



Department of Health and Social Security  
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*Hay then the wale*

*NOT PART OF THE  
PACK BUT BC.  
thought it might  
be useful.*

Dr J D Cash  
National Director  
Scottish Blood Transfusion Service  
Headquarter's Unit  
Ellen's Glen Road  
EDINBURGH EH17 7QT

Your reference

Our reference

Date

4th June 1982

Dear John

#### INSPECTION REPORTS

I have enclosed copies of the draft reports for your attention. Perhaps I might make a number of observations which may be 'disconnected' but nevertheless apply to many centres.

#### 1. Lack of time

All centres received an insufficient time to produce a comprehensive report. That is, selectivity had to be exercised and not all matters were pursued "in depth".

#### 2. General impressions

(a) All centres have insufficient storage space and inadequate clean room processing facilities. Many activities are poorly segregated.

(b) The attitude of staff was largely helpful and co-operative and I have been very impressed by the knowledge and ability of many people seen. In some cases it was surprising to observe a reluctance to accept responsibility by signing for an action.

(c) All centres seemed to be "in a state of flux" and it was almost as if a "moving target" was being presented!

*Its always like this*

#### 3. Practices

A number of unsatisfactory practices have been observed though in many instances centres seemed to have been forced into a particular situation through inadequate facilities. (Examples include centrifuges next to LAF cabinets; Deep Freezers overflowing with material).

In other cases different ways of doing things were noted (the significance of which was not pursued). Where differences exist confidence would be improved if some clinical feedback existed.

*this is QA testing.*

#### 4. Quality Control/Quality Assurance

Four of the five centres have not announced individuals as responsible for Quality Control (or Processing). In some cases an inadequate understanding of the concept exists and in other cases little testing is done. More emphasis needs to be placed in the future on 'in-house' testing and monitoring by centre staff and some investment will certainly be needed.

5. Written Procedures

SOPs

These are inadequate in most centres. I would prefer each centre to draw up its own Operating Procedures, Test Methods, Specifications etc with help as appropriate from other sources.

6. Computer Installations and Automated Grouping Equipment

We have discussed this topic together and I look forward to seeing progress on this matter.

7. Source Material

is the concern prisoners, or prison environment.

(a) I have not observed donor sessions under the worst conditions however, I wonder whether certain 'high risk' areas are necessary or desirable. Prisons and Detention Centres would seem to come under this category and I would be interested in your views on this.

(b) Donor sessions and the acceptance of particular individuals does seem to involve some "chance". Whether individuals on certain medicines or with particular illnesses are bled (and if they are whether that blood is subsequently processed) is apparently not consistent.

(c) Donor bleeding may well be an area which could benefit from investment. Such items as mobile centres, haemoglobinometers, improved balances/agitators, local anaesthetic administration are some examples.

8. Equipment Purchase

(a) Centres might be better installing balanced downflow LAF cabinets rather than horizontal ones.

(b) Some centres do not have their own equipment for sterilising contaminated materials but rely on the general hospital incinerator or CSSD autoclaves. At least with one's own autoclave it is possible to contain any hazardous biological organism.

9. Factor VIII

(a) Some centres may not be handling plasma in the optimum manner to achieve high FVIII yields. The reasons vary from excessive holding at room temperature to relatively long lag periods before it is frozen.

(b) There seems to exist an in-balance between centres with regard to FVIII availability. Is a pro-rata distribution necessarily sensible?

10. Hepatitis

(a) No rationalisation of test methods exists in Scotland.

(b) Some centres have relatively high false positive (also applies to syphilis testing).

- (c) Most hepatitis facilities 'show room for improvement'.
- (d) Will you be making the vaccine available for all staff when it is available?
- (e) Clearance procedures for blood and red cell concentrates sometimes assumes a negative hepatitis result. This could result in contaminated material being issued under certain circumstances.

11. Training

In view of the widely different experience and qualifications of staff as well as the diversity of responsibilities exercised I would like to see training more formalised and documented.

12. Usage of MRC IV Containers

It was noted that some centres use these containers for holding non intra-venous materials. This is a potentially hazardous practice and should be phased out.

13. Labels

Examples of contradictory labels, inaccurate description of container contents and the use of corridors and basements for printing activities suggest the need for a re-appraisal of this important topic.

Can I close by letting you know that I have sent a copy of this letter to all the Regional Directors so that a response to this letter as well as the individual reports can be made should they want to do so.

Kind regards.

Yours sincerely

*David Haythornthwaite*

D HAYTHORNTHWAITE  
(Medicines Inspectorate)