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DEPARTMENT OF HEALTH & SOCIAL SECURITY
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From the Secretary of State for Social Services

The Rt Hon Nicholas Edwards MP
Secretary of State for Wales

November 13

Dear Nick,

ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

Thank you for your letter of 18 October.

I am concerned that you have obtained from your officials such a negative impression of the Government's achievements in this area. This is the more surprising since your officials have participated fully in the forums which gave us the medical and scientific advice on which our policy has been based.

Perhaps the most worrying misconception is the statement "unreliable testing is better than no testing at all". This is the complete opposite of our thinking. We have based policy on the firm conviction that unreliable testing would be disastrous and would engender a false sense of security. This was the reason why we delayed the introduction of screening until we were satisfied that the tests to be used were sufficiently reliable. To achieve this objective the tests now in use have been subjected to a rigorous two stage evaluation, which to our knowledge surpasses what has been done elsewhere. The first step of the evaluation, which was carried out on a limited number of sera, identified two diagnostic kits particularly suitable for use in the BTS. The trials of these two kits carried out in the BTS was on a much larger scale and gave us a very clear indication of how the tests would perform in the field.

This first draft of the report of this evaluation did of course identify problems. This was the whole point of the exercise. The reasons for the apparent failures to which you draw attention were by no means clear cut and more work is being done to pinpoint the cause. The evaluation results were considered in detail by an "ad hoc panel" of leading experts (on which Welsh Office were represented). They had no hesitation in agreeing that routine testing of all blood donations should start, using these two test kits.

You mention the problems of quality control. Both manufacturers were called to meetings with officials and after lengthy discussions officials were satisfied with the assurances given. In addition a visit was made to Wellcome's premises.

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This was not a full quality audit. However nothing was found to alter our views on their ability routinely to produce satisfactory kits. In fact officials felt that the procedures used were good. The difficulties of ensuring that no batch variation occurs in such good tests can perhaps be best illustrated by the fact that two other manufacturers (Abbott and ENI) had to substitute fresh batches for the ones initially supplied to the PHLS for their evaluation since these had proved faulty. We are not of course depending solely on assurances from the manufacturers. The performance of kits in the NBTS is being closely monitored and comparative data collected. Furthermore the PHLS have supplied quality control sera to Transfusion Centres so that they can be used as a daily independent assessment of the kits performance. (You were advocating some such approach in paragraph four of your letter of 8 October.) A number of centres have been using the test for a few weeks. Data have not yet been quantified but preliminary indications suggest that the kits are satisfactory.

You raise the issue of the evaluation of other tests. It has never been an objective to establish a general scheme for testing all available kits in order to "approve" them. Evaluation is a very expensive business. We had the narrower objective of identifying one or two tests which could be used confidently by the NHS. This we have achieved. It is not our intention to do more formal evaluations in the BTS until tests become available which appear to offer significant additional advantages. However we are funding the PHLS both this year and the next to carry out evaluations. When appropriate we shall ask them to look at specific kits. (Several "Mark II" tests are known to be in preparation.) The "JAMA" article to which you drew my attention is not a full evaluation report. It concentrates solely on the level of positives and how many of these are "true" positives. It is however completely silent on the crucial issue of how many positives are missed ie the number of "false negatives".

I apologise for replying at such length. However, the introduction of mass screening of blood donations is a significant achievement for the Government in its fight against AIDS. It is important that within Government misunderstandings do not detract from this achievement.

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NORMAN FOWLER

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