

- 8 AUG 1985
 NEW SCIENTIST

Ministers delayed launch of AIDS test

THE BRITISH government stands accused this week of deliberately delaying the introduction of a blood test for antibodies to the AIDS virus. Six months after a test was introduced in the US to screen the country's blood donors, the British government last week announced its approval of a test developed by the British company Wellcome Diagnostics. Abbott Laboratories, which developed the US test, accuses Britain's Department of Health and Social Security (DHSS) of delaying official approval until a British test was available.

While public health officials in the US congratulated each other last week on keeping the nation's blood free of the AIDS virus, Britain's National Blood Transfusion Service still waits for a screening test for AIDS.

Experts from all over the US met last Wednesday at the National Institutes of Health in Bethesda, Maryland, to review the first three months of experience with a procedure for testing blood samples for antibodies to the AIDS virus. The mood of the meeting was one of elation at having made real progress at curbing the spread of the disease. Walter Dowdle, director of the US government's Center for Infectious Diseases, described the six screening tests currently available as "just fantastic".

Meanwhile, Britain's DHSS says it is waiting for a comprehensive and proper assessment of all screening kits on the market in order to identify the most appropriate one for the needs of the National Blood Transfusion Service. The department is alarmed about the number of "false positives" obtained with the tests now available. These are cases where the blood sample is wrongly diagnosed as containing the antibodies to the virus.

The tests, known as enzyme-linked immunosorbent assays (ELISA), cannot

spot the virus itself, but only the antibodies that the human immune system mobilises against it. If a blood sample contains antibodies, the person it came from must have at some time been infected with the virus.

The DHSS's reasons for delaying a test, however, do not stand up to scrutiny. There are six tests currently on the market; all are ELISA tests that work in much the same way, and research at the American Red Cross's Biomedical Research and Development Laboratories has shown that false positives turn up in all six testing kits on the market. False positives are probably caused by remnants of the substrate on which the virus used for the test is grown. "Currently, licensed ELISA tests cannot be used to define true positives," Roger Dodd of the American Red Cross said.

A definite diagnosis of AIDS requires a further test, called the Western blot. This is slow, difficult and costly for clinics to carry out. Abbott Laboratories is about to launch an alternative confirmatory test that relies on a better marker for the AIDS antibody that is made using genetically engineered antigen. It seems odd, therefore, that the DHSS insists on looking for the "best" test.

Secondly, although false-positive results are clearly worrying for the blood donor, they are not a problem for the National Blood Transfusion Service, whose primary concern is to keep blood free of pathogens. Data from 131 clinics in the US which collected and tested 1 128 166 units of blood were presented at the meeting in Bethesda. About 0.85 per cent of the blood was positive when first tested. Further testing confirmed only between 0.14 and 0.29

per cent of the blood as positive. The amount of blood falsely diagnosed as positive is, therefore, relatively insignificant.

The DHSS announced last Thursday that it had completed the first phase of its assessment of AIDS screening tests. It approves of three kits for use in diagnostic laboratories, and two have been chosen to enter the second phase of assessment—daily use at blood transfusion centres in Edgware and Manchester. These two kits are made by Organon and Wellcome Diagnostics. The arrival of the Wellcome kit was announced prematurely last week, before the DHSS had time to release its official statement.

Wellcome claims that its test will produce fewer false positives than other tests on the market and that it is easier and quicker to use because it avoids the need to dilute blood samples prior to testing. These factors could account for its support from the DHSS. However, Wellcome's competitors believe that the DHSS's approval was a foregone conclusion. The department, they say, may have been waiting for a British test because of the size of the market for AIDS screening tests.

Even if Wellcome's test fares well in its trial at transfusion centres, production will need to be scaled up. Special facilities will have to be allocated such that the AIDS virus is grown in sufficient quantity to screen the National Blood Transfusion Service's 2.25 million donations per year with minimal risks to safety of staff. Wellcome is confident, however, that it can produce the test on a large enough scale, should that be required. □

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