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Dr. M CONTRERAS
Director

MC/rme

19th April 1991

Dr H H Gunson
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Dear Harold,

Further to your letter of 4th April in reply to my letter of 15th March, I think that we should be able to find some means of sampling small pools of plasma prior to massive final pooling. I wonder where the impracticality of testing small pools lies in the light of the huge costs of discarded pools? Although I welcome the idea of fractionating plasma on a regional basis, I still think that something should be done to replace the "belt and braces" approach that we used to have when plasma was sent to BPL in 5-litre packs; tests performed on these packs by BPL gave a good Quality Control of HBsAg testing at RTCs and helped to prevent any but the lowest titre of HBsAg positive donations contaminating the large pools.

As you may be aware, NLBTC has always kept in contact with Dr David Dane as an honorary consultant. We have always taken his advice very seriously and he is highly respected by John Barbara, Pat Hewitt and myself. Dr Dane has told me that Brian Combridge used to find quite a number of positive 5-litre packs which had obviously been contaminated by moderate or high titre donations that should never have been missed at RTCs. Dr Dane has pointed out the danger of going straight from routine HBsAg testing at RTCs to a 20,000 donor plasma pool without an intermediate test step such as the 5-litre pack test. RTCs very occasionally will issue HBsAg positive donations to hospitals or send them to BPL because of clerical errors or through errors in testing. This is known to occur everywhere and is well documentated even recently in US Red Cross Centres.

At NLBTC , following the advice of Dr Dane, we believe that the NBTS and BPL should find some way of introducing "intermediate" testing in order to avoid the

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absurdly wasteful business of throwing away very large pools of plasma and the enormous amount of back checking needed to find the offending donation. In addition, the QC element of "intermediate" testing is extremely valuable. It might be useful if the "intermediate" testing included tests for anti-HIV and -HCV as well as HBsAg, even though the infectivity of these viruses will be destroyed by heating during the preparation of factor VIII. The expected number of HIV positive donations may be too small to make it worthwhile testing for this virus, but if RTCs can send strongly positive HBsAg positive donations to BPL why not HIV positive ones as well? We do not know whether the current tests for HCV and HIV could stand a dilution factor like the HBsAg test and still find nearly all the missed positives (from a study that John Barbara has done on 33 anti-HIV positive donors, 32 out of 33 donations would stand dilutions greater than 1:128). It could be that the only satisfactory "intermediate" testing would be a simple repeat testing at BPL from a pilot sample or a segment accompanying each donor's plasma (as is done in the plasma clinics in North America). In QC there is no substitute for checking what is actually issued; I think that the majority of RTCs would not mind this sort of check on their performance. The benefits would be to both the NBTS and BPL and the costs could easily be recovered from the lack of wastage of large plasma pools. Dr Dane advises us that if all plasmas are re-tested at BPL, they should perhaps pitch the sensitivity of the testing to be slightly less than that at the RTCs so that there was no endess endpoint questioning and quibbling.

In our opinion, the benefits of the introduction of this proposed QC measure would outweigh any theoretical advantage of introducing anti-HCV screening.

The disaster of throwing away so much plasma may have given the NBTS/BPL an opportunity to introduce a type of QC that the RTCs may need. When we consider that for every case of post-transfusion hepatitis due to HBV there may be half-a-dozen inapparent infections some of which will result in the carrier state with its various hazards, and that something rather similar may be occurring with HCV, and that it may be eight or nine years on average before post-transfusion HIV invection shows up as AIDS, we realise that clinical reporting of infectious illnesses due to transfusions only gives a very, very limited QC.

With best wishes,

Yours sincerely,

GRO-C

Marcela Contreras
Director

c.c. Dr D. S. Dane
Dr R. S. Tedder
Dr W. Wagstaff
Dr J. A. Barbara

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