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Dr A Smithies

AIDS

You will know there is a meeting with Dr Harris Thursday (Mr France will attend) and possibly a meeting with PS(H) Friday (but see below). I met Mr France on Tuesday. He is going to talk to CMO suggesting that I put a submission for Ministers to him (CMO) by the end of the week. He is also going to suggest to CMO and also PH(H) that the meeting is postponed until this submission has been considered.

I attach my first draft. I am revising the structure of this to reflect the starting point which CMO/PS(H) now want ie the speedy introduction of a screening test into BTS on available data, without waiting for confirmatory tests etc. I do not suggest you comment in detail on this version. My revision will, at Mr France's suggestion, include a decision tree. I think I may suggest to Ed Harris that Thursday be devoted to discussing my submission and inviting FD along. What do you think?

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5 June 1985

copy to: Mr A Williams HS1A ✓

AIDS AND BTS

Background

1. Ministers agreed in [] that blood donations should be routinely screened for the presence of antibodies to the AIDS virus (anti HTLV3). RHAs were asked to set aside funds in 1985/6 for this purpose.

2. Implementation of this policy requires:

- a. selection of suitable test;
- b. decision on the parallel provision of testing at other sites;
- c. provision of facilities to carry out confirmatory tests;
- d. decision on the counselling of donors found to be positive.

Choice of a test

3. Selection of a suitable test is extremely important. About 6 are currently available. There is a need to evaluate these in order to recommend a test which:

- i. has fewest false negatives - otherwise infected blood might get used;
- ii. has fewest false positives - otherwise significant quantities of blood will be dumped, donors dropped from panels, and donors caused anxiety; all unnecessary;
- iii. is most operationally convenient for large scale (2 million donations per annum) testing in the BTS.

Inevitably the final choice will involve a trade off between these factors and cost.

4. The PHLSB are carrying out the initial evaluation to check the technical performance of available kits. They will get information on performance against criteria i and ii. The results will be considered by an expert panel. They will advise which tests could be considered for use in the NHS. These tests will then be given field trials in the BTS. These will confirm on a wider scale performance against criteria i and (especially) ii, and also evaluate their performance in the BTS operational context.

5. The PHLS will have tested 2 of the available kits within the next two months. The others should have been tested by September. Pressure is being applied to PHLS with a view to improving on this timescale. However, it is important that scientific rigour is not sacrificed in the process. A test which fails to detect antibodies will be a danger to public health. A test which "detects" non-existent antibodies will be a cause of anxiety to donors and wasteful of resources. Field trials will be conducted on kits as soon as they have been cleared by the expert panel. The BTS will then be consulted on the final choice of a test and on its simultaneous introduction by all BTCs, and at alternative sites. The latter two points are important since
a. clinicians may well insist on using blood only from centres who are testing;
and b. we must avoid centres who are testing acting as magnets to those in the "at risk" groups who want the reassurance of a test and use the BTS as a means to that end (see below).

6. Further deaths among recipients of blood donations cannot be ruled out. Any such case will be politically embarrassing because some other countries have already started testing. We could be seen as complacent. Manufacturers of available kits can be expected to exploit any such cases to encourage early decisions to adopt their product.

Notifying Counselling of Positive Donors

7. Decisions are needed on whether we notify those whose blood donation is found on testing to be positive for anti HPLV3. If they are notified then they will need advice (counselling). It is possible to conceive of a policy which involved testing the blood, discarding that found positive, and deleting the donor from future panels. This approach would be consistent with the BTS merely safeguarding its supply and not providing a diagnostic service. On the

face of it such an approach would not require confirmatory tests on individuals or their counselling. However such an approach would be dogged by a host of ethical, legal and public health considerations.

8. It is doubtful whether BTS directors could or would sustain a policy of not informing donors who were dropped from panels of the reason. They would certainly be expected to refuse a policy of calling up again positive donors since this could lead to their staff being infected. The policy would also involve directors colluding in a possible risk to other health workers who might handle blood or other specimens from such patients. The UK would be in the minority in following such a policy. *Positive donors will also be liable to spread the disease if not counselled.*

9. It is ~~suggested~~ ^{concluded} that a policy of not informing donors could not be sustained ~~as~~ ^{as the} long term ~~policy~~. It might be adopted as a short term measure should pressure force the introduction of testing with the BTS. *It is recommended that donors found to be positive are informed.*

10. A decision to inform positive donors adds to the need to reach decisions on:

- a. counselling of donors;
- b. alternative sources of tests; and
- c. the provision of confirmatory test facilities.

Counselling

11. Donors whose blood is found to be positive to anti HTLV3 will need to be given advice. This will follow the results of confirmatory tests (see below). Decisions will have to be taken on how positive donors shall be informed of their result and to whom they should be referred for advice. The counselling will include advice on any changes necessary to their life style to avoid danger to others, and on what to do in case of symptoms developing. Counselling might be organised via GPs, STD clinics or by other means. A separate submission is planned.

Alternative Source of Testing

12. The first defence of the BTS against AIDS is the discouragement of donors in the high risk groups. This will still remain vitally important when screening is introduced. This defence will be jeopardised if high risk individuals use the BTS as a means of obtaining access to a diagnostic test. It is essential therefore that the announcement of the introduction of screening of blood donations is accompanied by publicity on alternative means of being screened. These facilities could be organised in a number of ways eg by open access from GPs or through STD clinics. An efficient way of providing ~~these~~ ^{laboratory} facilities would be to use the PHLSB. They have a network of local laboratories covering the country backed by central expertise. To enable PHLS to undertake this task will require an increase in their funding. This is considered together with funding for confirmatory testing below.

Confirmatory Tests

13. No one can be informed that they are positive on the basis of a single test. A confirmatory test (or tests) using a different test method is essential. The provision of confirmatory facilities needs to be concentrated in a few places. The PHLS have the expertise and organisation to undertake this task. They propose using 5 designated laboratories backed by a central laboratory ^{to take} ~~the~~ ^{confirmatory tests} ~~from all sources.~~ This task will require additional funding for PHLSB.

Resource Implications for PHLS

Initial Testing (para 12).

14. The provision of initial testing facilities can be regarded as a NHS function. The PHLS however are funded as a centrally financed service (CFS). The CFS is under considerable pressure and to fund them to provide this service will require a reordering of priorities both in 1985/6 and in subsequent years.

15. The revenue costs, in a full year for providing a service at all PHLS laboratories will be £538,000. In addition, additional safety precautions at laboratories will cost a one off £75,000. The cost in 1985/6 is likely to be £270,000 (revenue) and £75,000 (capital), a total of £345,000. In future years the cost will be £538,000 (revenue), at 1985/6 prices.

Confirmatory Testing

16. The annual revenue cost for providing confirmatory tests and a reference service to both the BTS and other laboratories will be £195,000. In addition the 5 laboratories will need some upgrading at a cost of £250,000. The cost in 1985/6 will therefore be £98,000 revenue and £250,000 (capital) a total of £348,000. In future years the cost will be £195,000 (revenue).

Advice Sought

17. Are Ministers content that:

- a. the work of evaluating tests proceeds as planned provided that all possible steps are taken to make a choice of test ^{no} later than September;
- b. blood donors found to be positive should be informed of this fact and counselled; and that a separate submission is prepared on how counselling should be provided;
- c. alternative testing facilities are provided by the PHLS network at a cost in 1985/6 of £345,000 and £538,000 thereafter;
- d. confirmatory tests are provided by the PHLS at a cost in 1985/6 of £348,000 and £95,000 thereafter;
- e. a reordering of CFS priorities be made in 1985/6 to find the necessary £693,000 required.