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EDINBURGH AND SOUTH-EAST SCOTLAND REGIONAL BLOOD TRANSFUSION SERVICE

REGIONAL CENTRE
ROYAL INFIRMARY
EDINBURGH EH3 9HB

Telephones
Department 031-[redacted]
Telex 72163

PROTEIN FRACTIONATION CENTRE
Received: 19 NOV 1984
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Refer to
DR. R. J. PERRY ✓

IN STRICT CONFIDENCE

DBMCL/KES

15th November, 1984

Dr. J.D. Cash,
National Medical Director,
SNBTS
Ellen's Glen,
Edinburgh

Dear Dr. Cash,

I have had several discussions with Dr. Christopher Ludlam following the discovery that some recipients of PFC Factor VIII have developed antibodies to HTLVIII during 1984, which must, at present, be attributed to infusions of PFC product. I spent several hours this morning with Dr. Ludlam and Dr. Perry, Acting Director of PFC reviewing the data and write now to report to you, as National Medical Director on our conclusions.

As I reported to the Scottish RTDS last week, it appeared that there are, so far patients in whom seroconversion is known to have occurred during 1984 and who have received exclusively PFC factor VIII, or (in one case only) commercial factor VIII several years ago which can be discounted from the present problem.

Initial analysis by Dr. Ludlam and Dr Tedder showed that one batch of product had been received by all but one of the patients and therefore was highly suspect. This batch (023110090) has been withdrawn.

We felt it was essential to look at the other batches used over the relevent period in the attempt to determine if any of them should also be considered for withdrawal (if stocks remained) or should be set aside for further ivestigation.

We reviewed the data in the following way;

1. Using his own records (confirmed where appropriate by BTS records) Dr. Ludlam prepared lists of all recipients of the implicated batch, all the batches received by the patients who were seroconverted and all the batches used in his patients during the relevant period.

2. We then prepared a table showing for each batch the proportion of the seroconverting patients who had received that batch (table attached).

3. We selected two recent batches (0030 and 0170) which had been given to almost all the patients and could therefore be suspect.

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4. For these two batches we reviewed each patient's record to determine if the timing of infusion of the batch was such that it could have caused seroconversion (ie more than one week before the first known positive antibody result). On this basis we were able to show that there were several patients in whom neither of these two batches could have been responsible for seroconversion. We feel therefore that these batches should not be considered any more suspect than the other batches listed.

5. The third column of the table shows for these two batches the number of patients in whom their involvement cannot be excluded by the date of administration alone.

6. There are several earlier batches (eg 768,784,773,791) which are not available for issue. These could merit a similar investigation but time was insufficient to do this on the present occasion.

One requires further serological investigation urgently. This patient did not receive the implicated batch and is not known to have other risk factors. Retesting of the first positive sampling is in progress but will not exclude an identification error. Should the testing of a new sample confirm positivity it will be necessary to review the data in the light of this finding.

Conclusions

1. On the basis of this investigation the conclusion reached by Dr. Perry, Dr. Ludlam and myself is that the initial view is correct, namely that the single batch 023110090 is probably responsible for seroconversion.

2. No other recent batches stand out as being distinctively strongly implicated.

3. There is therefore no obvious basis on which we could advise a selective withdrawal of one or more other batches.

4. There may be a need for further confirmatory examination of the patient exposure to selected earlier batches although stocks are exhausted.

Please let me know if you feel that we should undertake further investigation on these batch data at this time. I would like to record my personal note of thanks to Dr. Ludlam for the excellent initial data analysis which he had carried out which made it possible for us to conduct this review. Dr. Ludlam has specifically requested that the information relating to the batch associated with seroconversion be treated in confidence.

Yours sincerely,

D.B.L. McClelland
Director

Enc.

cc: Dr. C. Ludlum, Consultant Haematologist, RIE