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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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R E S T R I C T E D

SCREENING OF BLOOD DONATIONS FOR AIDS

Background

1. AIDS can be transmitted by the use of infected blood or blood products. Ministers have therefore agreed that blood donations should be routinely screened for the presence of antibodies to the AIDS virus. RHAs have been asked to set aside funds in 1985/6 to finance the introduction of screening by the Blood Transfusion Service (BTS).

2. Screening has not yet started in the UK. It is in use nationally in Australia, widespread in the USA and the Netherlands. France and Germany will introduce it nationally later this summer. Cases of AIDS contracted through the use of UK donated blood have not yet occurred but can be expected. When these are announced the publicity may well draw comparisons between action abroad and apparent inactivity here.

3. Implementation of a screening policy requires:

a. selection of suitable test;

b. parallel provision of testing facilities outside the BTS;

c. provision of facilities to carry out confirmatory tests;

d. provision of advice to donors found to be positive.

Selection of a Test

4. The options are whether to:

1. select an available test on current knowledge as soon as possible;

2. select after evaluation of tests by the Public Health Laboratory Service; or

3. select after both evaluation and BTS field trials.

5. The choice between these options will reflect the balance of advantage between having a test in place quickly as a defence against criticism of tardiness; or waiting until we have a test which can be confidently recommended for BTS use.

6. Adopting a test with a high level of false negatives (ie one which fails to detect antibodies that are present) would be worthless. Equally a test with a high level of false positives (ie one which detects antibodies that are not in fact present) would involve discarding quantities of blood and perhaps depleting the pool of donors. This could well lead to a shortage of blood and thus to postponement of non-urgent operations, and a lengthening of waiting lists. The BTS processes over 2 million donations per annum. This requires a test which will give consistent results and be carried out easily.

Discussion of Options

7. The merits of each option and the timescale for their implementation are as follows:

i. Select a Test immediately - This could be implemented in perhaps 2 months. This is not recommended. UK experts are not satisfied with the reports of evaluations from countries who have conducted trials. There are worries about the lack of reliability experienced. It would be difficult to persuade the NHS to have confidence in an unevaluated test. Ministers have announced that tests will be evaluated. This work is underway. The other health departments would need to be consulted if we departed from that approach.

ii. Select a Test on the Basis of the PHLS Evaluation - This could be implemented in perhaps 3/4 months. This is not recommended. The PHLS will have checked the sensitivity of the tests ie their ability to detect antibodies when present. They cannot check the specificity of tests (ie the rate of false positives). As explained in paragraph 6 above, this is particularly important in the BTS context.

iii. Select after PHLS evaluation and Field Trials in BTS - This may take 5 months to implement. This is the recommended option. It will enable the level of false positives to be measured. It will also allow operational convenience to be assessed. It might leave us without a screening test for up to 2 further months. It is hoped to bring forward the field trials and thus reduce the period needed for implementation. (A diagram of the selection process is at annex 1.)

Supply Constraints

8. Several tests are on offer. However, it is not yet known whether manufacturers could all supply the large numbers needed by the BTS. We may need to use more than one supplier. There is a British contender. This is being produced by Wellcombe (in collaboration with CAMR). It looks extremely promising. However there is a question mark over the speed at which this will be available on a large scale. We should not delay implementation of screening until this can be supplied.

Decisions on Consequential Matters

9. A number of other decisions are required as a consequence of introducing screening of BTS donations. They are based on the key assumption that donors whose tests are positive will be informed. Adoption of any other approach would be dogged by many ethical, legal and public health problems. Information would be suppressed which could put health workers at unnecessary risk. These donors could also, unintentionally, spread the disease. Such a policy might, however, have to be adopted in the short term if the other facilities discussed below are, for any reason, not ready when screening is implemented; eg if option 1 were adopted.

Confirmatory Tests

10. No one can be informed that they are positive on the basis of a single test. A confirmatory test (or tests) using a different method is essential. The PHLS have the expertise and organisation to undertake this task. They propose using 6 designated laboratories, backed by a central laboratory, to do confirmatory tests from all sources not just the BTS. They believe facilities

can be in place by September. It is recommended that the PHLSB be asked to establish these facilities and that the necessary funds are made available (see below).

Alternative Source of Testing

11. The first defence of the BTS against AIDS is to discourage donors in the high risk groups. This will still remain vitally important even 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 screening of blood donations is accompanied by the provision of well publicised alternative means of obtaining a test. These facilities will probably have to be organised through STD clinics. A separate submission on the provision of these facilities and the resource implications is planned. An effective way of providing a major proportion of the necessary laboratory facilities would be to use the PHLS. Again to enable PHLS to undertake this task will require an increase in their funding.

Financial Consequences for PHLS

12. The annual full year revenue cost of the proposals in paragraphs 10 and 11 is £733,000. In 1985/6 it will be around £367,000. In addition some laboratories will need upgrading at a cost of £375,000 in 1985/6. A total of £742,000. Funds for future years are the subject of a PES bid. For 1985/6 £500,000 could be met from within the CPS budget if Ministers give this priority over competing bids. The remaining £242,000 will have to be found from yet unidentified savings.

Advice to Positive Donors

13. Donors whose blood is confirmed to be positive to anti HTLV3 will need to be given advice. The advice will cover such matters as changes necessary to lifestyle to avoid danger to others. Advice will be needed by all who are confirmed positive, not only blood donors. Such advice will be a major contribution to preventing the further spread of this disease. A separate submission is planned on how this should be organised and the resource implications.

Back up to Screening

14. The screening test will be supported by the PHLS. They will help train BTS and other staff and organise a quality control scheme.

Summary of Suggested Strategy (see also Annex 1)

15. In summary the following strategy is suggested.

1. The test (or tests) should be selected after evaluation by the PHLS and field trials in the BTS. This would mean implementation of screening in October or November.

2. Evaluation and field trials should continue to be conducted on new tests which emerge.

3. Confirmatory testing facilities should be provided by the PHLSB.

4. Alternative testing arrangements should be organised. A separate submission on this is planned. The PHLSB should be asked to establish laboratory facilities.

5. The organisation of facilities for advising positive donors (and others) should be the subject of a separate submission.

Advice Sought

16. Are Ministers content:

1. with the strategy outlined above?

2. that steps are taken to secure the necessary increase of £742,000 in PHLS funding in 1985/6.

ANNEX I.

Timetable for PHLS evaluation and BTS field trials of screening tests for AIDS antibody.

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