Quick Draw

April 1, 2002 By Mike Barr

What a coup it would be if you and your doctor could know after a single week whether your new HAART combination would work over the long haul. New research from the high-flying lab of Anthony Fauci, MD, at the National Institutes of Health proposes exactly that. Imagine: Just check your viral load six days after starting the combo, and if it hasn't fallen by 0.72 log -- that's about a fivefold decrease, for example, from 25,000 to 5,000 -- you are 99 percent guaranteed to be on your way to treatment failure within three months.

Current federal guidelines call for a check at week four, when anything less than a 0.5 to 0.75 log drop is said to be cause for alarm. The International AIDS Society's recommendations are more stringent: If your viral load doesn't drop by 2.0 logs by week four, treatment intensification -- adding a drug -- or a wholesale change of regimen is due.

But the new NIH research, teased from data originally collected in the mid-'90s, might prove less of a boon than we might wish. As treatment-watchdog John James noted in his November 11 *AIDS Treatment News*, "The patients and treatments in this study were often not representative of what physicians see today." And that's putting it diplomatically. In fact, three-quarters (90 out of 124) were treated with *below-standard* protease-inhibitor monotherapy. And because all were new to therapy (no cases of nasty resistance), this six-day crystal ball may only apply to "best-case" treatment newbies. And there is further uncertainty as to how it might hold up with different classes of drugs. The NIH researchers themselves cautioned that a day-six viral-load test might have little predictive value "in regimens in which resistance can develop very quickly," as with 3TC and the NNRTIs. Practicality also presents a problem: Your viral load must be measured precisely on day six -- day five or day seven won't do.

So it remains to be seen how much this research could actually improve current clinical practice. Certainly identifying treatment failure as soon as possible would help predict drug resistance. But it's general practice never to base a decision to change therapy on a *single* viral-load measurement. The NIH researchers acknowledge that not only do both CD4 cells and viral load fluctuate daily, but the tests themselves lack pinpoint precision. In the best of worlds, you'd get your day-six viral-load result in a week. Reality often takes much longer.

The take-home? This news is provocative, but of little immediate use. "We agree that this study clearly needs to be corroborated in HAART-experienced individuals -- as well as with combination regimens that represent all current classes of drugs," Polis said. Still, he stubbornly added, "Evidence of a less than 0.75 log viral-load drop after day six would give me pause. A chat

between patient and doctor about adherence and absorption might save one or two drugs for future uses if it were determined that the combination wasn’t working.”
