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(FAXED)

CONFIDENTIAL

Dr Harold Gunson
National Directorate
HQ North Western Regional Health Authority
Gateway House
Piccadily South
MANCHESTER M60 7LT

Dear Harold

THE NEWCASTLE SAGA: HCV DONATION TESTING

I have spent a few moments hurriedly trying to prepare some assistance for the second option:- a national large scale validation study. In the circumstances, we now find ourselves, I think this will prove to be an exceedingly complex and sensitive exercise. I foresee immense difficulties (perhaps I need more thinking time) in moving from the trial into orderly full scale (UKBTS) screening. On the other hand, we should make every effort to maximise this disaster to our corporate advantage.

The following points spring to mind:

1. It will, I suggest, be important that all participants (other than Newcastle) start at the same time.

2. The study, I suggest, should be in 2 phases

Phase I: (Data collection designed to assess the efficacy of the two different screening second generation kits). This should finish on 15 July 1991. This data will be fully analysed by 31 July 1991 so that non-participating RTCs can make judgements on which kit to purchase for a 1 September 1991 start.

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Phase II: (15 July 1991 - 31 August 1991) The "public" reason for this phase will be (using only participating trial RTCs) to collect more screen test positives to allow more extensive studies in the confirmatory laboratories. This period

PLEASE GIVE BLOOD

/period could be extremely valuable scientifically, but, operationally, it will allow all participating Centres (particularly Newcastle!) the option of not stopping and then starting on 1 September 1991.

It will also ensure that non-participating Centres don't get jittery (product liability) in the month of August 1991! If you accept this idea, then we need to make final formal decisions about the HCV flow chart (algorithm) soon after 31st August 1991 - on maybe Friday 30th, for immediate promulgation to RTCs.

3. I would strongly advise that we have 4 participating Centres (2 Abbott and 2 Ortho). Ideally, the total blood collection programmes for the 2 Abbott should be comparable with the 2 Ortho. (I doubt very much we could get each Centre to do both Abbott and Ortho).
4. I would strongly advise that one Abbott Centre is paired with an Ortho Centre and that all screen positives are swapped for checking with the other technology (ideally this should be done blindly - some -ves included). This suggestion will also be of some P.R. importance to us and Departments of Health. It addresses the issue of donors being labelled in one region (but not another) as "dirty" - based on different technologies. It could also heavily influence the final features of the algorithm for donor management and plasma disposal (for fractionation).
5. Right now, it looks as though, when full screening begins, Edinburgh, Glasgow and Aberdeen will opt for Abbott. Thus, it would seem to me, that we should offer Glasgow only into this national (UK) study and the NBTS will have to find 2 Ortho Centres (because Newcastle have already opted for Abbott. I am sure Dundee and Inverness (using Ortho) would be happy to pitch in, but their donation collections are relatively small and this could be viewed as a disadvantage to Ortho.
6. The confirmatory testing associated with this study should, I suggest, be essentially similar in design to the first generation test study. The major

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/major immediate problem I foresee is funding, for it will be a much larger exercise - perhaps Newcastle can be persuaded to foot this bill: they seem to be well off! On a more serious note, I suspect you may have to go to the DOH!

I hope these comments are helpful. I have copied them to Ruthven because I will be on leave for the week of 20th May and I am keen to establish a wee bit of continuity in SNBTS managerial support for you.

Kindest Regards

Yours sincerely

GRO-C

John D Cash
National Medical & Scientific Director

cc: RM (16/6) (16/1)

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