Reference BLD/2/13

40A

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P2D1

BLOOD: RECORD KEEPING AND STOCK CONTROL

1. Following the report of the Committee of Enquiry into allegations concerning the misuse of blood at the National Heart Hospital, the Secretary of State has asked for a full review of record keeping arrangements with regard to blood. (I attached a copy of the PQ about the report.)

2. Central Management Services Branch has now accepted HS1's request to carry out a study into the record keeping systems used in Regional Transfusion Centres and Hospital Blood Banks. The terms of reference for the study:

> "To study existing systems for the stock control of blood at Regional Transfusion Centres, Hospital Blood Banks; to recommend a system or systems which would enable donations to be traced readily from collection to transfusion or disposal; and to cost such systems."

3. I would be grateful if you could notify formally the Staff Side representatives of those groups of staff who are likely to be involved. These will be principally technical staff in Transfusion Centres and Hospital Laboratories together with some nursing staff within hospitals. There will of course be local consultation at each of the venues chosen for the study.

4. In view of the difficulties experienced in obtaining a formal affirmative response to the proposed study on private practice in NHS hospitals, and given the urgency of this particular study (Secretary of State has asked us to put draft proposals to the Advisory Committee on the National Blood Transfusion Service in September), I would be grateful if the Staff Side could be "informed" of our intentions rather than their views being sought. I should add that we do not anticipate any adverse reaction. Indeed ASTMS and COHSE are in the forefront of campaigns to protect the Blood Transfusion Service and to protect the existing voluntary donor system.

5. We are preparing to write to Regional Administrators in the normal way and subject to your views, we propose to proceed on the assumption that the relevant Staff Sides will co-operate.

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14 May 1982

cc Mr Vallentine (CMS, Hebburn)

Agenda Paper 5

FDO PRINCIPALS MEETING 4 MAY 1982

BLOOD AND BLOOD PRODUCTS

1. As colleagues know, the blood required for the Health Service is obtained from donors by the National Blood Transfusion Service.

2. In England the NBTS comprises 13 Regional Transfusion Centres (SE and SW Thames RHAs share) and 3 Central Blood Laboratories (Blood Products Laboratory and Plasma Fractionation Laboratory; Blood Group Reference Laboratory); Wales has an RTC linked into the NBTS.

3. The main function of RTCs are to:-

- collect, group, test and issue blood.
- separate plasma for the Blood Products laboratory.
- manufacture one form of Factor VIII for treating haemophiliacs.
- provide a consultancy service for Regions on blood transfusion matters.

4. Among Central Laboratories' functions are to:-

- manufacture therapeutic products from blood plasma (BPL and PFL)
- manufacture blood grouping reagents (BGRL)

5. Since the inception of the NHS blood and its derivatives has been provided free to institutions providing health care, public and private sector alike, which reflects the fact that the blood has been freely (sic) donated by the public. The legal basis is provided by Section 25 of the NHS Act 1977 which authorises the Secretary of State to supply to any person, on such terms as he thinks fit, blood which he has acquired (provided it does not interfere with his duties under the Act and is not to the disadvantage of NHS patients - Section 62).

Collection and Issue of Blood

6. Whole blood is collected by the familiar mobile teams but extraction of plasma only with red cells re-injected (plasmaphoresis) is also carried out at some BTCs.

Issues are made to blood banks in hospitals (or groups of hospitals) with pathology laboratories, ie having facilities for cross-matching, on a request basis. Supply to private hospitals is provided direct by a BTC where it is satisfied that adequate pathology facilities exist, otherwise the private sector draws its requirements from NHS pathology departments.

Recording and Control

7. Blood banks should record collection receipt and issue of blood. The Department has said very little about recording and control the only guidance being issued in 1951 and 1964 (NHB(51)89 and HM(64)5 respectively) which advocated:-

- that there should be a uniform system in blood banks
- the use of printed registers obtainable from BTCs
- inspection of registers by Regional Transfusion Directors who should consider instances of waste, misuse or extravagence.

Not surprisingly no reference was made to the private sector but the Department's 'expectation' has been that where blood is issued to private hospitals, blood bank registers should record the amount and type of blood supplied. There is no overt control over private hospitals' records.

Recent Developments

8. In early 1981 the Department became aware, through reports in the national press, of allegations about the sale of blood abroad by a doctor at a London hospital. It was as a result of this that interest in the control of blood and blood products

became aroused and has become of particular concern to the Department. Auditors will also know (Regional Treasurers meeting of 4 November) of the Department's change of policy towards the private sector by the proposed introduction of charges to reflect the handling costs of supply. This latter development, which need not be regarded as directly related to the former, clearly adds an additional dimension to the need for adequate control of blood-issues.

Audit review in North West Thames

9. BTC. Enquiries at the RHA in early 1981 elicited an assurance that officers and the Medical Director were satisfied that comprehensive records were maintained and audit's review of the arrangements in operation suggested a satisfactory situation; each pack numbered and accurate records of receipts issues and returned packs maintained for each NHS and private institution served.

10. Hospital Pathology Departments. A dipstick exercise showed that recording arrangements varied; amongst the problems arising were:-

- failure to record issues received from the BTC
- regular transfers of blood between hospitals on an unrecorded basis
- failure to record/identify whether time expired packs had been returned (complicated by the additional problem of non-plasma blood identification)
- no inspection of registers by the BTC.

The Need for Full Control

11. Whole blood has a life of 28 days although 21 days is generally used to provide a safety margin. Time-expired blood can be of significant value eg for production of plasma and albumin and requires a similar degree of control to that merited for fresh blood. Attention therefore has to be focussed on the collection and control of blood and blood products throughout the chain (from initial 'collection' from the donor to ultimate disposal)

12. The Department recently asked Regional Transfusion Directors (through their chairman) to investigate the standard of record keeping in the NBTS and to prepare a report for an Advisory Committee. The RMO member of the Committee was to make a parallel investigation of hospital blood bank records. The object is to identify an existing system, or introduce a new one enabling unitsof blood to be traced from collection to transfusion or disposal (including use/disposal in private hospitals). Consideration will also be given, it is understood, to the inspection of private hospitals' blood registers as part of the regular statutory inspection of private hospitals which health authorities carry out under the Nursing Homes Act 1975.

Action by Audit

13. The question of further audit involvement in this field at the present time is directly influenced by the current activity by the Department noted above. The logical next step would therefore appear to be to obtain FB4 representation in these deliberations. The attached Annex provides some initial views about the factors which require consideration and which might form a framework for discussion with the policy division.

T Nunn

Annex.

Initial questions about Control Procedures

B T Cs

i) Controls over initial collection by mobile teams to identify diversion of blood before delivery to B T C. Scope for disposal of untested blood may be limited but the need/feasibilty to match donor records with blood actually recorded as received by B T Cs must be considered

ii) internal control - reconciliation of blood packs collected with those finally recorded in the blood bank register with adequate identification of blood rejected after test and disposal

iii) identification of blood diverted to production e.g. for Factor viii and non - plasma blood. The need for manufacturing (conversion) accounts

iv) records of issues to hospitals, including emergency issues (note activities of voluntary organisation involved) and supporting documentation

v) records of return of time expired blood and disposal for manufacturing or to waste

vi) records of issues e.g. plasma to Central Blood Laboratories and accounting for products supplied. Note: products supplied by C B Ls are worth £12 M a year

vii) security:- access to blood and blood products and opportunities for removal and falsification of records

Hospitals

i) basic requirement for a record in an acceptable form which records all receipts from the B T C and how used - patient, other hospital including private, identification of time expired blood and disposal; supporting documentation including receipts and discharges where appropiate

ii) copy issue notes supporting deliveries from B T C, particularly should be retained to provide a prime record for control of B T C drivers

iii) security - as for B T C

iv) desirability of clinical audit of blood and products booked to patient treatment.

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SMD

HOSPITAL BLOOD BANKS SERVICED BY REGIONAL BLOOD TRANSFUSION CENTRES IN ENGLAND AND WALES

Region	No. of NHS blood banks serviced	No. of private hospitals serviced direct	Comments
Northern	20	0	
Yorkshire	20	0	
Trent	23	0	
East Anglian	12	0*	*plus 2 Armed services hospitals
NW Thames	37	12*	*includes 2 private laboratories serving private hospitals
NE Thames	31	0	
SE/SW Thames	62	4	
Wessex	11	0	
Oxford	11	0*	*plus 2 RAF and 1 USAF hospitals
South Western	16	2	
West Midlands	37	1	
North Western	33*	1	*includes 6 hospitals served by Lancaster sub-centre
Wales	18	0	