Women on the Verge

HIV meds have been tested mostly on men, leaving positive women to guess how treatment might affect them. Can a new drug study provide answers?

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In 2001, when Ida Byther-Smith started HIV meds, she didn't expect side effects to include hot flashes. But two years later, the Chicagoan hit menopause abruptly, -at 53—though women in her family typically go through the change much later and more gradually.

"My doctor didn't know why," says Byther-Smith, now 57. A nurse said some HIV meds seemed to rush meno-pause,- but that no studies existed to prove it. "I was afraid," Byther-Smith says. "We still don't know if it was the meds"—or how else they might affect her.

Indeed, mystery surrounds women's HIV treatment. "Women aren't just smaller replicas of men; they may be completely different in how they absorb, metabolize and clear HIV drugs," says Monica Gandhi, MD, of the Women's Interagency HIV Study (WIHS).

Though WIHS has been gathering data on women and HIV treatment since 1993, survey results can take years to emerge, says Gandhi. Meanwhile, questions and HIV med choices grow.

So far, Gandhi says, "we know women have more side effects than men," maybe due to body-weight and hormone differences, among others. Several reports, for example, find that nausea affects more women than men on the protease inhibitor (PI) Norvir (ritonavir). Extra side effects, adds Gandhi, make women "switch combos more frequently, putting them at higher risk for drug resistance."

Details are murky, largely because most HIV meds are tested in men, who constitute 70% to 80% of most HIV clinical trials, says Judith Currier, MD, of UCLA's Clinical AIDS Research and Education Center. Reasons include some women's lack of childcare and transportation and a higher fear of side effects. But the makers of the new PI Prezista (darunavir), for people who've tried previous HIV combos—hope to buck the boys' club.

Tibotec Therapeutics, Prezista's manufacturer, will focus a 48-week study on women, including comparative substudies of people of color. The GRACE (Gender, Race And Clinical Experience) study will analyze Prezista (boosted with Norvir) by gender.

Currier, a study creator, says that since “HIV is an epidemic among women,” GRACE will enroll 70% women.

The study will track Prezista’s longer-term effectiveness, resistance and side effects, following the drug’s FDA approval last June. “We tend to discover gender differences long after a drug is approved,” Currier says. “The findings on liver toxicity in women on nevirapine [Viramune] is a good example,” she adds, pointing to research from 2004 through 2006 showing the med’s pronounced side effects in women.

Treatment advocate Dawn Averitt Bridge, a GRACE community adviser, says those findings plus pressure from positive women and treatment advocates have created the perfect climate for changing HIV drug research. “There’s no excuse anymore,” she says.

But Currier says getting 70% female enrollment will be tough. Byther-Smith explains, “We don’t see anyone in the HIV drug ads who looks like us, sowomen feel [the drug companies] aren’t interested in us.” And a 2005 WIHS study shows that trials might have mistakenly excluded some women who met entry requirements. But Byther-Smith isn’t pointing fingers. “If women don’t step up,” she says, “it won’t change.” —Rebecca Minnich

If you take or might start taking Prezista, consider enrolling: GRACEstudy@wilm.ppdi.com; 866.512.7943.

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