Triple Crown Win for HIV?

June 19, 2012 By Laura Whitehorn

In May, advisory committees of the U.S. Food and Drug Administration (FDA) recommended approval of three new ways to test, prevent and treat HIV. PrEP for prevention, the "Quad" pill for treatment, and an over-the-counter, at-home HIV test for, well, testing. At press time, final decisions on approvals of all three are pending. The FDA panels considered these new tools strictly in terms of what scientific data indicated about their potential benefits. The discussion about how best to wield these tools in the real world continues.

Here's a snapshot of the starting gate:

For Prevention: Truvada as Pre-Exposure Prophylaxis (PrEP)
First out was the idea of using daily doses of the HIV drug Truvada (tenofovir plus emtricitabine) to prevent HIV-negative people from acquiring the virus. It will be the first drug approved as a form of oral pre-exposure prophylaxis, or PrEP, and it must be taken daily and used with condoms and other safer-sex measures.

Committee members voted, though not unanimously, to approve PrEP for men who have sex with men or for the negative partner in a stable relationship with a positive person. By an even slimmer margin they gave the go-ahead to PrEP for other groups.

Among the issues under debate: Will HIV-negative people be able to stick to the rigorous daily dosing schedule necessary for Truvada to work as PrEP? How will possible side effects be monitored and managed? Is it ethical to provide pills to high-risk HIV-negative people in the United States when 750,000 HIV-positive Americans are not currently receiving meds?

For Treatment: the Quad
The advisory panel also recommended approval of a four-drug all-in-one pill to treat HIV. The tablet, nicknamed the "Quad," would be for first-time HIV drug takers. Taken once daily, it contains two experimental compounds, elvitegravir and cobicistat, plus already-FDA-approved HIV drugs Viread (tenofovir) and Emtriva (emtricitabine).

For Testing: the OraQuick In-Home HIV Test
Another panel recommended approval for OraSure's oral swab–based rapid in-home HIV test. Despite data showing that the test is less sensitive than other HIV tests (missing as many as seven positive diagnoses per 100), the panel recommended approval on the grounds that potential benefits to public health outweigh these risks.

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