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Dear Harold

U.K. ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED DISEASES: INTRODUCTION OF SCREENING FOR HCV ANTIBODIES

I have read the Minutes of the last meeting of the above committee and the attached letter from Phillip Mortimer several times. I have also consulted with Pat Hewitt and John Barbara and the three of us are of the opinion that we are going "over the top" with the proposed screening for anti-HCV.

I accept that, although non-A, non-B post-transfusion hepatitis caused by HCV or other agents, is not a major health problem in the U.K., the NBTS has no option but to introduce screening of blood donations for anti-HCV. I am still extremely disappointed by the decision of the Department of Health to recommend that the cost of HCV screening should be added to the cost of blood components. If purchasers are asked to keep a "steady state" and if Transfusion Centres do not have additional money to devolve to users, then the necessary funds to pay for the additional cost of blood components will have to come from other areas of health care. My reason for introducing the aspect of funding yet again is that the proposal from the advisory committee and from Phillip Mortimer is extremely complicated and astronomically expensive. If many Transfusion Centres are doing the minimum for HBsAg screening, just referring their positives with a letter to their GP without even checking whether carriers have been followed up, why should we be doing so much laborious, "high-tec" and expensive confirmatory testing, counselling and referral for an agent that seems to be less aggressive and dangerous than HBV and HIV?

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The procedures proposed are so time consuming and complicated that they are bound to lead to errors and, perhaps to the release of units positive for HBsAg, HIV, or HCV. I do not think that in these times of financial constraints and with the introduction of the NHS Act, I could have the justification to have an army of people involved in the significant extra amount of clerical and laboratory work required for the introduction of the proposed protocols.

Under 4.2, **the procedure for confirmatory testing** will be very time consuming and involve a significant extra amount of clerical work. The serum sample will be referred for RIBA; if RIBA reactive, then a plasma sample will be sent to the Reference Lab. The protocol states that when a repeat reactive is found on screening, then plasma "from the donation" must be separated into 2 x 1ml tubes (supposedly under laminar-flow, if destined for PCR) and then frozen pending the RIBA result. At this stage, it would be better to discard the plasma donation since it will have been subjected to an "open" procedure and I think that David Donald would not accept the plasma for fractionation. On the other hand, if we want to do this as a closed procedure, we would need to use sterile docking. If the serum sample is RIBA reactive, then the plasma sample will be retrieved and forwarded for PCR. So, for every repeat reactive screening test, we will need to aliquot and freeze plasma samples (i.e. in many cases we will have already frozen the plasma!). According to Phillip's figures, the vast majority (i.e. 60 out of 68 samples) will **not** need PCR (category B in his report); hence it is unnecessary to keep all these plasma samples. We would suggest to keep the plasma from the ELISA repeat-reactives in quarantine in the freezer. We would then discard plasma packs found to be RIBA reactive and send the RIBA-negative plasma packs for fractionation. If the relevant RTC wished to pay for a PCR, then the whole plasma donation would not be discarded and could be sent frozen to the Reference Laboratory for PCR. Those Centres without enough money to pay for PCRs would just discard the plasma donation and, either counsel the donor themselves and obtain a repeat sample for ALT testing and repeat HCV testing or simply send a letter of referral to the G.P.

4.3. **Plasma for fractionation (and appendix 3)**

According to this, we should be doing ALT testing on **all** our samples found to be repeatably reactive for anti-HCV. This will mean that **every** RTC will need to have in-house ALT testing facilities and that serum samples from anti-HCV repeatably reactives will need to be rushed to the Biochemistry Laboratory for ALT testing. From our experience in the multi-centre study on surrogate markers, we have seen that true HCV seropositives do not overlap very well with samples with high ALTs and we will therefore get in a muddle when we have ELISA positives but unconfirmed, with high ALT levels due to obesity, high alcohol intake, etc. Should this ALT and LFT testing not be done by the specialists when HCV seropositive subjects are referred to them? If we are not careful we might end up becoming a weight watchers clinic! There will be a group that will argue that if we are doing ALT testing, then we should be doing anti-HBc screening (and perhaps there is more reason to do such screening). According to the protocol, for the largest group of ELISA positives (RIBA negative) we can use the plasma only if the

ALT is normal. For all others (categories C, D, E and F2) we discard the initial donation (except for F1) and either counsel/reassess the donor or retain the donor in the panel for plasma donations only. We doubt the cost effectiveness of all this very complicated protocol. We feel that it is not worth the cost, if we are to be charged £50 per RIBA. We might as well discard the plasma at the beginning and not bother about ALT/RIBA/PCR since it will only enable us to use the plasma (on which we already make a loss) for fractionation. The other tests would be relevant to the donor, but if we are not able to counsel due to financial constraints, why test? The more we think about it, the more we are in favour of performing RIBA at RTC level. After all, RIBA is not that complicated a test and we have very good scientists in Blood Transfusion Centres that could manage such testing. I would not be in favour of doing PCR for HCV at NLBTC since it is much more complicated than the type of PCR that we do for HLA typing and platelet typing.

4.4 **Information to be given to blood donors**

The only way in which we think that this leaflet would work is if it was amalgamated into other leaflets. Pat Hewitt tells me that she has problems trying to get donors to read all the necessary literature and notices.

4.5 **Counselling**

This will be irrelevant at NLBTC in the absence of funding.

4.6 **Return of repeatably unconfirmed anti-HCV donors to active donor panels**

We feel that this does not bear thinking about. We expect that this will lead to more confusion with more algorithms to follow!

4.7 **Monitoring test results**

The more we think about it, the more we think we are going over the top with this testing for a virus that has not been shown by anybody to cause immense health care problems in the U.K. Why should we monitor anti-HCV results when no-one has been the slightest bit interested in monitoring HBsAg results? Would it not be better and more cost effective to do something about HBsAg screening in Transfusion Centres? There seems to be a big problem, judging from the discarded pools at BPL, with quality control of HBsAg screening. Pat, John and I feel that these protocols are a counsel of perfection in an ideal world with unlimited financial and staffing resources; but they are simply not very workable! With all these categories, the proposal is a recipe for disaster, with the possibility of lots of clerical errors and mistakes. We will be so concerned with HCV reactives, that we might issue a unit found positive for HIV or HBsAg. The differential storage requirement and arrangement for referral of samples <u>demand</u> extra funding, or else we feel that we cannot comply.

We have come to the conclusion that RIBA needs to be performed at RTCs. Then we would not need to do ALT until <u>after</u> the RIBA result was known and would

avoid having to deal with RIBA-negative elevated ALT donors. Otherwise, we might just as well discard all repeat reactive donations without any confirmatory testing, but we strongly feel that this is not what we should do if we really care for our blood donors. The magnitude of the problem and possibility of mistakes with the introduction of anti-HCV screening is totally different from what we are used to dealing with at present, with the current mandatory screening tests. Phillip's letter refers to wishing to avoid RTCs doing one or two tests a week on reactive donors. At NLBTC we would expect, with an 0.5% repeat reactive rate, to be finding 25 repeat reactive donations per week. This is very, very different from one or two.

I am very sorry to be writing yet another controversial letter. I am sure that you must dread having to read letters with my headed paper. Perhaps when we decided to go into blood transfusion, we never envisaged that life would have so many problems and that financial and operational issues would be so high up in our agendas!

With best wishes.

Yours sincerely

GRO-C

Marcela Contreras
Director

c.c. Dr. R. S. Tedder
Dr. P. Hewitt
Dr. J. Barbara

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