

New HIV test to determine recent seroconversion.



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An HIV test that may soon be used in Australia can actually determine whether HIV infection has occurred in the previous four months. The test is called a "de-tuned ELISA" or STARHS (serological testing algorithm for recent HIV seroconversion). The ELISA (enzyme-linked immunosorbent assay) test detects antibodies in the blood after three to four weeks of infection. (The period in-between is usually referred to as the "window period".) The de-tuned ELISA however is basically a less sensitive version of the standard test – and can therefore only detect antibodies after about four months (129 days on average). The standard current procedure is if a test is positive (or indeterminate) using a standard ELISA, it is then confirmed using a Western Blot. If both tests are positive then the person from whom the blood comes is definitely HIV-positive. If the Western Blot is negative or indeterminate then the whole procedure is repeated. The de-tuned ELISA would be used on a confirmed positive sample. If someone tests positive to the standard ELISA but negative to the de-tuned ELISA then they are most likely infected within this recent period.

Why?

HIV *incidence* is the number of new HIV infections and is a measure of the dynamics of the epidemic. Incidence is often calculated in per 100 person years. HIV *prevalence* on the other hand is an estimate of the total number of HIV infections so it is a calculation of the total size of the epidemic. HIV incidence has previously been estimated by back-projections based on the number of documented newly acquired HIV infections (as opposed to HIV diagnoses). Newly acquired HIV infection is defined as newly diagnosed HIV infection with a negative or indeterminate HIV antibody test result, or a diagnosis of HIV seroconversion illness within one year prior to HIV diagnosis. The number of documented new infections is a lowest estimate of actual new infections because only a proportion of new infections can be confirmed in this way. For example, in 1999 the number of documented cases of newly acquired HIV infection was 156, although the estimated number of new infections is actually 450.

Advantages

HIV incidence data are useful in a mature/established epidemic such as Australia's. Keeping reliable incidence data is also important and if, as seems to be the case, there is shift among some gay men towards less regular HIV testing, then the use of technologies such as the de-tuned ELISA will be even more important in the future. This test method is also less vulnerable to selection bias than the current system of documenting new HIV infections, perhaps, because the current system can only identify a newly-acquired infection among those who test regularly and those who have a documented seroconversion illness (which means that they would have to be suspected as being at risk of HIV infection). However, there is still some bias because it will still only include those people who have an HIV test.

Disadvantages

As HIV is a notifiable condition in all Australian states there are concerns around confidentiality and partner notification, and that the test may be used to facilitate tracking of HIV infections. This has been raised as an issue in the US in states where HIV is notifiable. Partner notification and contact tracing may be pursued more enthusiastically if newly-acquired infections can be pinpointed more accurately. If, as seems to be the case, that people at the time of seroconversion, and early in the course of infection, have a higher viral load and are therefore understood to be more "infectious", then communicable diseases surveillance systems will be interested in spending energy on tracking these.

History

De-tuned ELISA, or STARHS, was developed in 1999 by San Francisco's Blood Centers for the Pacific in collaboration with the US Centers for Disease Control (CDC). At the 6th Conference on Retroviruses and Opportunistic Infections in 1999 early results from a study were presented using the de-tuned ELISA for the screening of 5.2 million blood donors from across the US. These data showed that HIV incidence was greatest in the Southeast US and among lower socio-economic groups and ethnic minorities.

At the International AIDS Conference in Durban 2000, the increase in HIV infections among men who have sex with men in San Francisco was presented—based on data from anonymous testing sites, where HIV incidence had increased from 1.3 per cent per year in 1997 to 3.7 per cent per year in 1999.

This increase was detected by using the de-tuned ELISA on stored blood samples. The use of this test at anonymous testing sites explains why an increase was not seen in sentinel surveillance at the municipal STD clinic from 1995 to 1999, although HIV incidence at this site remained at a constant high rate of five percent per year. Men presenting at anonymous testing sites may be more representative of gay men than those attending STD clinics.

The test in Australia

The de-tuned ELISA has until now been used only in research settings. In the future however the use of this test may be standard practice in most states, although at the time of writing this is not currently the case.

If and when this does happen, it raises several issues related to confidentiality and informed consent.

Some of the issues related to confidentiality have been referred to above. And in terms of informed consent, it may be that pre and post-test counselling guidelines will need to be changed or updated to ensure that all people who present for an HIV test are informed that this supplementary test will be applied. These guidelines will certainly have to be reviewed in light of the availability of this new technology.