



Home Free?

Home testing also raises legal issues

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The FDA is considering two kinds of kits: the direct access kit, which will allow an individual to produce an analyzable blood sample and send it to a lab, and the true home testing kit, which would allow an individual to test him or herself and determine the result.

Most people learn of their HIV status by a personal communication from a doctor or other clinic worker and, although CDC statistics show that counseling is often inadequate or missing altogether, those situations provide the opportunity to ask questions and receive counseling (which is required by law in many states). The Direct Access kit will provide counseling during telephone contact with a counseling center; a true home-testing kit might not. Counseling should include warnings about problems HIV positive folks may encounter if they are not careful about whom they tell. Although there is legal protection against discrimination, it isn't always effective in preventing problems, so people should be counseled on how to avoid trouble by being careful about disclosure. Sole reliance on printed materials for counseling may be inadequate, since a pamphlet can't respond to questions and may be written in language the test-taker doesn't understand.

The testers - and anybody else who comes into possession of HIV information -- may be subject to a variety of laws and regulations governing HIV confidentiality. These laws, which differ from state to state, impose legal liability on unauthorized use or disclosure of information, but may also impose reporting requirements that could be complicated by home testing. Unless carefully controlled and monitored, home collection or testing kits might be improperly used by employers or others seeking to avoid legal protection against the misuse of HIV information. Many states now legally require reporting of HIV positive results to public health departments. Licensure of home kits will raise questions about how such reporting will be administered when the doctor's office or a clinic is excluded from the process.

Home kits should substantially increase the numbers tested, which will predictably increase the absolute number receiving inaccurate results. There are already lawsuits by people claiming severe emotional distress on being told -- falsely, as it turned out -- that they were infected. False positives are a fact of life with mass screening. Even a test that comes closer to 100 percent accuracy than present HIV tests will generate many inaccurate results when 10 or 20 million people take the test, especially under home collection conditions.

When home testing increases the number of people who know their positive HIV status, it will also increase the number who need to be aware of legal constraints. A person who knows that he or she is positive when applying for insurance but fails to reveal that on the application may be guilty of fraud and subject to cancellation of insurance and other penalties. If a person engages in sexual activity that might transmit HIV, knowing his or her serostatus to be positive, he or she may be guilty of a felony in many states. Your state of knowledge will be critical in determining liability in many circumstances.

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