UNILATERAL INTRODUCTION OF ANTI-HCV TESTING AT NEWCASTLE RTC IN APRIL 1991

A joint statement by J.A.J.Barbara and H.H.Gunson

We consider that the premature action taken by Newcastle RTC with respect to anti-HCV screening of blood donations was an unsound policy for the following reasons

1. Effects on National Policy

1.1 The reason for a declared uniform date for introduction throughout the NBTS, Northern Ireland and SNBTS was to ensure that patients would receive the same standard of care irrespective of where they lived in the UK. This was the reason why HHG contacted each RTD during the early February to reconcile the diverse dates which had been given for the commencement of testing, ranging from April to October 1991. The compromise reached was 1 July 1991.

Dr. H. Lloyd, Director of the Newcastle RTC, did not raise any objections to the agreed starting date of 1 July 1991. However, we can only conclude that he intended to begin testing in April 1991, since he used the specious argument for taking this premature action that he wished to ensure that all products for issue had been tested by 1 July (letter from H.Lloyd to H.H.Gunson, 1/5/91,U 37).

The reasons why we regard this argument untenable is that the two commonest blood products, platelets and red cells, have expiry dates of five and 35 days respectively. It would not have been necessary to begin routine screening during April to ensure that

these products were tested prior to issue on 1 July 1991. The third product commonly issued is fresh frozen plasma which has a shelf life of one year. Special arrangements would have had to be made for this product since testing in April would not have been effective to ensure that all of this product, including stocks held at hospitals, was tested by 1 July.

1.2 The Department of Health did not decide until early February 1991 how the cost of anti-HCV testing was to be financed. Their decision was given to RTDs by letter on 5 February 1991 (letter from H.H.Gunson to RTDs, 5/2/91, E 18). Even at this stage it was not possible to fully define the costs since the NHS Procurement Directorate, who were responsible for negotiating the price paid for the test kits, had not finalised the price of the tests with the companies concerned.

Dr. Lloyd acted unilaterally by agreeing to purchase test kits directly from Abbott and had included a price for these in his budget for 1991/2 (letter from H.Lloyd to H.H.Gunson 16/12/91, G 8) despite receiving a letter to all RTDs stating that they should not conclude contracts, so that the NHS Procurement Directorate could negotiate the best possible prices (letter H.H.Gunson to RTDs, 27/2.91, U 23).

Notwithstanding the element for the licence fee paid to Chiron, Dr. Lloyd's action may have contributed to the intransigence of Abbott with respect to their price for test kits (memorandum from E.Evans, NHS Procurement Directorate to H.H.Gunson 3/4/91, L 87).

Abbott agreed to some flexibility later in April, but even then needed more time to consider prices (letter from E.Evans to H.H.Gunson 18/4/91, L 97).

1.3 If one RTC acts unilaterally and introduces a routine screening test, it may force others to adopt the practice to avoid the perception that the Service was providing two tiers of service and quality. In the event all other RTCs decided to keep to the nationally defined policy. Had this not occurred, chaos may have resulted. Although one RTC, which has carefully set up equipment for commencement of testing, has trained staff and has obtained adequate finance, could begin routine testing with confidence, others who had not taken these steps necessary for this approach, might incur errors if forced into premature testing. It should be born in mind that, at this time, of the 20 RTCs in the UK only six had previously carried out a significant number of anti-HCV tests.

2. Inadequate infrastructure for routine screening

2.1 Superiority of second compared with first generation tests.

Newcastle RTC commenced screening using Abbott second generation tests. Since there was no proof, apart from information from the manufacturers, that second generation tests were preferable to first generation tests, ACVSB decided at their meeting on 25 February 1991, (minutes, Y/VSB 258-262), that the bank of specimens from the Ortho/Abbott first generation trial should be tested with the second generation tests and any other tests which

were available before the introduction of routine testing. This policy was endorsed in a memorandum from J.C.Dobson a senior administrator at the Department of Health to J.Murphy of the Information Division of the Department dated 9 May 1991 (H 2). Dr. Lloyd was informed of this decision (letter from H.H.Gunson to all RTDs, 3 April 1991, E23).

2.2 Confirmatory testing, counselling and medical referral of donors.

Systems for confirmatory testing, counselling and procedures for medical referral of blood donors found positive for anti-HCV were not in place when Newcastle commenced screening. These matters were resolved at the meetings of the UK ACTTD at their meetings on 25 March and 10 June 1991 (minutes, Z/TTD 75-78, Z/TTD 79-90). The results of discussions in the UK ACTTD were requested by the ACVSB at their meeting on 9 May 1991 (minutes, Y/VSB 289-295).

2.3 Failure of communication.

Whilst it is true that Dr. Lloyd was not a member of the UK ACTTD he did attend meetings of the Northern Division where matters relating to the introduction of anti-HCV testing must have been discussed. The minutes of these meetings could be checked but one of us (HHG) has no recollection of him pressing for a date earlier than 1 July 1991 for the commencement of anti-HCV testing, apart from his letter to the National Director, dated 7 February 1999, stating a preference for approximately 1 April 1991 as a possible date (letter H. Lloyd to H.H.Gunson, E17).

Indeed, when challenged on his reasons, stated above, for beginning routine testing in April 1991, and asked why he had not informed the National Director of his decision to unilaterally introduce screening he stated that he thought that the National Director would attempt to talk him out of doing so and this is why he informed him after the event.

There is no doubt that Dr. Lloyd's decision was not in the interest of the Service as a whole and was taken in the knowledge that he was flaunting the decisions of the Department of Health who had made it clear through the ACVSB that they were the responsible body to determine when routine anti-HCV testing should start and the steps which should be taken prior to its introduction.

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