Prevention Suspension

On HAART, your CD4s have ballooned. Is it time to bail on your prophylactic drugs? The feds weigh in with updated guidelines.

February 1, 2000 By Doug Allen

As soon as HAART sent some CD4 counts through the roof, PWAs began asking if and when it was safe to quit popping pills to prevent opportunistic infections (OIs). After all, the kickoff point for such prophylaxis was always marked by a dip below a certain CD4 level, or "threshold." (That's because, while the infectious agents that can cause OIs are found in most people, they generally produce symptoms only in those with very low CD4 counts.) The question was whether studies in people would parallel encouraging lab findings that HAART-induced replacement CD4 cells attack at least some opportunistic microbes as well as the original CD4s could. Last year, with the first promising results in, a group of experts revised the U.S. Public Health Service guidelines for OI prophylaxis. Now, for the first time, people with HIV have a standard of care for stopping preventive drugs for three OIs.

While the obvious benefits of reduced toxicity, resistance and cost are big, the emotional boost may be even bigger. "I think many people underestimated the psychological benefit of actually being able to stop one of your medications," says federal panelist Judith Currier, MD, associate professor of medicine at the UCLA Medical Center. "It's a real victory, and that's important."

But the revised guidelines stress caution. Currier notes that the people at lowest risk for an OI are those whose CD4s are above the given OI threshold and whose virus has been completely suppressed for three to six months. As viral load increases, so does OI risk—although by how much remains unclear. Current studies should answer that question soon. Until then, Currier advises, "I wouldn't take a patient off prophylaxis if his or her antiretroviral regimen is clearly failing to control viral replication." She adds that there is generally more evidence to support removal of primary prophylaxis (to prevent a first instance of a given OI) than of secondary prophylaxis (after one or more bouts), except in the case of CMV.

Recent research suggests that when the guidelines are followed, prophylaxis against the following three OIs can be stopped with minimal risk of illness:

Pneumocystis Carinii Pneumonia (PCP)
The Pneumocystis fungus can invade the lungs and other organs, so the feds continue to recommend that HIVers with a seriously compromised immune system—indicated by CD4s below

200 or a history of thrush—begin primary prophylaxis. And the new guidelines add two more red flags for starting such a drug: a CD4 percentage—the proportion of T cells made up of CD4s—below 14, or an AIDS-defining illness. But the panel cites three studies as evidence that "providers may wish to discontinue prophylaxis" when CD4 counts are greater than 200 for at least three to six months, adding that "additional criteria might include sustained reduction in viral load" for the same timespan. As to secondary prophylaxis, the panelists caution that "inadequate numbers of patients have been evaluated to warrant a recommendation to discontinue prophylaxis" for HIVers with 200-plus CD4s who have already had PCP. "PCP can be an immediately life-threatening condition, so if they've ever had it, we don't yet know the safety of discontinuing," Currier says. And for anyone considering discontinuing prophylaxis, Currier also advises weighing how well they tolerate the drug. In particular, Bactrim-takers who developed a rash and/or had to be desensitized when first taking the drug may have a harder time restarting.

Mycobacterium Avium Complex (MAC)

Primary prophylaxis against MAC—a serious disease caused by common bacteria that can attack a particular organ or spread through the bloodstream to the entire body—is standard in HIVers with CD4 counts below 50. Data from observational studies suggest a low risk of developing active MAC disease when, in response to HAART, a CD4 count of 50 or less rises above 100. Because of this, the new guidelines say that "a reasonable option would be to consider" stopping primary MAC prophylaxis when CD4s are over 100 and viral load is undetectable for at least three to six months. The panel recommends against stopping secondary MAC prophylaxis due to a lack of evidence of safety.

Cytomegalovirus (CMV)

The guidelines for CMV—a herpes virus that most often attacks the eye but can also invade the gastrointestinal tract and the nervous system—continue to discourage primary prophylaxis due to the severe toxicity, low effectiveness and high cost of the approved preventive drug ganciclovir (Cytovene). Instead, frequent eye-health monitoring is recommended for those who are CMV positive and have fewer than 50 CD4 cells. For secondary prevention, several studies have found virtually no recurrence of CMV retinitis in people with CD4 counts above 100 to 150 and suppressed viral load. Before HAART, retinitis typically recurred within six to eight weeks, but these study participants have stayed largely disease-free for 30 to 90 weeks. So the experts say that discontinuing prophylaxis "may be considered" when CD4s top 100 to 150 for three to six months. Any decision to discontinue should be made in consultation with an ophthalmologist based on such factors as the trend in CD4 counts and viral loads, location of lesion, vision in the unaffected eye and availability of regular eye-health monitoring.

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