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SCREENING BLOOD DONATIONS FOR vCJD

In June last year Dr. Eglin (then at the PHLS, but now at NBS) requested a meeting to discuss the provision of facilities to assist the NBS in evaluating potential assays to screen blood donations for CJD. These proposals were outlined at a meeting held on 28/6/01, and after discussions with members of the CJD policy team it was decided to invite Dr. Eglin and his colleagues to submit a full proposal.

This proposal was received in December 2001, although the cost of the project (£5.5m) was significantly greater than that originally envisaged. The proposal was however sent out to peer review in the normal way, after clarification of some of the experimental details. Seven reviewers' reports were received, including 2 from the USA. Although some of the reviewers were supportive of the proposal a substantial majority thought the proposal too expensive and would not provide either DH or NBS with the facilities needed to evaluate the tests. Consequently I have held two meetings over the summer with colleagues in the CJD Policy Team and Blood-borne Viruses Policy Team and the following actions have been proposed.

1. We agree with the recommendations of the majority of the reviewers that this proposal would not represent value-for-money and should not be supported.

2. The Ethics Committee(s) may rule that the collection protocol and/or analytical protocols are unethical.

3. The sensitivity and specificity of the test could not be assessed as there would be no way of linking samples to individuals and following them up to ascertain if they develop CJD. In addition we will not know if any of the UK samples are incubating vCJD.

4. Other DH funded institutions such as NIBSC and PHLS may be funded to do similar work and work planned in these institutions needs to be co-ordinated with the work planned by NBS.

5. A UK-wide effort is highly desirable and therefore formal links with colleagues in Scotland, Wales and Northern Ireland need be established.

6. A substantial amount of public funds could be spent in providing a large number of samples, which may be incompatible with the most promising tests.

7. Any suitable test which is presented to the NBS for evaluation or validation would already have a carefully designed protocol which should be quick and easy to

follow and therefore the blood services would be able to rapidly collect (within a few weeks) a large cohort of test samples which would be compatible with the test under examination.

PROPOSED COURSE OF ACTION

Despite the above reservations it is recognised that the blood services, in partnership with DH, should make provision for the evaluation of a CJD blood screening test when it arrives. In particular, arrangements with collaborators in the USA should be agreed in advance to enable the rapid collection and transport of blood samples when needed. Moreover it is essential that all potential stakeholders such as the other UK blood authorities, PHLS and NIBSC are able to contribute to the planning of these provisions and NBS is able to draw upon the necessary expert advice.

Consequently RDD and the PH policy teams have considered a number of ways to take this matter forward.

- Ask MSBT to establish a working group to advise on the steps which need to be taken to ensure the blood services can rapidly assess CJD screening tests when they become available. It is envisaged that this working group will draw its members from MSBT, the UK blood authorities, PHLS, NIBSC and DH.
- DH should set up a stand alone committee for this task
- Agree to the suggestion by Dr. Eglin and his colleagues that they should set up a steering group for this purpose.

On consideration it is felt that the optimum path would be to ask MSBT to set up a designated working group to assist NBS plan for the introduction of a CJD blood-screening test. This group would contain all the necessary stakeholders, yet be independent and have the authority of MSBT behind it.

ACTION REQUESTED

Do you agree to the proposal that MSBT be asked to establish a working group to advise NBS on designing the protocols and facilities necessary to assess tests to screen blood donations and blood products for CJD?
