2010 Treatment News in Review (Part 2)

December 30, 2010 By Tim Horn

The second of a two-part glimpse at the most significant HIV/AIDS treatment news of 2010:

Test and Treat

Evidence in support of early HIV treatment has been coming in fast and furious. So much so that it prompted the U.S. Department of Health and Human Services to update its treatment guidelines in December 2009, recommending treatment for all people with HIV once their CD4s hit 500. And this past May, the San Francisco Department of Health--with the backing of Project Inform and other groups--began recommending treatment for all city residents testing positive for the virus, regardless of their CD4 count.

What has prompted this sense of urgency? First, a number of cohort studies have indicated that delaying therapy until the CD4 count falls below 350 is associated with poorer survival and a higher risk of non-AIDS-related disease and complications, compared with those starting treatment with higher CD4s. Second, mathematical models suggest that getting and keeping as many HIV-positive people on therapy as possible will effectively reduce average viral loads in geographic communities and, in turn, reduce the likelihood of ongoing transmission of the virus

Both are ambitious goals, to be sure. Yet not all experts are convinced we have enough data to support these recommendations. There are concerns that patients will be coerced into starting therapy before they're ready, along with questions regarding the short- and long-term safety risks of prolonged treatment, as well as adherence and cost issues.

To help address these questions--and to determine, once and for all, if starting therapy early further improves disease-free survival--the START trial moved this year into its second, pivotal phase and is hoping to randomize more than 4,000 HIV treatment-naïve individuals to either begin therapy immediately or to delay treatment until their CD4s fall below 350.

"Getting a study like START has been an activist priority for at least 10 years, and luckily, it is now being run when treatment is at its safest," Simon Collins of the United Kingdom's HIV i-Base said in an AIDSmeds web exclusive on the subject of early treatment. "Many activists continue to believe in the importance of this study, probably many more than those who think we already know enough without the data it will provide."

Revising the Definition of Disability

A September 13 report issued by the Institute of Medicine (IOM), arguing that the criteria used by the U.S. Social Security Administration (SSA) to gauge HIV-related disability is outdated and should be overhauled to include new qualifications based on CD4 cell counts and specific sets of medical conditions, resulted in a firestorm of controversy.

The HIV Infection Listings, established in 1993, are the criteria currently used to determine whether people living with HIV are disabled by their infection and eligible for benefits. For example, a person living with HIV and a history of employment may be eligible for Social Security Disability Insurance (SSDI)--and, with it, access to Medicare--once a serious AIDS-defining illness has been diagnosed, such as *Mycobacterium avium* complex or cytomegalovirus. Other benefits, including Social Security Income (SSI) and Medicaid for people living with HIV who have limited employment histories, are also dependent on disability status as determined by SSA.

Since the Listings were created, the IOM report argues, HIV care has advanced and the disease has dramatically changed from a uniformly fatal condition to a potentially chronic manageable infection, in which CD4 cell recovery and a return to physical health--and ability to work--is an expected positive consequence of contemporary ARV treatment. Conversely, a number of non-AIDS-related health complications are becoming increasingly prevalent among people living with HIV receiving ARV therapy--such as neurocognitive impairment, chronic kidney disease, osteoporosis and a number of treatment-associated side effects--many of which can cause disability and were not included in the original 1993 HIV Infection Listings.

Though the he IOM recommendations, which were requested by SSA, will only apply to new Social Security disability applicants once the existing criteria are amended--current disability claimants will not be effected by the proposed changes--activists question the logic of changing a system that continues to work for so many. Some claim, for example, that revisions for new claimants will effectively create a two-tier system for disability beneficiaries.

The process is just beginning, however. While SSA welcomed the IOM report, it has not yet acted on its recommendations. Sometime in the coming year it is likely that SSA will host a public comment period, based on its interpretation of the recommendations, before it decides whether or not to move forward with changes, likely in 2012.

ADAP Waiting Lists

As of December 16, 2010, there were 4,732 individuals on AIDS Drug Assistance Program (ADAP) waiting lists in nine states, according to the National Alliance of State & Territorial AIDS Directors (NASTAD). This is a 32 percent increase from the 3,586 individuals reported to be on ADAP waiting lists in October 2010.

In addition, 19 ADAPs, including seven with current waiting lists, have instituted additional cost containment measures since April 1, 2009 (reported as of December 9, 2010). In addition, 11 ADAPs, including four with current waiting lists, reported they are considering implementing new or additional cost-containment measures by the end of ADAP's current fiscal year (March 31,

2011).

Why is ADAP a mess, asks Trenton Straub in the October 2010 issue of *POZ*? One reason, says NASTAD, is that demand is growing because more people are unemployed and losing health insurance. Additionally, ADAP funds are shrinking because of state and federal fiscal crises. What's more, the nation's efforts to test more people have led to more diagnoses. And then there's the fact that HIV meds are working--which means more people are living longer and taking meds.

Fortunately, the House of Representatives has approved an additional $60 million for ADAP in fiscal year 2011, which should help--but by no means solve--the waiting list situation in many states. The increased funding was included in a bill that will fund all federal programs next year at existing levels, except in some instances.

HIV and Aging Research to the Fore

Brittle bones, the relentless exchange of muscle for fat, weak hearts, and forgetfulness are common occurrences among men and women in their senior years. What if, however, these health issues begin to happen during a person's 40s and 50s? That's exactly what researchers fear is occurring in people with HIV--and we don't fully understand why.

The data emerging from recent scientific conferences paint a troubling picture--they increasingly suggest that diseases common among the elderly are now occurring at a much earlier age in people with HIV. In addition, several immunological alterations characteristic of HIV infection, notably declines in the immune system's ability to mount effective responses to disease-causing pathogens, are similar to immunosenscence: gradual deterioration of the immune function brought on by aging.

Is this accelerated aging or something else? There are believers that it is, and there are skeptics. Where both sides agree, however, is that much more research is necessary.

Enter the Coalition for HIV and Aging Research and Policy Advocacy (CHARPA), a newly formed group of activists hoping that the National institute of Allergy and Infectious Diseases (NIAID) will begin to explore the issue with zeal and determination (not to mention funding).

Right now [NIAID is] just paying lip service to HIV and aging by given it an 'awareness day,'" claims Lei Chou of the Treatment Action Group referring to a September 9 press release from the institute dedicating September 18, 2010, National HIV/AIDS and Aging Awareness Day. In response, CHARPA has called NIAID and other divisions of the National Institutes of Health to the mat in the form of several research demands, highlighted in our October 5 web exclusive on the subject.

In addition to HIV & aging research advocacy, CHARPA also intends to work on other areas, such as disease prevention and care guidelines. It will also explore how Ryan White programs and health care reform will affect the aging HIV population and whether or not safety nets will be there as people's needs for ancillary care grow.