The DHHS HIV Treatment Guidelines: A questionable revision that is unquestionably unaffordable.

July 13, 2010 By Joseph Sonnabend, MD

It's a disgrace that people on ADAP should have to be placed on waiting lists to receive treatment.

Last week I had a chance in Washington to hear the opinions of some ADAP advocates about early treatment for HIV. This past December, the new U.S. guidelines revision from the Department of Health & Human Services (DHHS) changed the recommendation as to when to start treatment, from ?350 CD4s to ?500 CD4s. They also wrote the new guidelines in such a way that treatment initiation could be interpreted to be recommended at even higher CD4 numbers.

Despite increased attempts to encourage testing, it's unfortunate that in some places, like Washington DC, most people have 200 or fewer CD4 lymphocytes when they first test positive. For those in the trenches - working hard to get people tested and to bring those who test positive into care, early treatment is largely theoretical. It has little practical interest since most if not nearly all of those testing positive in their communities are already, without question, in need of treatment because their CD4 cells are so low.

But the new guidelines revision is likely to become an important practical concern. While today, so many people who first test positive are likely to have such a low CD4 count that they urgently require treatment, with greater encouragement of testing, it's probable that as time passes, the first positive test will be associated with higher CD4 numbers, stretching the limited available resources--like ADAP--even further.

When is it best to start treatment? The truth is that we do not yet have evidence of the best quality to support the view that for HIV positive people with greater than 350 CD4s, the benefits of treatment outweigh the risks. The opinions of the guidelines panel and others who favour starting treatment at higher numbers are most certainly not held by all experts in HIV medicine, and not even by the WHO whose guidelines were also recently revised and now suggest starting treatment at 350 or fewer CD4s. A randomized controlled trial to determine when it's best for people with greater than 350 CD4s to start antivirals has yet to be completed.

The relevance of the revised U.S. treatment guidelines to ADAP is that as asymptomatic people with CD4 numbers greater than 350 test positive and are linked to care, their doctors will now write prescriptions for antivirals. This could mean that people who most definitely need treatment to prolong their lives may have to compete for medications with those who are not definitely known to need such treatment.

Even today, I wonder how many people swelling the ADAP waiting lists are asymptomatic with CD4 counts greater than 350. In fact, to what extent is the increase in the number of people on waiting lists *a result of the revision of the guidelines*, making it more difficult for those in greatest need to receive treatment? Of course this is connected with how states prioritize the way they make medications available. There is no uniform prioritization scheme; waiting lists are handled differently by different states.

Particularly in a time of limited resources, it is imperative that we recognize that the need for treatment is not of equal urgency across the board. Where health care is in effect rationed, should not those most in need be the first to receive treatment?

In this respect the new DHHS guidelines seem to have been put together with no thought given to the realities of how health care is delivered in the US, when it is delivered at all, and completely in oblivion to the economic circumstances of those for whom they recommend costly treatments.

Recommendations made without concern about how they are to be paid for also means there was no thought given to the funding implications of recommending treatment of a person with 50 CD4s and one with 500 CD4s in the same way. There was no acknowledgment that the need is urgent in one case and much less so in the other.

Should we not be concerned that there is a uniform, science-based system of ADAP prioritization in place as long as a full implementation of the guidelines recommendations is clearly unaffordable? Should we not be concerned that the expense of treating a person with 500 CD4s could make it more difficult for a person with 50 CD4s to receive medications?

In raising the recommended CD4 level at which to start treatment, it should have also been DHHS' task to recognize the budgetary burden this imposed and come up with a system of prioritization that is medically sound.

If one assumes that those who have 200 or fewer CD4s on their first test are likely to be in greater economic difficulty than those who have higher CD4 numbers on their first test, then the guidelines revision may have a disproportionately negative effect on the health of those already dealing with so many other problems.

Put in another way, when the starting CD4 is raised from 350 to 500 or higher, the total number of people eligible for treatment vastly increases, with an increase in the total medication bill, but without any budgetary provisions to meet the increased cost.

It is possible that some advocates for people with HIV may feel that swelling the waiting lists with healthier HIV positive people not definitely known to benefit from the drugs can be used as a tool to persuade Congress to increase ADAP funding. If so, this must be coupled with an assurance that a system of prioritization is in place that will ensure that those with the greatest need receive treatment priority in the ADAP system.

We would not have so many problems if we definitely knew that starting treatment at greater than 350 CD4s produced a net benefit compared to deferring it to a CD4 count of 350. It's really quite remarkable that after fifteen years of HAART we don't yet have an answer to this question.

A reliable answer can safely be obtained by completing a clinical trial that is now enrolling. The Strategic Timing of Antiretroviral Treatment (START) study will tell us if early or deferred treatment is better, worse, or makes no difference. There is nothing standing in the way of obtaining this answer except perhaps the most recent DHHS treatment guidelines revision.

The economic consequences of raising the CD4 count for treatment initiation will not only be felt by ADAP. We have yet to see how managed care companies will deal with a greatly increased medication bill. The most rational response would be for entities that pay for medications,(private insurers, Medicare,the VA) to find out if paying for early treatment is worth it by supporting trials like START.

Similar problems were faced after AZT was approved for people with more advanced disease. A "when is it best to start" trial with AZT could not be enrolled in the US and it was left to the Concorde trial in the UK and France to provide an answer. In the meantime, thousands of people received no benefit or were hurt by commencing early treatment with AZT at a time when there was no reliable evidence demonstrating its positive effects outweighed the negative.

The rush to treat in the U.S. above a 350 CD4 count may make enrolment in START more difficult and lead to a similar delay in answering the "when is it best to start" question and require the trial's completion to be dependent on enrolees outside of the US.

Would it be too much to hope that ADAP and even private insurers might support START by presenting enrolment into the trial as a safe option for those with greater than 350 CD4 lymphocytes? Perhaps START could open new enrolment sites, in cooperation with state ADAP offices, to facilitate this.

Faster enrolment could expedite the completion of the START trial. It could also help stretch limited state ADAP resources even further, because they will not have to cover the costs of treatment for those they enroll in the START trial.

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