Failure of rapid HIV tests

Reason for posting: The British Columbia Centre for Disease Control has found problems with the sensitivity of 2 rapid HIV tests: the Fast-Check HIV-1/2 (serum) and the Fast-Check HIV-1/2 (whole blood) (see page 119 of this issue).[1] When the serum samples of 407 HIV-positive patients were screened using the rapid serum test, the test's sensitivity was 99%. However, repeat testing of these samples using different test lots produced variable results. Also, when the serum samples of people at risk for HIV infection were tested using both the serum and whole blood tests, discordant results were found. Furthermore, when the whole blood test was applied to 63 specimens from HIV-positive people taking antiretroviral therapy, the test's sensitivity was only 86.5%,[1] far below the sensitivity of > 99% (consistent with standard laboratory-based screening methods) previously reported for either test.[2,3]

The sale of the kits has been halted by the manufacturer (BioChem ImmunoSystems Inc., now Adaltis US Inc.). Only lots judged by the company to be affected have been recalled. A Health Canada advisory recommends that anyone who has received a negative result from a rapid HIV test since March 2000 (when the tests were first licensed in Canada) should be retested using standard methods.[4] In Canada, 8425 Fast-Check serum and 14 191 Fast-Check whole blood test kits have been sold.[1] Since the Health Canada advisory, as little as 20% of patients with negative results may have returned for repeat testing (see page 180 of this issue).[5]

The products: The rapid HIV test kits are enzyme immunoassays that detect IgG antibodies to HIV type 1 and 2. Although the tests have similar designs and components, the serum test is intended for laboratory use and the whole blood test for point-of-care use. The test kits are to be used by health care professionals where appropriate counselling is available and are not intended for unsupervised home use. For the point-of-care kit, capillary blood from a finger or heel prick is introduced into the device and mixed with a buffer; a colour reaction occurs on a test strip in about 15 minutes. The cost of the point-of-care kit is about $15 and is not covered by provincial health plans[6] (unlike standard HIV screening). The whole blood kit is the only one currently licensed for rapid point-of-care testing in Canada.

Health Canada has published guidelines on the use of rapid HIV test kits.[7] As with all HIV testing, specific, informed consent is required from the person being tested, and standard counselling procedures need to be modified to accommodate the same-day delivery of results.[8] Patients with a positive result from a rapid test need to be aware that the test is a screening tool and that the result is not diagnostic; a venous blood sample must be sent for confirmatory testing at an approved laboratory (with the usual 1–2 week wait), followed by appropriate public health reporting and contact tracing.[6,7] Before the current concerns about sensitivity, patients with a negative result needed to be retested only if the test was administered in the "window period" (usually 3–6 months after HIV risk activity, when screening tests are unreliable) or if symptoms of immunosuppression or hepatitis C developed.[7]

Rapid HIV tests offer the advantage of allowing access to hard-to-reach populations, including injection drug users[9] and people visiting STD clinics.[5] The kits are also useful in rural and remote settings[8] and allow timely HIV prophylaxis for women in labour[6,10] and for health care workers after needle-stick injuries.[6,11]

The performance problems of the rapid HIV tests may relate in part to their inability to detect low antibody titres in people taking antiretroviral therapy with low viral loads. Why specific lots have failed has not yet been made public.

What to do: By the end of 1999 nearly 49 800 Canadians were HIV positive, but one-third of them may be unaware of their status.[12] Laboratory-based screening tests can take up to 2 weeks and require the patient to return for their test results. However, in a 1995 US study 25% of people tested did not return for their results.[2] In contrast, rapid HIV point-of-care tests require only 1 visit and may be particularly useful in environments where patients may be unlikely to return for test results. Unfortunately, it is these patients who may be unaware that they may have been falsely reassured by a negative rapid HIV test result, creating a significant public health challenge, especially if the tests were done anonymously. Any patient who can be identified to have received a negative result from a rapid HIV test any time in the last 2½ years needs to be tested again using standard laboratory-based screening procedures.

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References

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