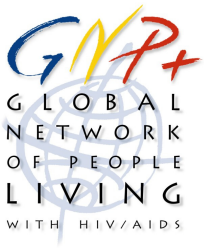

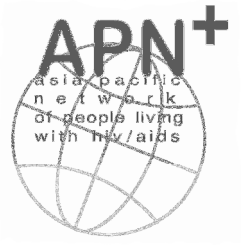

Consultation on WHO ART Guidelines

Defining Standards of Treatment and Care
ICAAP9, Bali, Indonesia

Global Network of People Living with HIV
Asia Pacific Network of People Living with HIV

August 2009

Introduction

This report presents the key discussions and recommendations that emerged during a meeting held during the International Congress on AIDS in Asia Pacific in Bali (ICAAP9) on August 12 2009 between 09.00 and 11.15. The meeting was held as a satellite meeting of ICAAP9 and was open to People Living with HIV (PLHIV) who attended ICAAP9. The meeting was co-hosted by GNP+ and APN+ (Asia Pacific Network of People Living with HIV). There were 22 participants from 6 countries of the region, with ages from 27 to 67 years.

At the last minute a demonstration at the plenary of the ICAAP9 conference was called on access to treatment for Hepatitis C at the same time as this meeting. Several of the pre-registered PLHIV for this meeting were mobilised for that demonstration. Because Hepatitis C is such a serious issue for many PLHIV in the region, their involvement in the demonstration was understandable, but it did reduce the number of participants in the discussions on WHO guidelines on ART.

The purpose of the meeting was to provide an opportunity for PLHIV from Asia and the Pacific to have input into the upcoming revision of the WHO's Recommendations for Antiretroviral Therapy (ART) for HIV infection in adults and Adolescents.

Overall the discussion aimed to gather the views and issues to be considered relating to the upcoming WHO ART Guidelines review and specifically to look at:

- how people feel about treatment
- the sort of support that people on treatment need
- when to start treatment
- balancing quality and equity of care in treatment
- how people see treatment as prevention

After an introduction to the session by Dr Susan Paxton, an Advisor from APN+ who facilitated the meeting, Dr Marco Vitoria from WHO, set the scene with a short presentation entitled “Considerations on WHO ART Guidelines”.

The participants then self selected one of three groups for the discussions. The questions each group considered were asked to discuss were as follows:

Group 1: Personal perspectives: how we feel about treatment and what we expect from ART

1. What are the main factors to consider in starting treatment?
2. What are the good things and what are the bad things about being on treatment?
3. What kind of support do we need from healthcare workers to answer our concerns about whether or not the drugs are working?
4. What kind of support do we need from healthcare workers to help us with side-effects, drug interactions and avoiding resistance?

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

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. What medical interventions do we want for people living with HIV who are co-infected with hepatitis C?

4. 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?

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

1. How do ARVs play a role in HIV prevention? How do we use that information to advocate to governments?

2. Should all women living with HIV who are pregnant or trying to get pregnant start ART instead of just taking ARVs to prevent infection in their baby?

3. How willing would people be to take part in trials of taking ART perhaps earlier than now thought to be necessary for their own health?

4. How willing would people be to take part in trials of taking ART in order to see if it prevents HIV being passed on to others?

Feedback was taken from each group. Because of the time pressure on room availability at ICAAP9, the meeting was very limited in time and one of the constraints of the discussions was that the other two groups were not able to comment on the findings of each group.

Feedback

Group 1

Question 1 What are the main factors to consider in starting treatment?

Most people started treatment on the strong recommendation of their doctor in the face of falling CD4s and feelings of tiredness, and symptoms of fever or weight loss. Clinic nurses were also seen as being quite influential in persuading people they needed to start treatment. As one participant mentioned, “The nurse said that I had no option but to start”.

There was apprehension about side effects and concern about resistance developing. But generally people felt that if they wanted to live longer and not get sicker, they had to start treatment. They were encouraged by seeing colleagues who had started treatment and were doing well on it.

Question 2 What are the good things and what are the bad things about being on treatment?

The good things were around their health and how they felt, and having more hope for the future. People talked about feeling fresher, more active and having a normal appetite. They did not get sick as often and looked healthier. People reported starting to look to the future and in some instances, being ready to have a baby.

The bad aspects reported were mainly around side effects. Some were concerned about putting on weight and others about not being able to put on weight. There were reports about problems with eyes and ears, and their skin getting darker and wounds taking longer to heal. Anaemia, low blood pressure, osteoporosis, were mentioned. Bad dreams and feeling more emotional were also raised. From a practical point of view people had problems making sure they took their medication on time.

Question 3 What kind of support do we need from healthcare workers to answer our concerns about whether or not the drugs are working?

Concerns centred around the need for more information and the stigma and discrimination people felt in the healthcare setting. A common experience was being told they needed to start treatment but not receiving sufficient explanation about why and about what to expect. They wanted to know about what side effects to expect, and drug interactions especially with supplements. Additional information on nutrition was lacking as most reported hearsay about certain foods (coconut, soya and broccoli) that were supposed to be beneficial for PLHIV. Most of the recommendations were from well-meaning people who were trying to be of help. Moreover in Asia, there is a tendency to consider treatment of HIV and/or its side effects by using traditional medicines. These were sometimes positioned as “miracle cures” or direct-selling (Multi-level marketing) companies, and left PLHIV vulnerable to scams. Traditional therapy is also seen as an alternative rather than a complementary treatment. They felt they should be told about problems such as taking grapefruit (with Efavirenz) and some detox regimes (that could reduce the efficacy of the antiretrovirals). There was a lack of any emotional support which they felt they needed. Many of the healthcare providers are not well qualified, and the positive people felt they are discriminated against. Often they had to wait for two hours to spend just five minutes with the doctor. Doctors were too rushed.

Question 4 What kind of support do we need from healthcare workers to help us with side-effects, drug interactions and avoiding resistance?

Concerns about reactions to medication were often not taken seriously. When people experienced side effects such as dry lips or skin problems they were just told, “That is normal” without any suggestions on what to do about it. Healthcare providers are more concerned with opportunistic infections than side effects. It was suggested that a booklet could be made available which described the various drugs, their side effects and what actions could be taken to deal with them.

Group 2

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

The group was clear that starting treatment earlier at a CD4 count of 350 offered significant benefits. The advantages in starting earlier include preventing opportunistic infections and bringing down viral load and increasing CD4s. Starting treatment earlier also potentially prolongs lives.

However, the group identified some serious concerns in starting earlier. These centred around two main issues. One was side effects and the other was the risk of resistance in a situation where there are limited second-line options. There are stockouts from time to time in many countries of the region, and the group expressed fear that by starting treatment earlier, the chances of a stockout would be greater and that could then cause resistance to develop. As one participant said, “distribution problems of ARVs is still a big issue here”. As people develop resistance and with more people on ARV this would put more pressure on second-line regimens which are more expensive. Would there be money to pay for those expensive second-line drugs? On an individual level people feared being in a position where they started treatment earlier, became resistant earlier and then found themselves without treatment options available to them at all.

The resistance issue could also be compounded if people started medication, felt better, stayed healthy and then decided that they did not really need to take the medication and may not adhere to their regimen.

It was clear that people did not like the thought of being on treatment unless it was essential, and starting earlier meant that “people would be on medication for a longer time”. By starting treatment earlier people would have to suffer toxicities and side effects for a longer period of time.

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

There was a difference in what people felt between what they saw as the practical situation and what the ideal should be. As one participant said, “This is a ‘Catch 22’ situation and a tough choice”. The question implied a situation where a choice had to be made between two options whereas they felt that they wanted to not have to make that choice.

This group agreed unanimously that given the current situation, they would prefer to postpone treatment, and start treatment at CD4s of 200 if necessary, in order to have a better range of drug choice and better monitoring later.

However, ideally they would like to have the option of starting treatment earlier if there was a guaranteed greater range of drugs available and if drug distribution problems were resolved.

In this context they wanted to see patent rights on new drugs abolished so that there would be a greater affordable choice of drugs. They also suggested that the quality and the monitoring of quality of drug production within countries should be improved. This is because in some countries in the region it has been claimed that there is a variation in the active ingredient in some local drug production. This can lead to resistance where levels

are too low and variable, and that then limits the options for the future.

Question 3 What medical interventions do we want for people living with HIV who are co-infected with hepatitis C?

There was energetic comment on this subject especially because both hepatitis C and TB are common co-infections in the region with many PLHIV having an intravenous drug user background, and with 70 – 80% of those people being co-infected with hepatitis C. The group was quite clear in that hepatitis C treatment must be available at affordable prices. This includes access to monitoring of liver function and other monitoring, hepatitis C viral load measurement, and interferon. While interferon might be available in some countries, it is far too expensive for most people to consider. The group felt that if ARVs can be accessible, then so should hepatitis C treatment be.

Although TB was not part of the question, the group discussed its treatment too. They would like to see TB and ARV drugs combined into one tablet. They would also like to see more monitoring to address side effects of TB drugs and want more research on how drug interactions between TB drugs and ARVs could be reduced.

Question 4 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?

The group was again unanimous and unequivocal in its response to this question. WHO should state the best treatment and monitoring options in the guidelines. The guidelines should not take into account resource constraints. Then governments should take on board the responsibility for the implementation of those guidelines.

Group 3

Question 1 How do ARVs play a role in HIV prevention? How do we use that information to advocate to governments?

The group felt that it is clear that taking ARVs lowers transmissibility of HIV and leads to better health, but the extent to which this is considered as a factor in treatment programs depends on the country. Treatment as a role in prevention is not a common notion in countries where there are low rates of access to ART. In some countries there is a fear of side effects that might delay uptake of ARVs and so the prevention effect is not as great.

The group felt that there were two views of treatment as prevention, the individual view and the population view. In the individual view, for example in the case of sero-discordant couples, the issue is one of the sexual health of both partners and issues such as family planning. It is doctors, PLHIV and their groups that are more interested in the individual view.

The population view looks at it in a way that says if you treat 'x' percent of positive people you have a 'y' percent decrease in infections and a consequent 'z' percent reduction in costs to the state. Governments are clearly more interested in population than individual issues and the previous equation may be a good argument to use in advocacy to governments.

It was also felt that ART contributes indirectly too, by changing social attitudes to HIV and

hence leads to less stigma and more testing, in turn leading to less transmission. It can even act to mobilise treatment for other diseases which might be lagging behind in treatment access.

Question 2 Should all women living with HIV who are pregnant or trying to get pregnant start ART instead of just taking ARVs to prevent infection in their baby?

The participants started off by making the observation that it depends on when the woman finds out that she has HIV. The reality for many pregnant women is that it is in fact as a result of testing because of the pregnancy that their diagnosis is made. It can also be because they feel unwell, or their partner is diagnosed. For this reason it is very important to continue to promote earlier testing for most-at-risk populations.

It also depends on what ARVs are available in that area.

The decision should be a personal choice for the woman, and that decision should be made on the basis of correct and balanced information. The information should take into account that there are two lives involved, each with rights, and should be delivered in an appropriate way. This implies the need for more resources, such as counselling, to assist the woman in the process of making a decision. Even group counselling in low resource settings is better than no counselling.

If the pregnant woman decides she wants to start ART she should be allowed to do so.

Question 3 How willing would people be to take part in trials of taking ART perhaps earlier than now thought to be necessary for their own health?

It was thought that fear and concerns may prevent people from taking part in such a trial. Part of that fear is about side effects and having to suffer them before necessary and potentially for longer. And part of the consideration is that in starting earlier it might cause resistance to occur earlier and before the availability of second-line treatments. By starting later, people would feel that it might delay the need to go onto second-line regimens. As long as their CD4s can be maintained at what was described as 'an acceptable' level, people would tend to delay treatment.

Another factor mentioned was the fear of stockouts that are currently common enough to be of very serious concern in many countries. People are likely to want to delay starting treatment (even if it is a trial) until stockouts are no longer an issue. (It is interesting to note that these are exactly the same concerns raised by Group 1 independently when they discussed starting treatment earlier.)

A necessary condition of people going onto such a trial would be that stockouts are addressed, and second-line regimens are available.

Question 4 How willing would people be to take part in trials of taking ART in order to see if it prevents HIV being passed on to others?

It was pointed out that studies to date have been conducted retrospectively so that couples were not 'taking risks' for the study. Such a study as the one suggested, requires if it is to be useful, that the negative partners are potentially putting themselves at risk. This was felt by the group to be ethically 'tricky".

The question about participating in the trial must also be addressed to the negative people who would be involved in the trial. Because of the possible risk involved, all partners involved must have clear and full information before making a decision.

The difficulty in conducting a trial was also discussed. It may be that behaviours will change during the trial just by being part of it, and that might affect the results.

It was felt that provided there is a sound ethical consideration, sound methodology, and both HIV+ and HIV- partners are informed then some PLHIV will probably be willing to participate in such a trial, but not all.

Group 3 also made some general comments about the subject covering all questions. ART guidelines are only one of many components and sources of information that PLHIV and their partners need in order to address wellness and a healthy life. People should have full information to inform their decision about starting treatment, trials and so on. Before embarking on trials or implementing new guidelines there needs to be guaranteed access, no stockouts, and trained healthcare providers.

In an overall sense they believed that WHO guidelines focus on the public, whereas clinical guidelines focus on the individual. As well as input into WHO guidelines, PLHIV should have input into clinical guidelines. There may be a tension between the two.

Summary

PLHIV see huge benefits in treatment and know that eventually they will need to take ARVs. But in the Asia Pacific region there is some reluctance to start treatment earlier based purely on some practical issues. In starting they want to be assured there will be nothing that will threaten their long term treatment effectiveness related mainly to resistance and the need to rely on second-line regimens which are either not available or not affordable right now. People are also very aware of side effects and their fear of them causes a reluctance to take treatment until it is 'really necessary'.

They do not believe that guidelines should be compromised by lack of financial and other resources and that the new guidelines should be based on 'best practice'. If this seems at odds with the first statement, it is because they aspire to optimum treatment but live with the day-to-day practicalities of what is possible, even if it is not optimal.

Note: The participants in this discussion were attendees of a regional conference. By definition they do not represent the huge majority of PLHIV living in the region who could never aspire to be at such an event. However, the participants were well-informed and sincere people whose views most likely reflect those of many PLHIV of the region.