FDA ignores critical information on home HIV tests

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Los Angeles, London, New Delhi, Singapore and Washington DC (May 29, 2009) The FDA is ignoring critical information in deciding whether to approve an over-the-counter, rapid HIV test for home use, according to a recent article in the journal *Medical Decision Making* (*MDM*) which is published by SAGE.

As the price of the HIV test rises, some lower-income individuals who are at greater risk for HIV infection will not be able to afford it. The FDA has been criticized because it bases its decisions on small studies performed in non-representative populations.

"When approving new technologies, the FDA should focus less on the general population and more on the people who will actually use these technologies," said co-author A. David Paltiel, PhD, of the Yale School of Medicine. "The disconnect between approved indication and actual use is stark."

The test in question is the OraQuick ADVANCE 1/2, a rapid, point-of-care test that can detect antibodies to both HIV-1 and HIV-2 in 20 minutes using a simple cheek swab. The test is already FDA-approved for use in health care settings such as hospitals, drug treatment facilities, state and local health departments, clinics, community-based organizations, and university health centers throughout the United States.

The FDA has asked the manufacturer to collect data on the ability of the test to correctly detect both the presence and absence of HIV infection

when employed by untrained users. However, it has not requested any further information on how the manufacturer's retail price will influence the demand for home testing in populations with high-rates of undetected HIV infection. Using a mathematical analysis, the authors demonstrate that many of the highest-risk individuals will be unable to afford home testing at the price the manufacturer is likely to propose. By failing to take into account the relationship between retail pricing, consumer purchasing behavior, and HIV risk, the FDA may overestimate the test's ability to identify previously undetected cases of HIV infection.

"The information currently sought by the FDA is not sufficient to address the true benefit of the HIV test for home use," write Paltiel and co-author Harold A. Pollack, PhD of the University of Chicago School of Social Service Administration. "Our analysis suggests that a cheaper test may do a better job of finding HIV infection. The home HIV test product might actually work better at a lower price."

More information: "Price, Performance, and the FDA Approval Process: The Example of Home HIV Testing" in *Medical Decision Making* is now online and freely available for a limited time at mdm.sagepub.com/cgi/rapidpdf/0272989X09334420v1 .

Source: SAGE Publications