t on the agenda and it needs to be there (United Kingdom).

(7) Enrolling women on treatment without testing CD4 is not necessary
- People are promoting B+ because we don’t have CD4 counters, but actually new research shows that there are point-of-care CD4 test pens available at US$ 10 each and they are ready to be rolled out. If we have somebody like Gates or Clinton investing the money they could be available to very remote settings, thereby saving at least US$ 90 per annum on the ARV budget for each woman (if generic drugs cost US$ 100 per woman per year). Anywhere that we can have ARVs, we can have CD4 counters. So the argument that we have to have blanket ARVs for women for life because CD4 counters are too expensive doesn’t hold. (United Kingdom).

(8) The programme is not economically smart
- If someone is above CD4 350 cells/mm$^3$ and doesn’t need to start ARVs and their husband or children have low CD4 counts and do need the medication, the money should be spent on putting the husband and children on ARVs. Use the money that we would have spent on option B+ to invest in programmes around negotiation of condom use and to purchase male and female condoms because we know they are proven to work (United Kingdom).

(9) Mental health of women
- Women will go home and she can see her partner and children are sick and she is not likely to be feeling that sick and she has to deal with the guilt (United Kingdom).
- We all know it is a big decision to start on lifelong medication. It doesn’t work simply like that – just starting treatment right away at the same time as you are diagnosed. These are huge life-changing issues, both the diagnosis and decisions following the diagnosis (United Kingdom).

(10) Adherence
- She is likely to be experiencing some kind of side effects initially and it’s easier to cope with side effects when you know that you really need the medication. It is very difficult to start taking ARVs when you aren’t feeling sick and the medication is what makes you feel sick (United Kingdom).
- As much as the women are told they need to continue taking ART after they give birth, they will not see the need for continuing after delivery (Kenya).

(11) Resistance
- Look at TB and malaria drug-resistant strains and superbugs caused by not finishing antibiotics courses. Is resistance build up to ARVs through less than full adherence any less likely? (United Kingdom).
• One of the things we’ve been told is, if you start treatment earlier, you have to get to second- and third-line treatment earlier. We know that in Africa, we don’t have easy access to second- and third-line regimens (Kenya).

(12) Concerns raised about contradictory messaging
• We have invested a lot into treatment literacy and the negative effects of long-term treatment (resistance, etc.). Now we are telling women to take ART forever even if their CD4 is very high. Young women are particularly concerned about this. How will we ensure that people move away from their assumptions about taking ARVs for life? (Uganda)
• The messaging should be that we’re investing in women. Through this investment in health, we’re also strengthening the role of women in the community. But it’s difficult because then men are excluded from the equation (Denmark).

(13) Concerns around disclosure and gender-based violence
• We are sending a young woman home with a new baby and medication that she needs to hide because she’s terrified about in-laws finding it and even faces gender-based violence. Is the health care system going to be held accountable for this? Putting young mothers in this situation without making sure that there is a safety net in the community is like asking her to walk into the jaws of the lion. I don’t think anyone is putting any consideration on gender-based violence and the consequences of this (United Kingdom).
• It could lead to domestic violence, and the challenge is how do we bring men on board (Uganda).

3. Do you think the benefits of option B+ outweigh risks? If so, how and if not, why not?

(1) Yes, the benefits outweigh the risks because of lower risk of opportunistic infections
• We need to go with the scientific evidence. When our women are empowered and are able to understand the benefits of early ART initiation, it is the better option. We know that it has an advantage on TB, which is a huge risk for women living with HIV. Women are able to go about their business, and B+ means that less people are hospitalized because of opportunistic infections (Kenya).
• NOTE: Others disagreed with this point
  i. In the United Kingdom, few people living with HIV are hospitalized because of opportunistic infections, so this point may not be relevant in some settings (United Kingdom).
  ii. There is not a lot of scientific evidence on when to start treatment. There is still a lot of debate in the scientific community on the benefits of starting treatment at CD4 counts of 500 cells/mm$^3$ and above (United Kingdom).

(2) It depends on country context
• Context is the critical thing. If there is universal access to ART, food security, good health care systems, continuity of distribution, etc. then it is a different situation and might then be better for the woman (United Kingdom).
• Option B+ is just being rolled out in certain provinces where there is the highest prevalence, and I don’t think that sounds right (Uganda).
(3) Needs better implementation and information

- It is important to have all the players in society involved (not only at the health care system level), because if we don’t have what we need to support a woman in treatment it is very difficult (Denmark).
- We must invest in community follow-up and make sure there are other people in the community who are motivated to follow up on the women to make sure that women always come back to care (Kenya).
- Must have task shifting. If one health worker is mandated to test, give counselling and give medication, then the quality of services decreases. If other staff take on some of these tasks, the care will be better (Kenya).

(4) It is unclear – there are too many unknowns about adherence, resistance and side effects associated with long-term ART

- My major concern is the impact on young pregnant women. Being diagnosed during pregnancy is hard enough. Taking ARVs during pregnancy is literally sickening. But to put young healthy women on ARVs for life is very challenging. As well as all the other issues mentioned, it would need greatly increased counselling on treatment literacy, which is just not going to happen because of the lack of person power. So, women will go away confused or with too little information, and it is highly likely that adherence will not be good. So, as women have said, she loses out in the long term, since there may not be other ARV regimen options, plus she has drug-resistant HIV. If this woman manages to be adherent, there is then the issue of long-term side effects, and we simply do not know the outcome of a person who takes ARVs for decades, since we haven’t yet got to 20 years of triple combination therapy. I am one of the lucky ones – I am still on first line after 13 years, and I thought I have no side effects, but after two broken bones in two years, I discovered I have severe osteoporosis with high risk of spinal fracture. That is after 13 years. Maybe it would not happen if I were younger, but we simply do not know. So my concern is for the health and well-being of young women and heading down a path that we really don’t know where it will ultimately lead (Australia).

4. In countries where B+ is being implemented or being considered, what requirements or key conditions must be met before implementation?

(1) Address gender-based violence

- Gender-based violence is a parallel pandemic, and there is no discussion of how health care workers are trained to bring up this issue with women and no accountability of health centres if gender-based violence happens at home as a consequence of this roll-out (United Kingdom).
- Human behaviour must be addressed, male violence, fear of disclosure, rejection (Jamaica).

(2) Less stigma in health care settings

- You never hear men being told off if they have HIV and want to have babies – and yet there is increasing documentation about women being stigmatized if they are HIV-positive and get pregnant (United Kingdom).

(3) Ensure the 3 C’s of HIV testing are maintained under option B+. 
WHO/HIV/2013.46      © World Health Organization 2013

• This means that the test is voluntary (consent) and includes counselling (United Kingdom and Uganda) and that the woman’s confidentiality is maintained (United Kingdom and Uganda).

• Informed consent cannot begin and end with the first or second clinic visit (Jamaica).

(4) Integrate other important services, including sexual and reproductive health and TB/malaria with ART and antenatal care to create a one-stop shop and improve women’s access to these services (United Kingdom).

(5) Ensure universal access to ART to address equity issues (United Kingdom).

(6) Health care workers must be motivated and paid well (Uganda).

(7) Address implementation concerns, including making sure that providers are trained, women are given adequate information and their human rights are respected, supply chain issues are addressed, etc. (Kenya).

(8) Ensure that communities and women living with HIV are involved in the implementation and monitoring of option B+. Women living with HIV need to be involved at all levels and not just as community peer educators. There should be stakeholder groups that include women living with HIV to review and monitor implementation of option B+ and suggest relevant adaptations for the context (United Kingdom).

(9) Condom use promotion and distribution must also be maintained. I fear we will lose the prevention successes that have already been accomplished if we just adopt option B+ and forget about other prevention interventions (United Kingdom).

(10) There must be guidelines to ensure a standard is available for monitoring, measurement and advocacy.

• The use of guidelines by programmers and implementers requires the involvement of other stakeholders such as counsellors, women and other people living with HIV, civil society organizations and individuals involved with mediation and resolution (Jamaica).

• The role of peer mentors, social workers, partners and family members should be included in the guidelines preamble and in country strategic plans (Jamaica).

5. There may be conflict or confusion in pregnant women starting ART for life, regardless of CD4, while others in the general population are starting ART at a CD4 count of 350 cells/mm³ (or perhaps even 500)? What does this mean for messaging within the community?

(1) Concerns around the question itself

• Some participants did not like the question, since it implies the decision to move towards option B+ has already been made.

(2) Treatment must benefit the person taking it.

• Treatment must benefit the person taking it first, and then the other benefits can be taken into account. We can’t turn women into the “pig in the middle” where she is blamed for taking medication (if resistance develops or for other reasons above) and blamed for not taking
medication (if her infant or partner acquires HIV). At least with condom programmes, there is an understanding that prevention is a joint responsibility (United Kingdom).

(3) Treatment for life may be a difficult message for young women
- A lot of money has already been spent on treatment literacy to educate women on how long to take treatment, when to start, etc. Now we are changing the message to be take treatment for life when you are diagnosed. Young women, especially, might not be receptive to this message because of concerns around how treatment will affect their body. They want to remain pretty (Uganda).
- This very same issue came up with a focus group discussion we had with young women with HIV. None of them wanted treatment for life. Many were opting for treatment holidays because they were scared of long-term effects. However, they were afraid to tell their providers that they were taking a medication holiday (Switzerland).

(4) Messaging should be that we’re investing in women and should include men
- From the positive side, the messaging should be that we’re investing in women. Through this investment in health, we’re also strengthening the role of women in the community. Then when you think of equity issues, such as women not part of family planning, it’s pretty difficult because the men are excluded from the equation (Denmark).

(5) Need to make it clear how ARVs work in the body and ensure adequate information about HIV and ARVs reach communities
- I don’t like treatment for life. I’ve wanted to take drug holidays for the mental ease in the past. But one thing that would be helpful to understand is how HIV and ARVs work in the body. One of the reasons they start people on treatment earlier and earlier is that untreated HIV causes many inflammatory conditions that get worse when you’re not on treatment. For example, if you have gum disease and you’re HIV-positive, when you are not on ARVs, those chronic conditions accelerate. I don’t think people are aware of this. I experienced this first hand. That’s why I don’t take drug holidays anymore. If this information is accessible, it may encourage people to be on treatment for a long time (United States).

(6) Address women’s concerns about moving to second- and third-line regimens and clearly explain why they need to start treatment earlier.
- One of the things we’ve been told if you start treatment earlier is that you get to second- and third-line treatment earlier. We know that in Africa, we don’t have easy access to second- and third-line regimens. Also, the fear of resistance. That’s what makes people feel that they should start treatment early (Kenya).
- Women may also wonder why they should start early if others in their family start at CD4 >350 cells/mm$^3$. We have to answer their questions around why they should start earlier (Uganda).

(7) We need to consider disclosure and gender-based violence in our messaging.
- The issue around disclosure. Sending a woman home with new baby and medication that she needs to hide because she’s terrified about in-laws finding it. Carrie Foote’s friend in the United States who is an obstetrician recommends a medication holiday immediately after giving birth because of all the other things going on for a young new mother. When we’re talking about resource-poor settings, sending her home and she is terrified and even faces gender-based violence ... Who is going to pick that up? Is the health care system going to be
held accountable? Option B+ is irresponsible without putting safety nets in place beforehand. I don’t think anyone is putting any consideration on gender-based violence and the consequences of this (United Kingdom).

- In the Homerton studies about gender-based violence, it was shown that being pregnant is correlated to the risk of gender-based violence. Putting pregnant women on ARVs may make it even more dangerous for them because it makes it more difficult to keep their confidentiality (United Kingdom).
- There is a WHO report which shows that gender-based violence is higher during pregnancy worldwide – without HIV being present at all (United Kingdom): http://www.who.int/reproductivehealth/publications/violence/rhr_11_35/en/index.html

6. While this might not be true, the current impression is that civil society leaders in the North tend to be more skeptical of B+ than civil society leaders in the South? Is this a fair generalization? If true, can you help us understand the reasons for this dichotomy and key issues that should be addressed to harmonize viewpoints?

(1) We are all women living with HIV that bring our own experiences to the table but we learn from each other.

- We are all women living with HIV, but we cannot be seen to be homogeneous. We have a history in terms of the regions that we come from. But we also have a history in terms of understanding issues, especially from the human rights perspective. So, the difference in how we look at things can be related to that. There are going to be differences because where I come from, we are more disadvantaged, and it makes us more likely to take it in any way, however it comes (Uganda).

(2) Women in resource-limited settings are grateful for opportunity to have improved access to ARVs

- Women from the North have not experienced what it feels like to be on a waiting list. Where I’m from, there are 200 000 people who need to be put on medication and there aren’t resources to reach them. When we hear that B+ is a better option and you don’t have to be on a waiting list of 200 000, why not take option B+, which allows me to take treatment as soon as I want (Kenya).
- You may not get to start on treatment when you want because ART initiation is done by health care providers. So you will be put on treatment whether you want or not, or whether you understand the implications or not (United Kingdom).
- I’m not sure, but I was told that people in the North, as soon as they test positive, they are put on medication (Kenya).
- Not true that as soon as you test positive, you are put on medication (United States).
- In England, women and men are put on medication when their CD4 falls below 350 cells/mm³. But my doctor told me to not start until below 200. Now mine is up to 800 and I have an undetectable viral load. I am fortunate to have good support from my doctor and family and I have good nutrition – but 350 isn’t necessarily the magic time for ARVs to start. There are all these other factors at play also (United Kingdom).
(3) Concerns raised about whether this question was meant to divide the community

- I respect your positions. I know that when you’re in a dire situation, the last thing you do is bite the hand that feeds you. And we’re incredibly lucky in United Kingdom because we have free health care ... I feel that WHO and United Nations people do a divide-and-rule thing. What are the human rights issues with option B+? How come it’s not acceptable that we continue to have confidential testing? We are often told that women in the South aren’t complaining, why are you complaining? (United Kingdom).

- We should continue these types of forums so we can share our views with each other (United Kingdom).

- It is important that we not get pitted against each other. Clearly we have a lot of agreement around choice, equity, community support, having the basics in place, providing women with clear information and the need to strengthen human and community systems. We must draw out our commonalities but also respect our differences (Switzerland).