The Real Travesty of HIV Care in the United States

May 4, 2012 By Tim Horn

Roughly a year ago, I was asked by Jose Zuniga of the International Association of Physicians in AIDS Care (IAPAC) to serve as a writer and member of the first-ever blue-ribbon panel assigned with the task of developing international guidelines for improving engagement in HIV care and treatment adherence. The *Guidelines for Improving Entry into and Retention in Care and Antiretroviral Adherence for Persons with HIV* were first made available online ahead of print by Annals of Internal Medicine on March 5 and were eventually published in the May 1 issue of the journal.

The experience was eye-opening, to say the least. Working most closely with two of the smartest, dedicated and caring HIV-treating clinicians and researchers I can name--Michael Mugavero, MD, of the University of Alabama, Birmingham, and Melanie Thompson, MD, of the AIDS Research Consortium of Atlanta--I was most heavily involved in the sections focusing on entry into and retention in care. Basically, I was charged with reviewing to what extent people living with HIV are actually receiving regular care--irrespective of whether or not actual HIV treatment is prescribed--and coming up with recommendations to shore up weaknesses. How hard could this possibly be?

Well, it turned out to be much *easier* than I thought, **only because the national portrait of entry into and retention in HIV care has been consistently abysmal and the astounding dearth of data from well-designed studies exploring entry and retention strategies that could be used to construct well-formed recommendations.**
In retrospect, I would have liked for my job to have been much, much harder.

Reading through the rest of the IAPAC guidelines, it is abundantly clear that the pharmaceutical industry, along with public and private research networks, have done a bang-up job improving our ability to adhere to HIV treatment. Millions, if not billions, have been spent on transforming fistfuls of relatively toxic pills, taken multiple times a day, into safer coformulations and novel combinations that involve taking no more than one or two tablets or capsules once or twice a day. There have also been several well-designed studies exploring the utility of treatment adherence strategies, such as directly observed therapy, electronic pill bottle caps, text messaging, phone calls, educational programming and a variety of counseling methods.

Synthesizing all of the treatment adherence data for the sake of best-practices guidelines wasn’t easy, for sure, but the end result was a clear set of conclusive recommendations based on strong scientific conclusions.

However, none of this--the ability to prescribe easy, highly effective treatment regimens and a plethora of adherence tools to prolong our health and prevent ongoing transmission of the virus on a massive scale--matters if we can’t first get people living with HIV connected to regular care.

The situation is direr than I, for one, ever imagined. Only in recent years have data emerged, underscoring how far off we are from a central tenet of the National AIDS Strategy: Ensuring that *all* people living with HIV are well supported in a regular system of care.

Consider the following:

- U.S. Centers for Disease Control and Prevention analysis, published on November 29, 2011, indicates that for every 100 people living with HIV in this country, only 80 are aware of their infection, 62 have entered into care and 41 actually stay in HIV care.
- Another study of available data, published in a March 2011 issue of Clinical Infectious Diseases, paints a similar picture: Of the 1.1 million estimated to be living with HIV in the U.S., roughly 874,000 have been diagnosed, 656,000 have been linked to HIV care and 437,000 have been retained in HIV care.
- In 2010, a CDC analysis of 50 studies conducted between 1996 and 2009 indicated that 30 to 40 percent of people with HIV fail to enter or stay in care after their initial HIV diagnosis.
- Most recently, data from 12 clinics participating in the nationwide HIV Research Network indicate that as few as 1 in 5 people living with HIV meet three main criteria for being “fully engaged” in HIV care and that more than half of people living with HIV had gaps in follow-up appointments ranging from seven months to a year or more.

No matter which way your parse the data, it’s safe to conclude that the majority of people living with HIV in the United States aren’t receiving the professional medical care they need and the regular follow-up required to be effectively prescribed antiretroviral therapy. Numerous studies have shown that missed clinic appointments are independently linked with a decreased likelihood of receiving HIV treatment and significantly lower rates of undetectable viral loads if treatment is started. There's also data indicating that, compared with people who are seen four times annually after treatment is started, the risk of death is 42 percent higher among those with only three visits, 67 percent higher for those with only two visits and nearly doubled in those with only one visit annually.

Adding insult to injury, there has only been ONE controlled clinical trial--involving an intervention group and a control group--of a program designed specifically to improve engagement in care. The Antiretroviral Treatment and Access Study (ARTAS) involved the use of up to five one-on-one case management sessions to improve entry and retention in care among people recently diagnosed with HIV. Some statistically significant improvements were observed: A higher proportion of the case-managed participants, compared with those who didn't receive the intensive intervention, visited an HIV clinician at least once within 6 months (78 versus 60 percent) and at least twice within 12 months (64 versus 49 percent).

HIV care entry and retention data are also available from the Heath Resources and Services Administration (HRSA)-funded Special Projects of National Significance (SPNS) Outreach Initiative, an important evaluation of various intervention programs--enhanced case management, peer support, tracking missed appointments for outreach interventions, motivational interviewing, health literacy, life skills training and interagency connections--conducted by multiple sites that, unfortunately, lacked the scientific rigor necessary to yield strong, evidence-based conclusions.

Though the results from the SPNS Outreach Initiative were generally encouraging--the proportion with at least two clinic visits in the previous six increased from 64 to 87 percent at six months and 79 percent at 12 months--it is unclear which intervention worked best, which factors were associated with the best HIV care engagement rates or which intervention was the most cost effective. In fact, many of the same questions apply to the case management strategy studied employed in ARTAS: Can such controlled clinical trial data be repeated in a variety of non-academic settings, such as AIDS service organizations, community clinics, drug recovery programs, jails and prisons and housing programs? How should these findings be interpreted in areas where resources are not available for intensive case management? Where, and under what circumstances, is case management cost effective?

And what about interventions to improve entry and retention that haven't yet been explored in any evaluable programs? For example, are pay-for-performance-for-patients (P4P4P) initiatives--offering financial incentives and non-monetary awards to patients who enter and are successfully retained in care--cost effective? While many clinics currently engage in the practice and P4P4P has been shown to work in smoking cessation programs, there is not yet any data to support it as a way to bolster HIV care entry and retention rates. Fortunately, one such study--HIV Prevention Trials Network 065, or the Test and Link to Care (TLC)-plus trial--is looking at engagement in care and whether such incentives can help.

Even more fundamental questions remain: What's the best method for monitoring entry into and retention in care? What are the best measures of retention--a certain number of clinic visits, with lab work, within a calendar year?--and how can these data be collected, analyzed and acted on local, regionally and nationally?

Importantly, where are the dollars--particularly from the pharmaceutical industry, which undoubtedly wants to maximize the number of people living with HIV in the United States on antiretroviral therapy--and nationwide consortia to conduct the great deal of entry and retention research needed to produce scientifically validated best practices?

It’s easy to understand and appreciate a central goal that runs through the National AIDS Strategy, the U.S. Department of Health and Human Service’s HIV treatment guidelines and priorities set by city and state health departments: Getting people living with HIV on treatment. But we’re putting the cart before the horse. The first order of business needs to be getting people living with HIV tested for the virus and fully engaged in the care required to responsibility foster and accommodate the therapy options we’ve all worked so hard to obtain.