36

ARTICLE IN THE NEW SCIENTIST - 8 AUGUST 'MINISTERS DELAYED LAUNCH OF AIDS TEST'

1. PS(H) has asked for briefing about the article in the New Scientist on the 8 August. The points in the article are dealt with in the order that they are made.

2. Claims that the Anti-HTLV III Tests have been made available to screen the UKs blood donors for six months

FDA licensed two diagnostic kits in March 1985. The introduction of screening tests in the USA went ahead on a voluntary basis from then on. Many blood banks were still not screening their donations at the time of the Atlanta Conference in mid-April. PHLS commenced evaluation in late May and issued the report in mid-July. Abbotts Laboratories withdrew the kits it had initially submitted to PHLS for evaluation. Information from the American Blood Bank Association indicates that Abbott have had to inform blood banks that some hundred thousand tests have been faulty.

3. Abbott Laboratories said to accuse DHSS of delaying official approval of tests. A copy of the letter is attached in which Abbott has written to the New Scientist denying that it or any employees have accused DHSS of delaying official approval.

4. NBTS still waiting for a screening test for AIDS compared with USA. The prevalence of the AIDS virus in the USA is considerably greater than that in the UK. The number of AIDS cases/million population in the USA is 40.9/million.The number of AIDS cases per million population in the UK is 2.5 per million. Clearly there is much greater risk of a blood donor being infected with the AIDS virus in the USA than in the UK.

5. DHSS waiting for comprehensive and proper assessment of all screening tests. Reports to officials and professional advisers from the USA for some months before and after FDA licensing of the tests suggested that the level of false positive results was high. Quite apart from donations needlessly being jettisoned all reactive donations would require record cards flagged, continued surveillance of the donor and possibly difficulties over confidentiality. It was for these reasons that it was agreed an evaluation of the available tests was required. Whilst DHSS informed Health Authorities that they were carrying out an evaluation of the tests at no time has any Health Authority been prevented from instituting tests should they wish. However in the BTS content RTDs advised DHSS of the consequences of unco-ordinated introduction of screening into the Blood Transfusion Service for

the donors; the effect on recruitment of donors; the probability that introduction of screening attracts high risk donors and thus the need for alternative testing sites. All this pointed to a co-ordinated national implementation. This was agreed with PS(L) and MS(H).

6. American Red Cross Biomedical R & D Laboratories Results on Six Testing Kits

The American Red Cross has not tested the kits tested in the PHLS. They have only tested American FDA licensed and unlicensed tests.

7. Need for Western Blot Method of Identification

British Scientists are unconvinced of the value of the Western Blot confirmatory tests for anti-HTLV III. It is a subjective test and dependent on the skill of the operator. There are a number of alternative methods of testing other than the ELISA which the PHLS Reference Centres intend to use to confirm the results.

8. Abbotts New Test

Second generation tests are being produced by all companies. Abbott have apparently produced an alternative confirmatory test based on the Western Blot method. This might be introduced into PHLS laboratories if it proves to be useful.

9. Wellcome claims that its tests will produce fewer false positives.

Wellcome were a late entry to the diagnostic kit field but they have based their technology on a methodology already familiar to the NBTS. Moreover the specific nature of the test may well be the reason for its better performance. It was expected by all concerned in setting up the evaluation that Abbotts Laboratories who have an excellent record for diagnostic tests would have a satisfactory test. To the surprise of all their test was poorer in specificity/ no better than Wellcome in sensitivity,* went quite haywire when specimens were heat treated (to inactivate any virus) and took more than twice as long to perform than the Wellcome test.

(i.e re false sit s)

*no more false negatives

10. Availability of Wellcomes Test

We have been assured that Wellcome will be able to supply the needs of the Blood Transfusion Service.

16 August 1985

cc:

MED SEB
Room 1025a Han House
Ext 3487