Project Inform’s Change of HAART

May 4, 2010 By Sean Strub

In my post last week about “test and treat”, I expressed concern that the San Francisco-based treatment advocacy group, Project Inform, was now strongly recommending treatment for virtually all who have HIV, regardless of their CD4 count or other factors.

I was curious as to what transpired between January, 2010, when they published a sensible position paper on when to commence treatment, and April 6, 2010, when they revised it with controversial new recommendations unsupported by conclusive science and which showed too little respect for patient autonomy and education.

But in the past 48 hours, something remarkable and encouraging has happened; Project Inform has updated their position paper on when to start treatment, backing off from their aggressive “treat everyone” stance.

Last week they advised treatment "*before*“ one’s CD4 count fell below 500, now they advise it ”*if*“ it falls below 500 (consistent with the new federal guidelines). Last week they advised at a certain point one should ”*begin*“ treatment, they now say one should, at that point, ”*consider*" treatment.

These are little words, but greatly change the meaning of PI’s paper. There has not been any dramatic breakthrough in HIV treatment in the past month, so one can only assume this change of course is in response to concerns expressed by medical, scientific and AIDS communities. Curiously, it now puts Project Inform at odds with the San Francisco Department of Public Health, which advises all people with HIV to commence treatment immediately.

Unfortunately, Project Inform has made this change without explanation and without leaving the earlier version on their website, so the evolution of their position cannot readily be examined and understood. This is disheartening; real transparency in the organization’s position and process would dictate they leave the previous paper posted and explain why their position has changed.

The very debate and discussion Project Inform has presumably had internally over these issues is precisely the debate and discussion people with HIV need to hear and understand in order to make these decisions for themselves.

How does Project Inform determine these positions and make their policy decisions; is it the board of directors? Recommendations from outside consultants? This process isn’t easily found or described on their website and yet is is important for people with HIV to understand.

It is not easy for me to criticize Project Inform in print as I have greatly admired much of their work over the years. I knew and was friends with Marty Delaney in the late 1970s, before the epidemic, and was an enthusiastic supporter of his work in the early days.

In 1986, I produced a fundraising mailing for Project Inform that strongly advocated getting tested. On the outside of the envelope it read "*There are two ways to find out: Get tested or 2) Get sick*". I have always supported people knowing their HIV status--anonymously, if possible, which is what most people would prefer--but that is a different decision than starting a lifetime regimen of extremely powerful drugs.

Over the years, Marty and I often disagreed on antiretroviral treatment strategies. He was generally more aggressive in his approach, while I am typically more cautious (although quick to acknowledge that antiretroviral therapy saved my life).

Marty and I never argued and it never got personal, because we always agreed that giving information to people with HIV was the solution to most issues where there were differing expert opinions. We trusted individuals to make the best decisions for themselves when they were given a full range of information, including about the important controversies.

But in recent years, Project Inform--to someone who knows it mostly from its website--seems to have veered closer to a party line model, where they see one approach and are trying to tell people with HIV that is what is best for everyone. The other side of issues is less-often addressed on their website, which increasingly echoes the messages from pharmaceutical companies and government agencies, rather than heralding the independent and diverse perspectives and experience of people with HIV.

Project Inform isn’t in the habit of looking to me for advice, but I’ll offer some here in a sincere hope they’ll consider these points as they continue to evolve their organization as well as their position on when is best for one to start treatment.

The new PI position on when to start treatment is certainly an improvement over their quickly-aborted position from last month, but it still is lacking in several important ways. I’ve pasted their position paper below, in italics, with my comments and suggestions interspersed as noted.

Some of my comments may appear as so nuanced as to be irrelevant, or simply a question of semantics. But the nuance and semantics are extremely important in influencing how people with HIV make treatment decisions, how clinicians treat HIV and how the public perceives people with HIV.

> *Project Inform is concerned that nearly half of all HIV-positive people in the United States do not know their HIV status or have not engaged in care and treatment that could prolong their lives and prevent new cases of HIV infection. We believe this results, in part, from a*

lack of understanding of the benefits of treatment, the fear of side effects of HIV drugs, the need for support services to make care and treatment possible, fears about disclosure of HIV status, and the belief that care and treatment services are unavailable to low-income people.

Actually, I believe the “nearly half of all HIV-positive people in the United States” statistic PI cites includes an unknown but probably significant number of people who have chosen not to go on treatment for reasons PI fails to note. Many people with HIV, particularly those with higher CD4 counts, make an informed decision to delay or forego antiretroviral therapy, perhaps because they have a stable CD4 count or manageable viral load, or are enjoying success with alternative or complementary therapies.

Not going on treatment is not always just because of a “lack of understanding”, “fear of side effects” or the other concerns cited. It is important to respect these choices by acknowledging that they exist and that fear of side effects or other concerns are legitimate considerations in making an informed choice.

Although researchers continue to gather evidence regarding the optimal time to start treatment, federal guidelines have shifted in favor of earlier treatment. These guidelines allow for varied interpretation by HIV providers. In this document, Project Inform -- a trusted provider of HIV treatment information for 25 years -- presents its position regarding HIV testing, when HIV-positive people might consider engaging in care and treatment, and important considerations for starting *care and treatment.*

This is all true, but greater clarity would be gained by noting here that “in favor of earlier treatment” means for those below 500 CD4 cells, when previously the federal guidelines only recommended it for those below 350. Raising it to 500 is not a view universally supported. From a paper in the Lancet earlier this year "We therefore do not believe that there is convincing evidence to conclude that deferral of initiation of ART to a CD4 count of 350 per ?L causes net harm, particularly in terms of mortality, compared with starting at any higher level. (Andrew Phillips, Dominizue Costagliola, Caroline Sabin, Jonathan Sterne, The Lancet, Volume 375, Issue 9715, Page 639, 20 Feb 2010)

Every person in the US aged 13 years and older should know his or her HIV status and consider being tested every year as a part of routine medical care. Some people concerned about testing for HIV fear that, if they are HIV-positive, people they do not want to know may find out or that they may experience discrimination. However, important federal and state laws prohibit both the disclosure of medical information and discrimination against people living with HIV/AIDS.

Simply citing the existence of federal and state laws as a counterpoint to fears of discrimination and stigma neglects the reality that those laws are often unenforced and discrimination can cost one’s safety, job, housing, social network and even freedom. Should we leave the keys in the car simply because there is a law against stealing?

When advocating testing, it is also important to advise that those testing positive will be reported to state health departments and some states use that data to target behavioral interventions which can lead to criminal prosecutions for failing to disclose one’s HIV status or even for engaging in non-risky behaviors, like spitting. To encourage testing without advising of these possible consequences is irresponsible.

It would be prudent for PI to provide advice on how one can get tested anonymously, which is not as easy as it once was but is still possible, rather than having one’s name and HIV infection reported to the state.

If one is HIV-positive, the idea of entering HIV care for life can be daunting. This includes coming to terms with an HIV diagnosis, disclosing one’s status to others who should know, learning how to take care of oneself and take meds, and how to fit all of this into one’s everyday life, as well as other concerns. Project Inform encourages people to use local support services such as case managers, social workers and support groups for help in navigating these life changes.

Introduction of who “should” know diminishes the choice of a person with HIV to keep that information to him or herself. I encourage people to disclose their HIV positive status, as I believe it is good for their health, is ethical (the moral and ethical obligation to disclose was codified in the 1983 Denver Principles) and helps combat stigma. But I also recognize that not everyone has the same degree of safety and choice in disclosing, so the decision is a personal one and should be respected.

Whether or not they choose to start treatment right away, all HIV-positive people should be linked immediately to a qualified medical provider to monitor their health and consider starting treatment. People who learn they are HIV-positive can take steps that will greatly prolong their lives and reduce the risk of passing *the virus to others.*

Reducing the risk of passing HIV to others via antiretroviral treatment is a good reason for someone to choose to commence treatment. But if a doctor recommends treatment for that reason, without informing the patient that it is an important factor in his treatment recommendation, it is irresponsible.

We must be able to trust that our doctors are giving us their best advice about our own health, not recommending treatment in order to “protect” society by making us less infectious.

Nearly 1 out of 4 people living with HIV also have hepatitis C. Project Inform encourages everyone to get a full physical exam and medical history done with the appropriate screenings, including those for possible viral and bacterial co-infections. HIV treatment has greatly improved the survival and quality of life of people living with HIV. A healthy, newly infected person who starts HIV therapy immediately can reasonably expect to live a near-normal life span.

A fuller disclosure would note that many newly-infected people who choose not to start HIV therapy immediately can also reasonably expect to live a near-normal life span.That option is not solely available to those who start HIV therapy immediately, as one might assume from the PI statement.

In fact, it is entirely possible--if not likely--that some who have HIV and do not start therapy until their CD4 count is below 500 may have years free from drug side effects and ultimately live longer lives than those who start therapy with a high CD4 count. That’s why the START trial must be completed. It will provide people with higher CD4 counts the most powerful tool to help make them make the right treatment choices.

Based on current data, Project Inform believes that the long-term damage from untreated HIV is greater than the potential damage caused by long-term use of HIV medications.

This is misleading. PI’s statement compares the risk of a person who has HIV and goes on treatment against the potential side effect damage from long term treatment. This statement does not even consider people with HIV who choose to wait before starting treatment and in so waiting are able to avoid years of accumulating toxicities and side effects.

Does Project Inform think that those who wait a decade, remain clinically healthy without opportunistic infections and don’t start treatment until their CD4 count hits 500 are likely to suffer more “long-term damage” than those who start treatment immediately, when their CD4 counts are high? I’m asking, as I don’t really know the full extent of what PI is saying here.

We know that below 350CD4 the damage from HIV is unquestionably greater than that from the drugs. We don’t know if this is true above 350CD4 and unless PI has a private line to God they don’t know either. Project Inform and the SF Department of Public Health should be advocating strongly for the START trial instead of inhibiting START by implying that it is unnecessary because they think everyone with HIV should be on antiretroviral treatment.

The biggest unanswered question for people with HIV is when is best, on average, to start treatment. That has not been yet been determined by science. For some people it is likely that the risk of long-term use of HIV medications is greater than the risk of waiting until their CD4 counts drop below 500, or 350 or whatever level. We simply do not yet know when in the course of HIV infection the benefits of treatment clearly outweigh the risks.

Compared to earlier drugs, newer HIV medicines are generally more tolerable and have fewer side effects, including those that may impact a person’s appearance. In some cases, people can switch to a more tolerable regimen if their first one doesn’t work out. However, *others may still find it difficult to tolerate the drugs. Longer-term toxicities of newer drugs are still unknown.*

This would be more accurate if it referenced “treatments” instead of “medicines”. Earlier treatments often involved much higher doses than what is used today; that dosing was as great or a greater a part of the problem than the medications themselves. It also should be noted that longer-term toxicities of older drugs are better understood but the full range of their toxicities is still unknown. Just recently new problems were discovered with two HIV drugs that have been prescribed for more than 20 years.

HIV-positive people should be ready to stay on treatment once they start in order to maximize the benefits of their HIV therapy and to reduce the risk of drug resistance and other preventable health issues. Drug “holidays” are not recommended. Patients and providers should work together to routinely assess and secure housing, mental health, substance use services or other forms of needed support to ensure their ongoing adherence to care and treatment.

Drug “holidays” are not recommended by whom? There are a number of successful trials on treatment interruptions. At the very least the issue of treatment interruptions is unresolved or controversial. There may even be more trials showing merit in treatment interruptions than there are those showing danger. Here’s a good review of the situation on treatment interruptions from Dr. Joseph Sonnabend’s blog.

What I know for certain is that treatment interruptions are widely utilized in various forms by many people with HIV, including some who are highly sophisticated about and have had great success in their treatment. While PI may not recommend them, it would be more useful for their constituents if they acknowledged the diversity of opinion on the topic.

Based upon a review of currently available data, Project Inform believes that all HIV-positive people who are ready to begin treatment should start if their CD4 counts fall below 500.

This is consistent with U.S. federal guidelines. It would be more informative--and “inform” is central to PI’s mission--if it was noted that this is a recent and controversial expansion of the US guidelines and that most other countries, including Canada and England, use 350 CD4 cells as the threshold at which to recommend treatment.

Some evidence shows that starting treatment above 500 CD4s -- or during acute infection to lower the chance of a low nadir CD4 -- may decrease damage to the immune system, promote better longer-term health outcomes, and extend a person’s life.

True, but it would be more helpful if these two issues--treating everyone above 500 and treating during the acute infection stage--were addressed separately. Many experts would argue that there is more evidence in favor of treating during acute infection--the closer to the point of infection the better--for some period of time than there is for treating everyone over 500.

Deciding whether to start treatment above 500 CD4s is an individual choice to be made with a qualified medical provider. Project Inform believes that people who delay treatment should monitor theirCD4 counts and viral and *consider treatment if they experience any deterioration of these lab results or new symptoms of disease*.

Keeping HIV under control with effective treatment may help HIV-positive people avoid transmitting the virus. However, treatment alone may not fully prevent transmission; therefore, it remains critical to engage in safer sex, prevent sexual infections, and/or use clean syringes. Public and private programs are available to make care and treatment affordable for most people with HIV.

However, the current state of the US health care system can sometimes make it difficult to find and access quality care and treatment. Through its National HIV Testing Hotline, Project Inform can provide support both to HIV-positive people facing these life-changing issues and those working to support them. We can also provide information about accessing free or low-cost health care and navigating complex health care systems:1-800-822-7422.

Project Inform has developed this position from current study results and expert opinions. We encourage all individuals to consult with their medical providers to make informed and cooperative decisions about their health. The information found in this paper is intended to support, but not be a substitute for, the relationship with these providers. Please email us with any questions regarding this document.

Note: entry edited to fix formatting errors on 5/11