Gimme a Break!

Strategic Treatment Interruptions—a.k.a. drug holidays—are the new dream destination. But are they for everyone? Keith Henry, MD, gives Emily Carter a travel advisory.

August 1, 2000 By Emily Carter

The newest acronym on everyone's tongue is STI—Strategic (or Structured) Treatment Interruption—which means stopping your anti-HIV regimen under doctor's orders. In addition to being an HIVer's wet dream, planned drug holidays are attracting the attention of more and more researchers and clinicians as a way to help solve the many problems posed by a lifetime on combination therapy. There may be times when using meds to clobber your viral load into undetectable submission is not for you—when your adherence is half-assed and causes drug resistance, say, or when the side effects are making you sick as a dog. But going off drugs for a definite or indefinite period isn't just a way to allow your body to come back from side-effect hell or forestall resistance. It is also being studied as a possible method of auto-vaccination: "By going off therapy, you let the suppressed virus come roaring back, forcing your immune system to react to HIV's full force," Martin Delaney wrote in these pages ("Happy Holidays," POZ, December 1999). "A few cycles of such on/off treatment, or 'pulsing,' could produce an immune response potent enough to control HIV without drugs."

Like many patients, I have done what might be called "nonstrategic medication interruptions"—I forgot to take them for a day or two. So sue me. In truth, after a long struggle with various meds—some made the promise of long life sound like a threat, so ill did they make me—I've made peace with my regimen. The benefits for me would be mainly psychological: how enticing to live like a "normal" person without the twice-daily reminder of Damocles' sword swinging over my head. But if I ever want to go on a drug holiday, I have at my disposal one of the premier proponents of such a move: my doc, Keith Henry. In addition to being the director of the HIV/AIDS clinic at Regions Hospital in St. Paul, Minnesota, for 12 years, Henry is a veteran who has seen at least 300 patients die since 1984 and has attended more than 50 funerals. Henry has no time for niceties, and he chooses not to underestimate his patients by sugar-coating the truth. His integrity is something that I, a patient of his for 11 years, have come to appreciate and rely on, so I jumped at the chance to pick Henry's brain recently about the ABCs of STIs.

POZ: What's behind the acronym STI?
Keith Henry: The definition of STI—Strategic Treatment Interruption—is not precise, since the concept of stopping HAART pertains to a wide spectrum of situations. Going off therapy, of course, is nothing new. What is new are some of the reasons to try an STI. There are at least five well-

defined rationales and goals for STIs: to stimulate the immune system (auto-vaccination), since anti-HIV immunity tends to wane after you're on HAART; to allow for the temporary return of a wild-type, drug-sensitive virus after the development of resistance; to stop therapy after a review of your overall HIV status suggests HAART was started prematurely; to allow your body to recover from toxicity; and to motivate you better when you go back on HAART.

What are the benefits of STIs?
There are as yet no proven long-term benefits. But we need to find some way to strategically address these five problem areas I just listed. Right now the most common use of STIs is clinical: to get rid of the side effects when they are out of hand. It's more of a motivational tool: to get people to keep taking their meds over, say, a five-year period, we offer them the reward of a holiday.

What are the risks?
They are numerous. Data from Dr. Steve Deeks at San Francisco General Hospital in a study looking at STIs for resistant HIV found that over a four-month period there was a significant loss of CD4 cells. While a temporary reversion of HIV to a wild-type, drug-sensitive virus did occur as hoped, the CD4 decline placed the patient at increased risk for AIDS-related complications. In addition, data from Dr. Veronica Miller in Frankfurt, Germany, and others has suggested that recycling drugs after an STI might result in viral suppression that only lasts a year or less. There is also a risk that even discussing STIs publicly will be misinterpreted as suggesting that it is no longer crucial to be highly adherent to HAART.

You recently published a paper suggesting that HAART is being overused and that a more conservative, long-term approach should be considered. How do STIs fit into that strategy?
Again, there's still no data that STIs work over the long haul for any of these five issues. And there is concern that by cycling on and off HAART, you may well increase your risk of developing drug resistance, undermine your adherence capacities and cause other clinical problems.

How many of your patients are on an STI?
There are about 450 patients enrolled in our clinic, and we see maybe 100 others in research and referrals. Of the total, about 22 percent are on some sort of STI. In fact, the group on no therapy is the fastest-growing category in our clinic. But it includes many situations: delaying therapy; stopping therapy in poorly compliant patients, to address side effects or to recycle drugs in persons with a resistant virus; and stopping a successful but premature therapy. If you put someone on meds too early, and the side effects are overwhelming, they get spooked about therapy. If their viral load is down, but they feel like hell, what's the point? But whether the term STI applies in each case is questionable.

What are your clinic's patients like?
Our typical patient is either an inner-city resident with a high burden of poverty, psychiatric illness and chemical dependency, or else a referral for a resistant virus or related severe side effects. This, coupled with the lack of financial support for proper adherence supervision, has influenced

my thinking about the need to be conservative about the use of HAART and very patient with a long-term view of managing HIV. Dealing with issues other than HIV is often a high priority for our patients.

Is that why you advocate STIs?
I am not an advocate for STIs per se. But I believe that anti-HIV meds are overused and often poorly managed. Work that I have done with Dr. Pablo Tebas and colleagues at Washington University in St. Louis modeling approaches to HIV therapy makes me think that a more cautious use of HAART can result in comparable or even improved long-term benefits at a reduced cost. I even think that something as controversial as pulse therapy—cycling on and off HAART—may be the best use of STIs.

How do you decide whether a patient is eligible for an STI? What viral load, date of diagnosis, CD4 count, side effects?
We use all of these criteria and more. But I can't generalize because I'm against cookbook approaches to care. Choosing to stop therapy for a time is a highly individualized decision and depends on what your rationale and goals are, your treatment history, adherence record, how you are actually feeling and your philosophy.

How often do you monitor an STI patient?
An STI, like starting HAART, is a big deal. We often follow the patient even more carefully for the first several months off HAART than when they were on it. For example, if we are dealing with a patient who's on a complicated regimen that is causing lots of side effects and who has a highly resistant virus, we often continue the STI for two to four months until the virus reverts to a wild type—if the patient feels OK and the blood-test results don't completely go the wrong way. And, of course, an STI doesn't always cause resistant HIV to revert.

Are patients usually ready to resume meds after an STI?
Motivation levels are usually higher when a patient goes back on therapy. But that really depends on the reason for the STI in the first place, and how well it worked. And then there is the decision of which HAART combo to start back on. If toxicity or adherence was the issue, avoiding certain drugs or complicated regimens is key. If the STI was for immune-boosting purposes, the same regimen as before might do. If it was for highly resistant virus, then the new regimen might well be four or more drugs picked according to treatment history and resistance testing.

After a patient starts on therapy again, what typical clinical response do you see?
There is no "typical" response. But generally I'm not discouraged—the patients do better than when they were off therapy. Their adherence is better, leading to better anti-HIV suppression. But after a year or so, resistance does creep back. There is still limited data, so I can give only an educated guess, but I support my patients, whatever their choice. We stick with a treatment strategy only if we're both smiling. If their blood work reflects a lower viral load and higher CD4 count, but they're miserable, that is not a "success."

Do you recommend an STI to a patient or do you wait for them to ask you?

If I see problems or side effects on the meds, I will bring up the possibility or even recommend it. But I hate to plant the seeds of doubt about HAART in a patient's mind unless it's warranted.

Do you ever argue with patients who want to do an STI but you feel shouldn't?
No. Ultimately it is their choice. My role is to be an experienced guide who is still learning from his mistakes as well as from the research and experience going on all around us. Patients frequently stop their therapy without my official OK for their own reasons. I want them to feel that they should not be afraid to let me know what is going on. Hopefully, a dialogue will allow for mutual decision-making. But these discussions take time.

Do other doctors advocate for STIs?
Lots of experienced clinicians have been exploring STIs for a while. The research has so far been defined by small studies, which have managed to open the minds of other researchers. But we desperately need bigger, better and longer studies.

If you do an STI, you risk an increase in viral load. But if your virus is undetectable, can you still have other HIV-related problems?
Yes. I've had patients who have labored mightily to reach the point of undetectability only to then die of AIDS—their CD4 cells were scraping the zero mark. Health is more than a viral-load measurement. One of my big disagreements is with the cookbook approach that says you should go on one of these combinations of anti-HIV drugs, and if that fails, you just keep trying other combinations. The data supporting this strategy are often based on limited studies, and when you try it in real, live patients, it doesn't work that well.

It's hard to think 20 years down the road with a medication regimen—whether or not it makes you sick.
It's unrealistic to start therapy early to get the lowest HIV level and expect someone to continue the therapy for 20 years. Maybe if you were expecting a cure—but there is no cure. Right now there's no drug in the pipeline, either, that's so miraculous it can fix lots of resistance and other screwups. Every patient is an individual, and finding the right regimen is more of an art than a science.

You've said that HIVers in the developed world are overmedicated and those in the developing world are undermedicated. Of course, drug companies still can't get their drugs to Africa. Why is it so hard to get AZT to pregnant women, for example?
It's political. That's why I boycotted the AIDS conference in South Africa—the government doesn't support giving HIV drugs to pregnant women. We have a lot to offer Africa, but first we have to get our own house in order. If rich countries can reduce the cost of HAART through development of more focused therapy (through STIs, for example), more parts of the world can benefit by figuring out how to use the least possible effective therapy. We need to figure out how to make that happen.

Are STIs 4 You?

Taking a break from HAART by way of a Strategic Treatment Interruption (STI) may or may not be just what the doctor orders. Here’s the brief:

PRO

- Your body may recover from drug toxicities.
- Your HAART-suppressed anti-HIV immune response may return.
- Your drug-resistant virus may revert to wild type.
- You may be better motivated to adhere when you resume HAART.

CON

- Your CD4 cell count may decline off therapy.
- Your wild-type virus may develop resistance.
- Your viral load may increase.
- Your drug regimen may not be as effective when you resume HAART

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