7/7 Heaven

February 1, 2002 By Mike Barr

A lifetime supply of HIV meds at half the cost! If that sounds to your ear like a late-night TV pitch, you likely missed December's AIDS-treatment headlines: A recent government study found that taking HAART only half as often may be just as effective as full-time treatment. A team of researchers at the National Institutes of Health (NIH) led by Anthony Fauci, MD, and staff clinician Mark Dybul, MD, developed an intermittent strategy -- seven days on meds, seven days off -- designed so that the time off is not long enough for the body to begin producing HIV again.

By cutting your pill burden in half, this 7/7 cycle -- dubbed "pulsing" -- offers the obvious benefit of limiting some of the nasty side effects of combo therapy, such as elevated lipid levels in the blood that can lead to heart disease. While the study followed only eight people for about one year, Dybul says that he is very pleased with the findings, adding that they provide "proof of concept" to proceed to larger, longer studies.

Boldly pioneering research into STIs (structured treatment interruptions), Fauci and his NIH team hit upon the idea of "pulsing" when they observed a delay of five to seven days between the time patients stopped taking their drugs and the reappearance of detectable virus in the blood.

In the study, HIVers on combo therapy with undetectable viral loads and CD4s greater than 300 were switched to a quadruple regimen of 3TC/d4T/ indinavir/low-dose ritonavir. They had no significant increase in the amount of HIV either in plasma or lymph nodes, and their CD4 cells remained stable. Side effects? On average, six months into the study, cholesterol levels fell by 22 percent, triglycerides by 51 percent. And what about the dreaded "R" word? Fauci's feds found no evidence of drug resistance in the Pulsing 8.

This news stole the show at December's ICAAC conference, and experts were quick to form a chorus of cautious optimism. If the apparent success of the NIH study can be duplicated in larger numbers of patients, the 7/7 treatment strategy could revolutionize the medical management of HIV -- not least in poor nations. Explained Dybul recently on National Public Radio's *All Things Considered*, "In Nigeria, Botswana and Ghana you can already get [the cost of HAART] down to $350 to $500 per patient per year. If you can get away with 50 percent less drug without sacrificing clinical efficacy -- and maybe even having clinical benefit in terms of toxicity -- you can now reduce that cost to perhaps $175 per person."

Sound too good to be true? Some resistance-wary physicians argue that the study was simply too short -- eventually HIV will figure out a way around the drugs. After all, the AIDS medical

community still rallies around cries for perfect adherence to drug regimens and the reverberating admonition to never miss a dose -- let alone skipping an entire week.

Of course, with strict adherence still essential, 7/7 poses certain practical problems. For one, how to remember if this is the “on” or the “off” week. And will this 7/7 approach work as well with other HIV meds? Sustiva, for one, isn’t pulsing-friendly: With its lengthy half-life, the NNRTI remains in the blood much longer than other antiretrovirals, thereby courting resistance. Drugs with harsh side effects may also wreak havoc. Ken Fornataro, the AIDS Treatment and Data Network’s ED, reports that he has clients who, against clear warnings not to try this at home, have already gone 7/7 solo. Not only are some getting hit by the same side effects each time they go back on their regimen, but a few also say that the intensity of side effects seems to build with each re-initiation.

Still, it is all systems go at the NIH for larger, longer 7/7 studies. Responding to criticism of his renegade research, the veteran Fauci is characteristically unrepentant: “Until the ideal AIDS drug comes along, keeping side effects to a minimum is the best approach.”

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