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RESPONSE TO MEDICINES INSPECTORS' REPORT
SOUTH EAST SCOTLAND BLOOD TRANSFUSION SERVICE

12 JANUARY 1983

CONTENTS

Bastds & Prisons

1. INTRODUCTION

The organisation of the report adds considerably to the difficulties of presenting this response. Some of the Inspectors' comments are classified according to the particular building inspected, while others are classified according to functions. In addition, we found it difficult in some cases to distinguish purely descriptive observations from comments which the inspector felt required a definitive response. We have therefore attempted in sections 3 - 6 to address briefly some general topics which are referred to at more than one point in the report. In Section 7 we have given our responses to each of the Inspector's comments in the order in which they appear in the report.

SCOPE OF THE REPORT

The Edinburgh Centre may have caused particular problems because of the large clinical blood banking element of our work and the presence of the clinical Cell Separator Unit. We were concerned that in looking at aspects such as crossmatching and clinical administration of blood, there was not time for sufficient consideration of the boundaries between the "production" and the "clinical" aspects of our work, and of the implications of extending concepts of GMP to the bedside.

We have some difficulty with many of the Inspector's comments in relation to cryoprecipitate as a clinical product: To respond adequately would involve detailed discussion of many aspects of Factor VIII therapy which are not, we feel, relevant to the Inspector's proper concern with the quality of our production of a standard and widely accepted blood product.

The SNBTS arrangements for Factor VIII distribution do not seem to us to be a topic for consideration in this report.

The Inspector's comments (23) on the clinical (in vivo) validation of products were appreciated. We were concerned however that these suggestions imply that regular quality control should involve parameters such as red cell and platelet survival, factor VIII recovery etc. It should be realised that the blood transfusion service may have difficulties in regularly obtaining clinical data of this type. We felt that the implications of this suggestion require further consideration.

The Inspector also commented (22) on the pursuit of "ever increasing" shelf lives for blood and blood products and questioned the desirability of this trend. It is our opinion that this comment touches on a trend of development which is being pursued by most if not all modern transfusion services, for very sound reasons of cost effectiveness. We feel it is not appropriate to include a response to this point in the document prepared by the S E Centre alone: A response on behalf of the SNBTS would, we feel, be more appropriate.

3. ACCOMMODATION AND FACILITIES

The Inspector's report comments at various points on the buildings and facilities of the S E Centre, and recognises that major changes were to follow shortly after the inspection.

In Summary, (i) moves completed to date

(a) Closure of the Archibald Place building

(b) Relocation in the new Royal Infirmary Phase I of the donor withdrawal suite, hepatitis testing laboratory, wash up and autoclaving facility, stores, and many of the other laboratories.

(c) Temporary relocation in Livingstone House of blood components processing.

(ii) building improvements now being planned and costed

(a) Enlargement and improvement of blood bank compatibility testing and issue areas.

(b) Construction of a new area for pooling clinical products.

(c) Construction of an improved environment for red cell washing and filtration.

(iii) further moves planned

The Inspector has stated (point 3) that blood components processing in Livingstone House must be considered an interim measure and must be transferred to Phase I Royal Infirmary "no later than June 85". He has also stated (point 38) that "the area (in Phase I RIE) presently being used as a temporary pharmacy should, when vacated, be converted for the use of the Blood Transfusion Centre into a processing and laboratory facility".

5. DOCUMENTATION

As mentioned in the National Medical Director's report, already referred to in (4) above, we are certain that the target of March 1983 for completion of full documentation of all procedures is not attainable. Priorities have been decided in the S E Centre for documentation of Standard Operating Procedures. These are given in Section 7 in the response to points 94 and 95.

Many of the requirements of documentation to improve the ability to 'trace' products through the BTS system will be met by introducing a comprehensive computer system. Funding has been sought for the phased introduction of such a system over the 3 years 1983/4 to 1986/7 and work in the Centre on planning the system has been in progress for 2 years.

6. TRAINING

The Inspector's report referred to the need for more formal training of staff in the blood components processing area.

This need is acknowledged, as is the need for improvements in training of other staff including donor team attendants: in the latter case, staff shortages have made it quite impossible to provide time for training.

There is a clear commitment on the part of the senior staff in the S E Centre to develop training programmes using training manuals which will be based on the SOP's for the relevant areas. It is envisaged that the introduction of these programmes will be phased over several years with priority being given to the areas mentioned above.

7. RESPONSES TO INDIVIDUAL COMMENTS AS PRESENTED IN THE REPORT. (The number in the left margin is the number of the relevant paragraph in the Inspector's report)

BLOOD DONATION

1.11.a "RESPONSIBILITY AND CONSISTENCY OF DECISION TAKEN OVER WHICH DONORS TO ACCEPT OR REJECT....WHETHER DONORS REALLY READ THE QUESTIONNAIRE. JUST HOW COMPREHENSIVE IS THE QUESTIONNAIRE?

We share the Inspector's concerns. The following actions have been taken: (i) a new comprehensive guide to donor selection has been prepared and is in routine use by donor selection staff (Appendix A). (ii) we have made a trial of a comprehensive donor health questionnaire administered by donor staff. This has been abandoned as we do not have enough staff to operate it and its use caused massive delays at donor sessions. (iii) we have introduced as a routine for all donors a detailed health check questionnaire which is self-administered (Appendix B). Positive responses are followed up by interviewing the donor before donation. Donor compliance is good and this system will continue. An evaluation of its efficacy will be undertaken if sufficient staff become available to conduct the necessary follow-up interviews of donors who have completed the questionnaire.

1.12.b. "THE LOCATION OF BLEEDING AND TYPE OF DONOR. FOR EXAMPLE , WHETHER PRISONS AND BORSTALS WERE REALLY APPROPRIATE OR NECESSARY AS A SOURCE MATERIAL. THE POSSIBLE ADVANTAGE OF A "MOBILE DONOR CENTRE" (CONSISTENCY OF ENVIRONMENT AND INCREASED PROCUREMENT CAPABILITY) WERE ALSO CONSIDERED"

(i) Prisons and Borstals. We do not visit these regularly. No such sessions have been held for two years. These donors will only be used in an emergency.
(ii) Advantages of a "mobile donor centre". This is the only solution to the problem of many of our most unsatisfactory session locations. Funds have been provided and the vehicle is under construction.

1.13.c. "PROBLEMS ASSOCIATED WITH BLOOD BAGS. (BLUNT NEEDLES, PIN HOLES, FUNGALLY CONTAMINATED OUTERS, SPLITS IN DONOR TUBE)"

It is not possible with our present staff to carry out detailed quality control of batches of packs or detailed inspection of individual packs before use and it is our view that the responsibility must rest with the pack manufacturer to supply a correct product. We are however, taking some steps to improve our control, (i) we now have relatively adequate store space making it possible to order larger stocks, to ensure that we have control over which batches are issued at any time, and to ensure proper stock rotation. (ii) consideration is being given to introducing a system whereby when a new batch of packs is brought into use a sample is inspected and used by a senior member of medical or nursing staff before the packs are released. (iii) guidance will be given to all donor staff (in the form of an SOP which will be used for training) on the inspection required of each pack before it is used (iv) consideration is being given to improving the system of documentation, reporting, and follow up with the supplier of pack defects identified at various points including withdrawal, components processing and blood bank. (v) a senior member of staff will be designated to be responsible for receiving and acting on all reports of pack defects.

14.(d) "THE PRACTICE OF PREFILLING SYRINGES FROM A VIAL"

No alternative is available. The Regional Director has actively pursued with several suppliers and the PFC the possibility of obtaining prefilled syringes: No suppliers have offered to produce these.

15.(e) "NON USE OF AUTOMATIC CUT OFF BALANCES DURING DONATION"

(i) Our discussions with Centres using automatic cut-offs suggest that accuracy and reliability are a problem, especially if floors are uneven. The present system has the advantage that donor staff must watch the balance (and so be close to the donor) during the donation. Our QA data on pack weights do not indicate that the present system is causing major problems. (ii) We know of no evidence that pack agitators lead to a better

product. A study proposal to investigate this is being developed jointly by staff in S.E. and W Centres (Drs Gabra, Smith and Prowse). This study will also investigate the influence of donation time on quality of the product (see 15f).

15.(f) "LACK OF DEFINITION OF A SLOW BLEED"

(i) We have defined a slow bleed as one which takes more than 10 minutes to take the standard volume. (ii) Donor staff will be instructed to adhere to an SOP which requires that venesection is terminated if donation is not completed within 10 minutes.

(g) "THE SURPRISING PRACTICE OF RETAINING BLOOD AT AMBIENT TEMPERATURE FOR UP TO 18 HOURS"

With the commissioning of the Livingstone House facility this practice has been terminated. Donations with the exception of those destined for platelet production are transferred to 4 C storage at point of collection within 30 minutes and stored prior to processing at 4 C (excepting transit to and from vehicles). These requirements are being incorporated in the relevant SOP's. The only situation in which we cannot yet achieve this standard is when blood must be transported from a session in small vehicles (Ford Estate cars) which have no refrigeration. We are investigating the availability of cooled containers designed for the American Red Cross Transfusion Service which may prove suitable.

18.(h) "THE NON USE OF SEGMENTS ON THE DONOR TUBE FOR CROSSMATCHING PRUPOSES"

The use of donor line segments will be introduced by April 1983.

19.(i) "THE VOLUME OF BLOOD TAKEN. THIS IS PRESENTLY 420MLS BUT MAY BE INCREASED TO 450MLS."

The pack in current use is difficult to centrifuge containing a 450ml donation. Donation size will eventually be increased to 450ml when a new pack design is introduced, and/or modified centrifuge cups are obtained, and suitable balances for pack weighing during donation are obtained.

20.(j) "THE RATIO OF 3 DONORS TO 1 DONOR ATTENDANT WAS HIGHER THAN SEEN ELSEWHERE. THIS HAS SAFETY AND TRAINING IMPLICATIONS AND SHOULD BE REDUCED"

We accept this and have been aware of it for some time. A bid was made in 1982 for a further 6 donor attendants and 1 nursing sister. This funding has not been received but we understand it will be given high priority during 1983-84. Since the inspections a new consultant has been appointed in charge of the blood donor service, and she is reviewing staffing levels requested for adequate donor care. It is anticipated that a further increase will be necessary. This need has been identified in financial forecasts for 1984-5. In the short term urgent steps are being taken to find temporary additional finance from within the Centre's existing resources to provide for extra staff. Training programmes have been designed but there is no possibility of implementing these until more staff are available.

21.(k) "THE USE OF A HAEMOGLOBINOMETER RATHER THAN THE COPPER SULPHATE TEST"

We are now using an OSM2 haemoglobinometer routinely in the donor centre to check all donors who fail the copper sulphate test. This has reduced the donor deferments for low haemoglobin from 5% to below 1%. Two further haemoglobinometers have been purchased and will be used in extended trials of their robustness, reliability and staff acceptability to staff on mobile sessions.

MISCELLANEOUS COMMENTS

22 "THE PURSUIT OF 'EVER INCREASING' SHELF LIVES OF VARIOUS PRODUCTS WAS BRIEFLY DISCUSSED. WHILST THE NEED FOR THIS CAN BE EXPLAINED THE DESIRABILITY OF SUCH A POLICY WAS QUESTIONED"

See section 2.

23 "DISCUSIONS WERE ALSO HELD ON THE CONCEPT OF CLINICAL VALIDATION OF PROCESSED MATERIAL. IN SOME RESPECTS THERE WOULD APPEAR TO BE ROOM FOR THE GENERATION OF MORE DATA"

See Section 2

24 "OUT OF HOURS SUPERVISION COULD WELL BE MISSING IN THE PROCESSING AREA. THIS SHOULD BE RECTIFIED WITHOUT DELAY."

From January 17, 1983 onwards we will provide for one trained MLSO to be responsible for out of hours supervision of laboratory assistants in the processing area. This MLSO will be present at all times during components processing.

"EDINBURGH IS A CENTRE WHICH APPEARS TO DO A NUMBER OF ACTIVITIES DIFFERENTLY FROM ELSEWHERE....."

We have difficulty in responding to the general comment but accept that where we are using practices which differ importantly from a universally accepted normal practice, the onus is on us to demonstrate validation of our practice. The specific points raised as examples were. (i) "STORAGE OF WASHED RED CELLS FOR FIVE DAYS" (this refers to recovered frozen red cells). The safety of this practice has been validated over many years by biochemical and bacteriological testing of all outdated units. The data, which show good red cell preservation and an exceedingly low rate of contamination, are given in appendix (c) . (ii) "THE TIME LAG BEFORE BLOOD IS COOLED". We have now adopted conventional practice as our facilities now allow us to do this. (iii) "DIFFERENCE IN CENTRIFUGE PRACTICE." We take it the reference is to centrifugation times and g- forces. With the purchase of new equipment our centrifugation protocols are now similar to those used by other centres. (iv) "REPEAT CHECKS IN GROUPING USING THE SAME REAGENTS AND EQUIPMENT." This practice has been modified. See reponse section 86ii. (v) "PIGTAIL PACKS." See response section. 61,62 (vi) "LACK OF AGITATION AND TEMPERATURE CONTROL OF PLATELETS." In preparation for the introduction of new plastic packs for prolonged platelet storage, rotators for platelet storage are now in routine use for all donations. Storage temperatures are monitored. Facilities for temperature controlled storage are provided for in planning of the new blood bank. Controlled temperature storage facilities are being installed in the components processing area to hold platelets (without

agitation) prior to transfer to the blood bank. Controlled (22C) storage of blood before platelet separation is not required as blood for platelet production is centrifuged within a very short period of receipt in the components processing area.

PHASE I RIE

34 "THE LACK OF SECURITY OF THE CENTRE 'OUT OF HOURS'. IT IS UNDERSTOOD THAT THE MAIN ENTRANCE MUST REMAIN UNLOCKED - A MOST UNSATISFACTORY SITUATION FROM THE SECURITY VIEWPOINT. PRIORITY MUST BE GIVEN TO RESOLVING THIS ITEM"

A computer controlled card access system has been purchased and will be operational in Phase 1 RIE in January 1983. This restricts access to holders of personalised identity cards. The system will operate in all 3 sites as soon as the suppliers overcome their problems in meeting the agreed performance specification for the system.

35 "SOME UNSUITABLE FURNISHINGS HAVE BEEN PROVIDED IN A FEW AREAS AND IT IS HOPED THESE WILL NOT DELAY THE USE OF THE DEPARTMENT"

We do not understand this comment.

36 "THE HEPATITIS LABORATORY HAS BEEN DESIGNED AS A 3-ROOMED SUITE BUT ACCESS TO THE CORRIDOR IS POSSIBLE FROM THE ROOM CONTAINING THE MICROBIOLOCICAL SAFETY CABBINET"

We accept this basic design fault in the building. A minor works proposal will be submitted to modify the access as shown on the sketch plan,(appendix D). This will allow access to all 3 hepatitis laboratories to be segregated from the main corridor; Access to this area will be restricted to designated staff.

37 "THE MICROBIOLOGY LABORATORY (DESIGNATED) IS NOT SATISFACTORILY EQUIPPED"

We have established a new microbiology laboratory which is equipped for the present level of bacteriological testing.

38 "IT IS STRONGLY RECOMMENDED THAT THE AREA PRESENTLY BEING USED AS A TEMPORARY PHARMACY SHOULD, WHEN VACATED, BE CONVERTED FOR THE USE OF THE BLOOD TRANSFUSION CENTRE INTO A PROCESSING AND LABORATORY FACILITY. THIS WOULD ALLOW THE MAIN FUNCTIONS OF THE CENTRE TO BE HOUSED TOGETHER ON ONE FLOOR."

See response section 3

LIVINGSTONE HOUSE CLEAN ROOM

41 "THE DESIGN OF THE DRAIN (NO AIR BREAK - WHICH SHOULD BE OUTSIDE THE CLEAN ROOM). WINDOWS INSTALLED WITH LEDGES AND RUBBER GASKET (ATTRACTS DUST)"

The responsible officer of the Building Division (Mr J. Stewart, Clerk of Works) does not accept the Inspector's criticism. The Building Division has been asked by the Regional Director to respond in writing to the point raised by the Inspector.

LIVINGSTONE HOUSE - CENTRIFUGE ROOM

42 "THE ARRANGEMENT FOR EXTRACTION HERE USING LARGE AND CUMBERSOME HOODS IS NOT THE MOST APPROPRIATE. IN PRACTICE LOCALISED POINT EXTRACTION IS USUALLY MORE EFFECTIVE"

We are of the opinion that the heat extraction system installed is appropriate for the heat outputs (3kw per centrifuge).

43 "IT MAY BE NECESSARY TO PROVIDE ADDITIONAL COOLING CAPACITY IN THESE TWO AREAS"

We have no evidence that additional cooling is needed. Temperature records in the centrifuge room are satisfactory.

44 "IT IS ALSO RECOMMENDED THAT THOROUGH SMOKE TESTS ARE CARRIED OUT UNDER VARYING WORKING CONDITIONS TO ESTABLISH THAT THE CONTRIFUGE EXTRACTS DO NOT CAUSE AN INFLUX OF UNFILTERED AIR INTO THE CLEAN ROOM ITSELF (EG BY WAY OF THE HATCH)"

The recommendation is accepted to carry out smoke tests to investigate this potential problem, and arrangements have been made with CSA Building Division to do this. Nevertheless, our discussions with the Building Division's Officers indicate that the risk referred to must be remote.

We take it that the main concern is that unfiltered air could be present in the downflow of the laminar airflow cabinets. For this to happen four faults would have to occur simultaneously.

(i) The air pressure in the large centrifuge room would have to be greater than that in the Guarded Systems Separation Area (G.S.S.A.).

(ii) Both hatches from the centrifuge room to the G.S.S.A. would have to be open at once.

(iii) The positive pressure filtered air system feeding the G.S.S.A. would have to fail.

(iv) The vertical downward flow of sterile air in the LAFCs would have to cease.

Faults (iii) and (iv) could happen in the event of a major power interruption but in the event of this occurring there is a firm instruction in the Standard Operating Procedure for the Operation of the G.S.S.A. that all processing will be abandoned until the power supply is fully restored.

"OLD" RIE SITES - CROSSMATCHING, ISSUE AND POOLING FACILITIES

47. "THE EXISTING CROSSMATCH LABORATORY IS DANGEROUSLY OVERCROWDED HANDLING ABOUT 6,000 UNITS A MONTH IN A VERY SMALL FACILITY"

48. "THE EXISTING ISSUE FACILITY IS MOST UNSATISFACTORY - IT IS OVERCROWDED AND BLOOD MAY BE LEFT FOR UP TO AN HOUR AT AMBIENT TEMPERATURE"

These criticisms are accepted in full. The attached sketch plan , appendix (E), shows the proposed enlargement of the Crossmatching Lab and issue room. Each crossmatching work station will have its own 4 C storage. These works are at present (December 1982) being costed by the CSA Building Division.

49 "THE EXISTING POOLING FACILITY IS MOST UNSATISFACTORY THERE ARE TOO MANY OTHER ACTIVITIES NEARBY AS WELL AS DRAUGHTS FROM OPENING WINDOWS. EVEN THE PROPOSED UPGRADING WILL NOT CONVERT THIS INTO A CLEAN ROOM ENVIRONMENT"

We acknowledge the inadequacies of the present pooling facility and have given serious consideration to the construction of a small clean room for pooling blood products (platelets and cryoprecipitate) immediately before issue from the

blood bank. We conclude that this is feasible. However, it must be noted that there are problems inherent in the operation of a clean room facility during out of hours periods in a busy blood bank which is manned for long periods by a single MLSO who must be instantly available to deal with emergencies.

If it was necessary to change completely, gown and glove to enter the clean room to pool platelets, the service could only be provided by having a second member of staff available during all out of hours periods. We consider that with the present commitment of our trained MLSO staff to various out of hours rosters it will be impossible to recruit staff for this new duty. In addition, there are financial implications in funding an additional person out of hours. We therefore propose the following solution:

Platelet and cryoprecipitate pooling to be carried out in a room within, but separated from, the Issue Area. (See Appendix E - Sketch Plan). The air suppy to this room will be supplied from the outside using a positive pressure filtered air system operating to the same specification as that used in the clean room in Livingstone House. The temperature of the air will be controlled at 22 C +-2 C by an incorporated air conditioning unit, to provide conditions for storage of platelets. Pooling will be carried out in a vertical laminar air flow hood. Personnel entry to the room will be by sliding door. Before entering the positive pressure ventilated room staff will remove their laboratory coats and put on disposable gown, hat and mask (the same procedure as adopted in clean room, Livingstone House).

STORAGE FACILITIES

51 "EXISTING STORAGE FACILITIES WERE SEEN TO BE INADEQUATE, WITH GOODS, EQUIPMENT AND RUBBISH CLUTTERING UP CORRIDORS"

Major inroads to this problem have been made with the availability of the new stores. Adequate storage, including expanded 4 C storage is provided for in the plans for the "old" Royal Infirmary site.

52 "INSUFFICIENT REFRIGERATOR SPACE WAS AVAILABLE SO THAT ONE REFRIGERATOR DESIGNATED FOR EXPIRED MATERIAL CONTAINED "IN-DATE" FVIII AND FREEZE DRIED CRYOP-RECIPITATE"

The storage of "in date" and expired material in a single refrigerator has ceased.

BLOOD PROCESSING

54 "ENTRY FOR STAFF AND MATERIALS IS VIA THE BACK DOOR WHERE ONE IS CONFRONTED WITH AN APPALLING MESS OF RUBBISH WHICH IS TOTALLY INADEQUATELY CONTROLLED AND REMOVED. WHIST IT MAY BE VERY DIFFICULT TO CONTROL THE COCKROACH AND RODENT INFESTATION IN OLD BUILDINGS OF THIS TYPE, THE UNACCEPTABLE HEALTH HAZARD POSED ATTENTION BY THE HOSPITAL AUTHORITIES"

The site referred to has been vacated.

55 "THE ONLY CONCESSION TO CLEAN ROOM WORKING CONDITIONS THAT HAS BEEN POSSIBLE IS TO SUPPLY HEPA FILTERED LAF CABINETS. THESE HAVE BEEN LOCATED IN STANDARD LABORATORIES OR WORSE, IN CORRIDORS. NO STAFF CHANGING FACILITIES ARE AVAILABLE. OUTER SURFACE OF BAGS ARE NOT SANITISED BEFORE ASEPTIC HANDLING"

Improved clean room conditions have been provided in Livingstone House - These are the subject of later comments and responses.

We do not accept the comment that the failure to sanitise the external surface of blood bags is a defect in our working practice. It is our understanding that the introduction of a system to sanitise blood packs in a large English RTC has not resulted in any documented improvement in the level of bacteriological contamination of separated plasma and we feel that further evidence is required before a case could be made for the cost-effectiveness of this change.

56 "UNDER SUCH CONDITIONS THE SKILL OF STAFF, A DISCIPLINED AND CONSCIENTIOUS APPROACH AND ADHERENCE TO GOOD HOUSE KEEPING PRACTICES ARE ALL OF IMPORTANCE"

We accept that these comments are valid regardless of working environment.

57 "WITHOUT WISHING TO DETRACT IN ANY WAY FROM THE EFFORTS OF STAFF SOME IMPROVEMENTS IN ASEPTIC MANIPULATION AND THE HOUSEKEEPING OF LAF CABINETS NEEDS TO BE CONSIDERED. EXAMPLES OF WORKING ON THE EDGE OF CABINETS AND WITH UNGLOVED HANDS IN A POSITION LIABLE TO CONTAMINATE CONNECTORS WERE SEEN"

We agree that there is a need to ensure that staff are trained to carry out manipulation aseptically, and to maintain those operational standards in practice. We disagree with the specific comment about ungloved hands as it is our opinion that gloves may become contaminated and are not "safer" than ungloved hands, and that gloves interfere significantly with manual dexterity to the detriment of the safety of the procedures. Staff are trained, and will continue to be trained, in how to avoid contaminating the opened sterile connectors. During early 1983, smoke tests on the LAF will be carried out during simulated operational procedures to highlight the parts of all manoeuvres which are accompanied by risks of contamination.

58 "THE WHOLE QUESTION OF TRAINING STAFF WOULD SEEM TO NEED SOME CONSIDERATION. BY ADOPTING A FORMALISED APPROACH IMPROVEMENTS SHOULD OCCUR"

(i) A standard operating procedure for the operation of the G.S.S.A. is now in use.

(ii) At present no formal training is given but in-service instruction is provided and as staff are under constant supervision assessment of their competence and continued adherence to good practice is continually taking place. The gradual production of Standard Operating Procedures will eventually build up to the detailed list of practices. Consideration is being given to providing regular periods in which formal training can be given on an uninterrupted basis to all the appropriate staff.

59 "IN TERMS OF SPEED OF PROCESSING IT IS UNDERSTOOD THAT DONATIONS TAKEN BY THE MOBILE TEAMS ARE NORMALLY PROCESSED THE SAME DAY (EXCEPT EVENING SESSIONS). BLOOD TAKEN IN THE CENTRE IS PROCESSED UP TO 7.00 P.M., THOUGH IT IS UNDERSTOOD THE CENTRE WOULD LIKE TO CONTINUE PROCESSING UP TO 11.00 P.M. THIS MUST, HOWEVER, BE DONE WITH ADEQUATE QUALIFIED SUPERVISION"

"Same day" processing now covers the majority of sessions and with new working arrangements starting in January 17, 1983, there will be a further increase in the proportion of donations processed on day of collection.

PIGTAIL PACK

61, "THE DEFINED USAGES FOR THE PIGTAIL PACKS ARE FOR THE PREPARATION OF PRECIPITATE BY THAW SYPHONING OR FOR PLASMA POOLING"

62. "THE INCREASE OF THIS PACK MAY DECLINE SHOULD THE MULTIPLE PACK WITH SAG OR SAGM INCREASE"

It is hoped to obtain funds to conduct a large scale trial of optimal additive packs which would remove the need for pigtails to be used in fresh plasma pooling. Development of the "tear bag" system may also remove the need for pigtails for this purpose. We consider however, that the present use of the pigtail connection system for fresh plasma pooling is a safe procedure which does not require to be altered on the grounds of microbiological safety. Data on the bacterial contamination of products prepared in the pigtail system are given in appendix F to support this statement.

Pigtail connections are also used for pooling of outdated plasma and also for pooling platelets and cryoprecipitate prior to issue from the blood bank. In the latter context we have made proposals (49) for improving the working environment. We would require further discussions with the Inspector to determine the standards to be attained for the pooling of outdated plasmas using pigtails.

CRYOPRECIPITATE PRODUCTION

64 "THERE IS A REDUCED RISK OF CONTRACTING HEPATITIS FROM A SMALL POOL DONOR SOURCE. IT IS ARGUED BY OTHERS THAT THE RISK OF CONTRACTING HEPATITIS IS SUBSTANTIALLY INCREASED WHEN A POOL EXCEEDS 10"

No comment. See Response Section 2

65 "EDINBURGH USE AN INITIAL POOL OF 3 BUT THIS IS LATER POOLED WITH 4 OTHER POOLS (MAKING A TOTAL OF 12 DONORS INVOLVED)"

In fact four or more pools may be issued at any one time to a particular patient. Hence, one treatment episode could involve a patient being exposed to 3, 6, 9, 12 or even more donors. We feel, however, that the inspector has missed the main point of the "donation-exposure" aspect of this system of providing cryoprecipitate. In fact, the factor VIII and fibrinogen yields are higher than with conventional cryoprecipitate so that for an equivalent dose of factor VIII (or fibrinogen) the patient is exposed to even less donors than would be the case with cryoprecipitate prepared conventionally. See also response to 74.

66 "THE INSPECTOR WOULD PREFER THE CENTRE TO INVESTIGATE THE POSSIBILITY OF USING ACCREDITED DONORS IN AN ATTEMPT TO REDUCE THIS RISK"

Because the triple pool is selected from donations of known group - ie from established donors - there is already an element of accreditation in the procedure. However, it is felt that the logistics of providing a panel of "fully accredited" donors for cryoprecipitate are not likely to make the procedure cost-effective. Nor are we clear how an "accredited" donor should be defined in terms of the risk of transmitting hepatitis, since all current evidence suggests that the great majority of cases of post transfusion hepatitis are clinically occult and can only be found by regular checking of the recipients liver function tests over long periods.

67 "CRYOPRECIPITATE PRODUCES A HIGHER YIELD OF FVIII FROM A GIVEN UNIT OF PLASMA COMPARED TO FREEZE DRIED INTERMEDIATE FVIII. IT IS ONLY BY PRODUCING 10.000 PACKS OF CRYOPRECIPITATE PER ANNUM THAT THE CENTRE CAN MEET ITS NEEDS"

It is true that, at the moment, self-sufficiency for factor VIII in the S E Scotland Region is dependent on the high-yielding cryoprecipitate production. However, developments are in hand which will increase the supply of high quality fresh plasma to PFC for factor VIII production: dependence in cryoprecipitate may be reduced in future.

68 "THE GAP BETWEEN NEEDS AND QUANTITIES OF FVIII AVAILABLE FROM THE PFC COULD BE SUBSTANTIALLY NARROWED IF A NATIONAL POLICY OF DISTRIBUTION WERE ADOPTED. THAT IS SUPPLY SHOULD GO TO THE CENTRES WITH THE GREATEST NEED"

No comment

69 "A SMALL QUANTITIY OF CRYOPRECIPITATE MIGHT STILL BE REQUIRED FOR ITS FIBRINOGEN CONTENT OR FOR THE TREATMENT OF VON WILLEBRAND'S DISEASE.

No comment

71 "THE CRYOPRECIPITATE IS PRODUCED FROM A TRIPLE POOL OF PLASMA FLASH FROZEN TO -30 TO -40 C. SIXTEEN SUCH POOLS ARE THAWED AT 2-3 C. THE CRYOPRECIPITATE DEPLETED PLASMA IS SYPHONED OFF AND THE CRYOPRECIPITATE IS FROZEN AND STORED FOR UP TO 6 MONTHS. (CONSISTS OF 4 BY 3 DONORS)"

The phrase in parenthesis is erroneous (see response to 65). The inspector appears to be under a misapprehension. Three donations are contained within each pack of frozen cryoprecipitate - not twelve. The volume of each pack is about 110 mls.

72 "THE TRIPLE POOLS OF CRYOPRECIPITATE ARE OF ONE ABO GROUP (NORMALLY 'O' OR 'A'). PATIENTS REQUIRING MORE THAN ONE TRIPLE POOL MAY BE GIVEN A MIXED POOL OF GROUP 'O' AND GROUP 'A' TO REDUCE THE AMOUNT OF 'ANTI A' PRESENT (ABSORBED BY 'SOLUBLE A SUBSTANCE')"

No comment

73 "INCREASED 'SIDE EFFECTS' ARE A CONSEQUENCE OF THE USE OF CRYOPRECIPITATE BUT AS USED IT DOES NOT APPEAR TO BE AMENABLE TO PURIFICATION"

No comment

74 "CONNECTION TO BAGS FOR POOLING AND THAW-SYPHONING ARE CARRIED OUT UNDER LAF PROTECTION. WHETHER BETTER FACILITIES ARE NEEDED WAS NOT RESOLVED - POOLED PRODUCT CAN BE STORED FOR UP TO SIX MONTHS, ALBEIT UNDER FROZEN CONDITIONS, SO A CASE COULD BE MADE FOR CLEAN ROOM FACILITY"

We agree that there is a case for the clean room facility to be made available for the connection procedures in thaw-siphon cryoprecipitate production. Investigations are planned to assess the feasibility of using the clean room for this.

We will also be investigating the effects of preparing the initial pool of plasma to be cryoprecipitated from two donors, rather than three, the donations to be collected in an "optimal additive system" with maximal plasma separation (300 mls) from each. As an extension of this, we will also be investigating the efficacy of the thaw-siphon process on the 300 mls of plasma from a single donation using a totally closed pack system. This is likely to result in about 50 mls of residual cryoprecipitate. These points are also relevant to paragraph 65.

"ALIQUOT SAMPLING MIGHT BE MORE REPRESENTATIVE THAN THE EXISTING SACRIFICE OF A SINGLE UNIT FOR TESTING PURPOSES"

It is our belief that aliquots which are frozen and thawed separately from the main bulk of cryoprecipitate are likely to give a less representative indication of the active contents of the whole pack than if the whole pack is thawed. Were aliquots to be collected from fully solublised cryoprecipitate prior to final freezing, we believe that this would cause a loss of activity. Hence, even though the current procedure involves the sacrifice of that pack, we believe that the standard of QA is thereby enhanced.

CELL WASHING

"THE MACHINE USED, AN IBM 2991, IS INAPPROPRIATELY LOCATED IN A CORRIDOR. BAGS ARE CONNECTED TO THE MACHINE WITHOUT THE PROTECTION OF HEPA FILTERED AIR"

Funds have been obtained for the purchase of a laminar flow canopy to protect the connections made in operating the IBM 2991 cell washer. This facility will be incorporated in the modifications to the "old" Royal Infirmary site, and should be operational early in 1983.

FROZEN CELL STORAGE

"RED CELLS IN THE CRYOPROTECTED STATE AND STORED IN THE VAPOUR PHASE OF LIQUID NITROGEN ARE GIVEN AN INDEFINITE SHELF-LIFE EVEN THOUGH TEMPERATURES ARE INADEQUATELY MONITORED"

We are investigating the availability of suitable temperature monitors but would note that there is an automatic and fully alarmed system to maintain the level of liquid nitrogen in the containers, and that the constant evaporation should maintain constant temperatures.

79 NO MICROBIAL DATA HAS BEEN GENERATED ON THIS PRODUCT. THIS WOULD SEEM WORTHWHILE AS NEONATES ARE PARTICULARLY 'AT RISK'."

We have introduced regular bacteriological QA on 4 samples of this product per week.

POOLING OF EXPIRED PLASMA

80 "POOLING IS CARRIED OUT IN AN LAF CABINET BUT THE ENVIRONMENT IS UNSATISFACTORY

This function has been transferred to Livingstone House.

QUALITY ASSURANCE

81 "THERE IS NO CENTRALISED QA FUNCTION AND SO FAR A DISTINCTION HAS NOT BEEN MADE BETWEEN A NOMINATED PERSON RESPONSIBLE FOR PRODUCTION AND ONE FOR QC"

As from March 1st 1983 a Chief MLSO with appropriate experience will be the person nominated to take responsibility for the coordination of quality assurance. The development of appropriate standard procedures for documentation, checking and reporting of QA data, and documentation of actions taken in response to QA reports, will be undertaken by this person working with appropriate senior members of staff.

83 "A QC PROCEDURES MANUAL IS AVAILABLE AND A SUMMARY OF THE 'TEST SUMMARY SHEET' WAS REQUESTED"

"Test Summary Sheet" was provided: copy at appendix G .

DONOR GROUPING

84. "MACHINE GROUPING IS CARRIED OUT ON A ~~TECHNICON~~ centrifuge MACHINE BUT THIS HAS BEEN UNRELIABLE AND REQUIRES CONSTANT OPERATOR SUPERVISION"

85. "INVESTMENT IN MODERN EQUIPMENT LINKED TO A COMPUTER WHICH COULD 'SCAN' AND 'COMPREHEND' LABELS MUST BE A PRIORITY. THE SCOTTISH TRANSFUSION SERVICE AS A WHOLE IS STILL IN THE PROCESS OF EVALUATING THEIR REQUIREMENTS"

Funding was requested for a new automated grouping machine for 1982-83. This has not been funded but the request is continued for 1983-84. The SE Centre has prepared a detailed operational requirement for this equipment, received proposals from suppliers, and reached a decision on the instrument required.

Funding for a comprehensive integrated computing system has been sought for the financial year 1983-84. This matter is still under consideration by the Common Services Agency.

86 "TO PROCEED TO AN EVEN MORE AUTOMATED SYSTEM WOULD STILL REQUIRE STAFF IN THIS SECTION TO BE ABLE TO 'FALL BACK' TO LESS SOPHISTICATED TECHNIQUES SHOULD IT BE NECESSARY. IT IS ~~NOT~~ NOTICEABLE THAT HEAVY RELIANCE IS ALREADY PLACED ON THE ~~TECHNICON~~ MACHINE. REPEAT GROUPINGS ARE MERELY SENT THROUGH THE EQUIPMENT A SECOND TIME USING THE SAME REAGENTS AND PAPER. IN OTHER FIELDS THIS WOULD NOT BE CONSIDERED GOOD OR SAFE PRACTICE THOUGH IT IS TRUE IN THE CASE OF GROUPING ONE HAS A 'LONG STOP' IN THE SHAPE OF THE CROSSMATCHING LABORATORY. (IN A REAL EMERGENCY CROSSMATCHING MIGHT BE BY-PASSED AND THE 'LONG-STOP' NO LONGER EXISTS)"

(i) it is accepted that full back-up procedures are mandatory and the development of these, with ongoing arrangements for staff training etc. would be an integral part of the introduction of new grouping equipment.

(ii) the practice of repeat grouping with the same reagents has been abandoned. All new donors are regrouped with different reagents. Any grouping discrepancies are investigated by manual testing.

(iii) Blood is not issued without a confirmation of ABO group even in real emergencies. A small stock of manually re-checked group O is maintained for "instant" release.

SYPHILLIS TESTING

87 "THIS IS CARRIED OUT MANUALLY AND BY MACHINE. ANTIPATHY WAS EXPRESSED TOWARDS THE TEST BY THE CENTRE STAFF"

The cost-effectiveness of syphillis screening is challenged by many transfusion specialists and the practice of screening has been abandoned in at least one major Centre of high reputation. it is the view of the Regional Director that the benefits of screening should be formally revaluated by SNBTS. When a new grouping machine is obtained, syphillis testing will be automated.

HEPATITIS TESTING

90 "THE MAIN BIOHAZARD AREA ALTHOUGH SEGREGATED AND ENTERED VIA A CHANGE ROOM MUST BE CONSIDERED AS UNSATISFACTORY. IT HAS A VERY SLIGHT NEGATIVE PRESSURE AND HEPA FILTERS DO NOT APPEAR TO HAVE BEEN FITTED ON THE EXHAUST DUCTING"

This laboratory has been vacated. We do not however, accept the implication that a negative pressure ventilation room is needed for routine blood donation hepatitis screening since the materials handled are of low infectivity . Negative pressure rooms are not, we understand, used in many other transfusion centres. A hepafilter will be fitted at point of air extraction in the ventilation system of the laboratory to be used for hepatitis testing in Phase I RIE.

91 "THE AUTOCLAVE LOCATED HERE USED FOR INACTIVATING CONTAMINATED ITEMS STILL RUNS ON A PRESSURE GAUGE (20LBS FOR 45 MINUTES) AND HAS NOT BEEN CHECKED OR REGULARLY MAINTAINED."

A replacement autoclave has been commissioned in Phase I RIE

MICROBIOLOGY

92 "A LEVEL OF MICROBIAL TESTING IS CARRIED OUT ON PRODUCT AND A LIMITED ENVIRONMENTAL TESTING SCHEME IS INCLUDED. THIS LATTER SYSTEM INCLUDES 'BIOTEST' CHECKS ON LAF CABINETS BUT THESE CANNOT BE CHECKED FOR PARTICLES OF FLOW (BY ANEMOMETER) NOR ARE SETTLE PLATES ROUTINELY USED. "BIOTEST" RESULTS ARE HIGHLY VARIABLE"

(i) We intend to maintain the present level of bacteriological testing products until there have been further SNBTS discussions about the appropriate levels of testing.

(ii) Environmental monitoring. From January 1983, air sampling and settle-plate checks will be made in the following areas:

(i) clean room air in LH
(ii) clean room LFC's in LH
(iii) cryo pooling LFC in LH
(iv) blood bank LFC
(v) cryobiology LFC

The frequency of sampling is as yet to be decided: details will be incorporated in the relevant SOP's. Results will be reported by Microbiology Section to the QA Officer.

93 "TEST METHODS APPLIED ARE NOT PHARMACOPOEIAL AND POSITIVE CONTROLS ON MEDIA ARE NOT DONE. SAMPLE SIZES ARE OFTEN SMALL".

Sample sizes are small by pharmacopoeial standards for pharmaceutical products, but there are obvious reasons for minimising the sacrifice of donated blood and its derivatives for QC purposes. We consider our sampling is not out of line with practices in other transfusion centres.

The bacteriological culture procedures in use are at present being reviewed with the intention of completing revised SOP's by mid 1983, which will be in line with accepted practices in other Centres. The matter of medium controls is particularly difficult in view of the range of organisms which we would require to detect: it is possible that this can be dealt with only by obtaining suitably tested supplies of media from an external source.

DOCUMENTATION AND SOP'S

94, "A WORKING PARTY AT THE CENTRE IS REVIEWING THE NEED FOR AND THE DETAILS TO BE INCLUDED. A USEFUL START HAS BEEN MADE."

95. "EXISTING DOCUMENTATION AND DATA GENERATION IS FAIRLY SUBSTANTIAL BUT IT IS NOT CLEAR WHETHER IT IS ALL 'USEABLE'"

Priority is being given to completion of comprehensive SOP's for donor selection, care and bleeding and for components processing. With our present staff resources we feel the completion of adequate SOP documents for all activities will take several years and unless clerical or word processing support is available this programme may have to be curtailed.

We accept that present QA documentation is not adequately accessible. It will be a priority of the person nominated to be responsible for QA to rationalise the presentation and distribution of QA information.

96 "WHEN IT COMES TO IDENTIFYING DONORS FROM A SPECIFIC BATCH OF PLASMA FULL TRACEABILITY IS MAINTAINED. HOWEVER, TRACING WHERE OTHER COMPONENTS MAY HAVE GONE FROM THE SAME DONATION (EG THE RED CELL CONCENTRATE) MAY NOT BE DONE WITH ABSOLUTE CERTAINTY"

We are not aware of the deficiencies referred to in documentation to trace components prepared from a donation. It is however accepted that the system is slow and cumbersome and that information tracing would be greatly improved by computerisation. See also 106.107.

PLASMAPHERESIS

97 "THE CENTRE HAS A SMALL (3 BED) MANUAL PHERESIS PROGRAMME GOING. ACCURATE IDENTIFICATION OF PATIENT AND RED CELLS FOR RE-INFUSION IS AIDED BY A COLOUR BAND AND SIGNATURE SYSTEM. THIS IS PROBABLY SAFE FOR ABOUT 7 OR 8 BEDS BUT CERTAINLY NO MORE."

We have no response to this observation

CELL SEPARATOR

98. "THIS CAN BE USED TO OBTAIN SINGLE DONOR COMPONENTS FOR A NAMED PATIENT (AS WELL AS FOR PATIENT TREATMENT)

99. "IT IS A COMPLEX PIECE OF EQUIPMENT WHICH REQUIRES THAT THE CORRECT CONNECTIONS SHOULD BE MADE USING ASEPTIC TECHNIQUE"

We feel there is a need for more discussion of the Inspector"s role and objectives in this area before a response can be made. We can respond to point 100.

100 "A FEW COMMENTS WERE PASSED OVER THE ABSENCE OF A 'USE BY' DATE ON AUTOCLAVED EQUIPMENT AND SOME CONFUSION WAS EXPERIENCED WITH THE USE OF AUTOCLAVE TAPE AS A SUBSTITUTE FOR ADHESIVE TAPE."

The need for autoclaving of reusable components of the patient circuit will be removed with the planned purchase of a new cell separator in 1983. All elements of the patient circuit will then be sterile disposables.

BLOOD BANK, ISSUE, WARD REFRIGERATION

104 "RETURNED BLOOD IS HELD AND PHYSICALLY EXAMINED BEFORE RETURNING TO STOCK. THIS DOES NOT PROVIDE TOO MUCH OF A GUARANTEE THAT HANDLING AWAY FROM THE CENTRE HAS BEEN ADEQUATE"

105. "IT IS UNDERSTOOD THAT NEW WARD REFRIGERATORS ARE TO BE PROVIDED IN THE NEAR FUTURE AND THESE WILL BE CHECKED DAILY BY CENTRE STAFF. (WOULD HAVE BEEN BETTER TO HAVE BEEN DOING THIS WITH EXISTING UNSATISFACTORY REFRIGERATORS"

We accept that this is an area where control is difficult.

It should be noted that unlike most RTC's, we issue a high proportion of our blood, crossmatched, to individual patients. It is

normal and correct clinical practice to order blood which is not, ultimately transfused and it is often essential that this blood is available close to the patient rather than held in the blood bank. There is no possibility of rejecting all blood which is returned untransfused, as wastage would be unacceptable. We have taken the following steps to improve the situation.

(i) Research and educational programmes including the introduction of blood ordering schedules to train clinicians to minimise the amount of crossmatched blood withdrawn from the blood bank: (see eg appendix H). (ii) Introduction, to relevant parts of the RIE, of a policy of issuing blood one unit at a time, for immediate transfusion. (iii) Introduction of monitored blood storage refrigerators to serve parts of the Royal Infirmary where policy (ii) above is not applicable. These have been in full operation since September 1982. A new staff post has been financed to carry out the surveillance of these refrigerators.

106 "DOCUMENTATION IN THIS AREA APPEARED SUFFICIENT FOR TRACING PURPOSES (THOUGH 'TRACEABILITY' MIGHT BE LOST AT WARD LEVEL)"

107 "'COMPATIBLE' LABELS ON EACH PACK SHOULD HELP ELIMINATE TRANSFUSION ERRORS PROVIDING THEY ARE READ AND UNDERSTOOD

These comments touch on points of fundamental importance to safe transfusion, since a high proportion of all serious transfusion mishaps occur as a result of documentation and identification errors occurring close to the point of transfusion.

(i) It is true that "traceability" of a unit of blood may be lost at ward or theatre level. The only safeguard is scrupulous attention to detail by clinical staff to ensure that all transfusions are fully documented and that all blood which is not transfused is promptly returned to the blood bank (the same applies to blood products).

(ii) There are important possibilities for the use of computers and machine readable identification systems to carry out pre-transfusion checks and to log transfusions, but implementation on anything other than a pilot trial scale must be considered to be several years distant.

(iii) Compatibility labels on packs are one important part of essential pre transfusion checks. Also essential is the scrupulous checking of the patients identity and the documentation accompanying the blood.

We have taken the following steps to improve safety in this area.

(i) Introduction of new blood and product request forms which elicit adequate identification information on patients.

(ii) Introduction, from September 1982 of a continuing programme of inservice training for all Royal Infirmary nursing staff of staff nurse or higher grade, which concentrates on informing staff of the biological basis of transfusion hazards and the practical aspects of safe transfusion (so far more than 200 nurses, including all senior grades, have received small group teaching).

(iii) A programme is being planned to extend this teaching during 1983 - 85 to staff of other hospitals served by our blood bank.

Appendix A

GUIDE TO SELECTION OF BLOOD DONORS

General Principles :

Selection of donors is based on the prevention of risk to

(a) the donor and

(b) the person who eventually receives the blood.

If it is possible the donation of blood might harm a donor then he/she will be rejected either permanently or temporarily (usually for a fixed period.)

Giving blood may be safe for the donor but the blood itself may contain some factor harmful to the eventual patient. In this case blood will not be taken unless it can be specially treated to remove the risk.

General Conditions :

There are general conditions necessary before a donor can be accepted to donate a unit (420 ml) of blood.

1. Age Donors must be between 18 and 65 years. New first-time donors may be accepted up to and including age 60 if they are in good health and have no evidence of cardiovascular disease.

   New donors between 50 and 60 years of age should be seen by the sister or doctor before donating.

2. Weight Donors weight (for a 420 ml donation) should be 8 stone. (50 kgms.) or more for men and 7½ stone (47 kgms.) or more for women

   First time donors weighing less should be deferred.

   Highly motivated female donors weighing between 7 stone (45 kgms.) and 7½ stone (47 kgms.) who have given before at the same weight can be accepted.

NB. There is a significant risk of reaction in first time female donors weighing 7½ to 8 stone. A short pack "i.e. 400 ml or less" may be taken from such donors for their first donation at the sisters or doctors' discretion.

3. /

3. Haemoglobin : Haemoglobin level must be equal to or > 11 gms/dl in males and 12 gms/dl in females.

4. Frequency :

Males. No more than once in twelve weeks or more than four times per year.

Females. No more than once every six months for young female donors and most women of childbearing age. Healthy older women with light regular menstrual periods may donate not more than once in twelve weeks or more than three times per year.

5. Carrier state :

Hepatitis B surface antigen detection at any time excludes all donations except with the Director's approval.

6. Occupation :

There are two potential risks relating to a donor's occupation.

1. a delayed faint may be dangerous for both the donor and those at his/her work. It is recommended the following minimum time should elapse between donation and going on duty or taking part in certain more risky hobbies.

a) 12 hours for drivers of public transport vehicles (including ambulances), heavy vehicles and operators of heavy machinery, fire brigade, train drivers, construction workers on high buildings, and hobbies such as climbing and motor racing.

b) Seven days or according to employment rules. Air crew of scheduled public transport flights, pilots private aircraft, parachutists.

N.B. The Forces usually have their own regulations.

2. Exposure to dangerous substances which may be transmitted in blood may occur due to the nature of the donor's work. This, very rarely, could harm the recipient. The Genetic Manipulation Advisory Council have therefore advised no persons working in

N.B. Other Laboratory Workers handling potentially infective material may donate if not under investigation or treatment for accidental exposure to such material.

General Advice on Acceptability :

Medical problems which normally exclude a volunteer from giving blood are usually those which

a) may be aggravated by donating or

b) might mean the actual procedure of donating could cause harm.

Some of these conditions are outlined in the alphabetical Guide. In all cases responsibility for the acceptance or rejection (either permanent or temporary) lies with the Sister or Medical Officer on duty. Consultation with a Medical Practitioner who is familiar with the donor is advised if in doubt.

N.B. There are forms provided to obtain details from the Donor's G.P.

1. Permanent unfitness.

Serious allergic disorders.

Chronic and disabling illnesses.

Almost all forms of cancer.

A history of two or more serious reactions to donation

1 (if $\geq$ 40) *

(*)see below Number 5.

N.B. See Alphabetical Guide for specific conditions.

2. Temporary unfitness

Applies to temporary sickness (e.g. colds) or to instances where the donor may develop an infection or reaction in the near future.

Surgical operations, depending on the nature of the procedure will require donor deferral for three to six months unless very trivial e.g.(removal of sebaceous cyst or teeth extraction).

Recent immunisation and certain drugs may require temporary deferral (see alphabetical Guide).

In /

In general if a donor has fully recovered from an illness, meets all other criteria, is free of signs and symptoms of active disease and is physically able to tolerate donation, he or she may be accepted at the Sister or Doctor's discretion.

3. Venereal Disease

It is usually inadvisable to question donors on this point active syphilis will be detected by the V.D.R.L test performed routinely on all donations.

Successfully treated venereal disease (except syphilis) can be accepted. (see alphaberical Guide).

4. Fractionation

Sometimes a donor although physically fit should only donate for a plasma collection which may be very useful.

e.g. plasma should only be used from donors who have had malarial infection, prophylaxis or recent exposure. (See appendix II). The same applies to cases if serology is doubtful.

Various infections and immunisations may result in antibodies of particular value and a"hyperimmune"donation given (see alphabetical Guide).

5. Donor Reactions

Donors who have fainted or had early signs of a vaso-vagal attack (marked pallor and perspiration) after donation may give blood again if a careful watch is made for early signs of a similar nature.

Two consecutive faints

(1 if > 40 years old) are cause for permanent deferral.

6. Contact with infectious diseases.

"Contact" in this context means close household contact. Donors whose work involves contact with patients with infectious diseases may be accepted unless under investigation or treatment as a result of such contact.

ALPHABETICAL GUIDE TO MEDICAL ASSESSMENT

This list is intended to be used as a guide for Blood Transfusion Service Staff answering donor's queries about their fitness to donate. If there is any doubt or difficulty with a donor, the medical advice of a Blood Transfusion Service Sister or Doctor must be obtained. In all cases the Sister or Doctor who interviews the donor has the full responsiblity for acceptance or rejection, either temporary or permanent.

N.B. A small serum donation may be accepted, discreetly, from a difficult donor provided there are no serious medical contra-indications. The problem may be discussed later with the Medical Officer at the Centre.

	Acceptable if donor not on antibiotics and acne is quiescent.	
CUPUNCTURE International	Acceptable after 6 months.	
DDICTION: DRUGS International	See "Drug Abuse".	
LCOHOL International	If possible, defer donors who are under the influence. Otherwise, take a small serum donation.	
LLERGY (Mild) International to defer during attack.	Defer during an attack or if on treatment. See Asthma, Dermatitis, Hayfever.	N.B. Transfusion of blood or blood products from a donor who is suffering from an acute allergy risks the temporary sensitisation of the recipient as well as transmitting certain allergenic materials or drugs.
LLERGY (Severe) International	Permanently unfit.	
NAEMIA Edinburgh	Do not accept if attending G.P. Otherwise, accept if Hb satisfactory and no symptoms (even if donor is taking self-prescribed iron tablets).	
NALGESICS International	Accept if donor takes an occasional tablet. Defer if tablets are prescribed as regular treatment.	

TICS Edinburgh. SBT recommend at least 2/52 since last.	Action depends on condition for which antibiotic is taken. See under illness in question. Donors taking antibiotics for Acne should be deferred.	Defer until 48 hours after [illegible] otherwise acceptable.
PRESSANTS International policy	Defer if taken as regular treatment. Acceptable only if an occasional tablet is taken.	
STAMINE TABLETS	See Hayfever.	
LARIAL TABLETS	See Malaria.	
CECTOMY WA. Red Cross.	Acceptable three months after operation. Provided donor is feeling completely fit and has had no complications.	N.B. If operation complicated by infection prolonging hospital admission > 7 days, defer at least 6 months.
IS ISBT	Acceptable if mild and not on regular treatment. Defer if severe, or acute, or on regular treatment. Consult Doctor or Sister if in doubt.	
ISBT.	Acceptable if donor takes occasional tablet. Defer if tablets are taken regularly. ISBT	Aspirin affects platelet activity and therefore a platelet donation should not be taken from a donor within 72hrs of ingestion of aspirin.

STHMA (Mild)	Consult Doctor or Sister. Edinburgh.	In general, accept if no severe attacks during last 6 months and if not on treatment. A young person who has occasional mild asthmatic-type attacks which can be avoided by regular use of inhalers may be accepted as a donor. The severity of the asthma is the important factor. The use of an inhaler is unlikely to affect the donation
STHMA (Severe) International policy.	Defer if on regular treatment with tablets or inhaler.	
THLETE'S FOOT	Acceptable.	
.C.G. Edinburgh	Defer until innoculation site is healed.	
.EEDING DISORDERS	Consult Sister or Doctor. NBTS '77	Obtain more information from donor and donor's G.P. and defer if necessary. Carrier state for Haemophilia and allied disorders does not usually debar but again obtain more information from donor's G.P., and the donation should not be used to prepare Cryo-precipitate.
.OOD DISORDERS e.g. any familial cell Haemoglobin abnormality.	Consult Sister or Doctor. NBTS '77	Defer and obtain more information from donor and donor's G.P.
.OOD PRESSURE (High) American Taken from Clinical Practice of B.I.T.	Defer if on treatment, otherwise refer to Sister or Doctor.	If not on treatment, free of symptoms, and if B.P. is normal when tested at the session (i.e. systolic less than 150mmHg, diastolic less than 100mmHg), donors may be accepted. A donor /-

CONDITION	ACTION	NOTES FOR SISTER OR DOCTOR
		A don[illegible]hose B.P. is between 150-200/90-100 when tested at the session can be accepted only if: (a) they have no other symptoms or history of cardiovascular disease. and (b) there are no other factors which might predispose to a donor reaction, e.g. previous history of fainting, anxiety, a first-time female donor, etc. If abnormal differences between systolic and diastolic pressure are found, e.g. 115/90, 170/40, defer donation. The donor may be accepted at a later date pending consultation between the donor and his/her G.P.
)D PRESSURE (Low)	Consult Sister or Doctor. WHO suggest 90/50 as a minimum.	Acceptable at Sister's or Doctor's discretion provided diastolic is not less than 50mmHg. Such donors must always receive the prescribed period of rest.
)D TRANSFUSION International policy.	Acceptable 6 months after transfusion. Check reason for the transfusion. Refer to Doctor or Sister if in doubt.	
.S NBTS '77	Acceptable when healed. Donors with a small septic spot may be accepted.	
:CHITIS (Chronic)	Consult Sister or Doctor. Edinburgh Canada.	Permanently unfit, 'Chronic' means with regular attacks of cough and spit every winter.

:CHITIS (Isolated attack) /-

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BRONCHITIS (Isolated attack) Edinburgh	Acceptable 1 to 3 months after full recovery depending on severity. Consult Doctor or Sister if in doubt.	
BRUCELLOSIS International	Permanently unfit.	
BRUCELLOSIS CONTACT	Acceptable.	
CARTILAGE OPERATION Edinburgh	Acceptable when fully mobile.	
CATARRH (Acute) Edinburgh NB: ATRB + NBTS say defer until symptomless	Defer for 2 to 4 weeks after attack has cleared.	
CATARRH (Chronic)	Acceptable if not on treatment. Use of a nasal decongestant does not debar.	
CERVICAL CONE BIOPSY Edinburgh	Consult Sister or Doctor.	Defer and obtain more information from donor's G.P. If Carcinoma in situ see below.
CERVICAL CARCINOMA IN SITU (or cervical dysplasia)	Consult Sister or Doctor.	Accept following lasar Rx after 1 year or 2 consecutive neg. smears. Accept following hysterectomy after 1 year.
CHICKENPOX Edinburgh	Defer for at least 2 weeks after donor feels well.	Hyperimmune donation may be taken up to 3 months after the onset of illness. See hyperimmune donation form about plasmapheresis.
CHICKENPOX CONTACT	Acceptable if donor has had chickenpox. If not, defer for 3 weeks.	
CHOLECYSTECTOMY NBTS w/n Red Cross.	Consult Doctor or Sister.	Defer for at least 6 months after comple

CONDITION	ACTION	NOTES FOR SISTER OR DOCTOR
CHOLECYSTITIS Edinburgh (WA Red Cross suggest ? 1yr after recovery)	Acceptable if symptom-free for at least 4-6 weeks.	
CHOLERA IMMUNISATION Edinburgh	Acceptable after 48 hours if donor feels well. Defer for 1 week if donor feels unwell.	
COLDS Edin.	Defer for 2 to 4 weeks, depending on severity.	N.B. Accept if a donor has no evidence of a cold but uses a "slight sniffle" hoping to avoid donating.
COLD SORE Edin	Defer severe lesions until healed. Acceptable if donor has small or healed lesions.	Hyperimmune donation may be taken up to 3 months after the onset of the illness.
COLITIS (Ulcerative) WHO	Permanently unfit.	
CONCUSSION	See Head Injury.	
"CONE"BIOPSY	See Cervical Cone Biopsy.	
CONTRACEPTIVE PILL International	Acceptable.	
CORONARY THROMBOSIS International	Permanently unfit.	
CORTISONE (Tablets)	See Steroids.	
CORTISONE (Intra-articular injection) WA Red Cross.	Defer for one week. Check reason for injection.	
CROHN'S DISEASE Edin	Permanently unfit.	
CYSTITIS (Mild) WA Red Cross.	Acceptable after full recovery.	

D & C Edin.	Acceptable after 1 period. Check reason for D & C.
DERMATITIS Edin.	Acceptable unless severe and requiring treatment. Donors with mild dermatitis requiring application of ointment may be accepted provided the total area to which ointment is applied is small.
DE-SENSITISATION INJECTIONS FOR HAYFEVER	See Hayfever.
DIABETES (Severe) Intravenal	Permanently unfit.
DIABETES (Mild) NB. WA Red cross accept for fractionation if in drugs.	See Doctor of Sister. Edin. { Acceptable if otherwise fit and not on tablets or insulin. Acceptable if on diet alone.
DIARRHOEA Edin.	Defer for 1 to 4 weeks, depending on severity.
DIGOXIN ISBT	See Heart Pills.
DILATION AND CURRETAGE	See D & C.
DIPHTHERIA WA Red Cross	Acceptable 3 months after recovery.
DIPTHERIA IMMUNISATION Edin.	Acceptable after 48hrs if donor feels well. Defer for 1 week if donor fells unwell.
DIURETICS Edin.	Acceptable if taken for pre-menstrual tension. Otherwise defer. Consult Doctor or Sister if in doubt.
DIVERTICULOSIS WA Red Cross.	Acceptable.

ICULITIS Edwin.	ceptable symptom-free for last 6 months.	
BUSE	Consult Doctor or Sister. International Policy.	At least 6 months should elapse after the use of parenteral drugs because of the risk of serum-hepatitis. Donors under the influence of oral drugs should not be accepted. In both cases, bear in mind the possibility that the history given by these donors regarding the abuse of drugs may be unreliable.
AL ULCER	See Peptic Ulcer.	
ERY (amoebic or bacillary) Edwin.	Defer until 1 month after fullrecovery or until all tests are clean.	
ERY CONTACT Edwin.	Acceptable if feeling well.	
E/EAR INFECTION : ACUTE } Edwin.	Defer for 4 weeks after recovery.	
E/EAR INFECTION : CHRONIC }	Acceptable if not on treatment.	
ERCING International	Acceptable after 6 months.	
	See Dermatitis.	
HALITIS WA Red cross.	Consult Sister or Doctor.	Check history of fits. Acceptable 6 months after full recovery.

CONDITION	ACTION	NOTES FOR SISTER
EPSY	Consult Sister or Doctor.	Febrile convulsions before age 6 years can be accepted. In general Epilepsy is a condition which debars blood donation. (Donors of all Rx for 5 or more years and free of fits for that time could be accepted. A fit may be dangerous and difficult to deal with during a busy session and upsetting to other donors. Therefore advised to defer indefinitely).
NTS: New Donors History of being prone to faints.	Consult Doctor or Sister.	Acceptability depends on ease and frequency of fainting, and if there is an underlying cause which itself makes the donor unacceptable.
Donors who have given before.	Permanently unfit if have a history of 2 consecutive faints or severe reactions to donation (1 reaction if donor is over 40 years of age).	
ROIDS - REMOVAL	Consult Doctor or Sister.	See under 'Operations'. Defer for at least 6 months.
S	See Epilepsy.	
IMMUNISATION	See Influenza.	
D POISONING	Defer until 1 month after recovery or until all tests are clear.	
D ALLERGY	Acceptable if not severe. See Allergy.	

is from USA – Clin. Practice of Bl. Trans.

NBTS

ISBT Canada.

	Acceptable.	
INFECTIONS OF NAILS Edin	Accept if not on tablets.	
LADDER DISEASE	See Cholecystitis.	
LADDER OPERATION	See Cholecystectomy.	
C 'FLU Edin	Defer for 2 to 4 weeks.	
C OPERATION	Consult Doctor or Sister.	See under 'Operations'.
C ULCER	See Peptic Ulcer.	
TIS - Acute	Consult Sister or Doctor.	Each case must be assessed individually by the Sister or Doctor. A donor with chronic mild epigastric pain which is relieved by regular or sporadic use of antacids, and who has been declared otherwise fit and well by his G.P. after full investigation, may be accepted.
- Chronic	Consult Sister or Doctor.	
Edin		
DENTERITIS WA Red Cross.	Defer for 1 month or more, depending on severity.	
N MEASLES	See Rubella.	
JLAR FEVER Dr Gray CH. '79	Defer for 1 year after recovery.	
ULAR FEVER CONTACT	Acceptable.	
	Acceptable after treatment.	

CONDITION	ACTION	NOTES FOR SISTER OR DOCTOR
GOITRE	See "Thyroid"	
GONORRHOEA Edin.	Defer until all hospital tests are clear.	
GOUT : MILD Edin : SEVERE WA Red Cross	Acceptable if not on treatment. Defer	
HAEMATURIA	Consult Sister or Doctor. WA Red Cross.	May be acceptable after recovery depending on underlying cause.
HAEMORRHOIDS Edin.	Defer if regular or severe bleeding is reported. Otherwise acceptable.	
HAY FEVER International Cruise.	Acceptable if symptom-free and not on treatment. Otherwise consult Doctor or Sister. Edin.	Acceptable if taking no more than 1 Anti-histamine tablet a day, if no symptoms. Donors prone to severe attacks should be advised not to give during the season when the polien count is high.
HAY FEVER : DE-SENSITISATION INJECTIONS Edin.	Defer for 1 week after course.	
HEADACHES Edin.	May be acceptable. If donor complains of regular headaches only accept if he has been investigated. Otherwise accept if the headache has gone and the donor feels well. For Migraine see under 'Migraine'.	
HEAD INJURIES : Minor WA Red Cross.	Acceptable 3 months after recovery. Consult Sister or Doctor if in doubt.	Must be symptom-free with no fits.
HEAD INJURIES : Severe	Permanently unfit.	

[illegible] TEST	Defer for 1 week.	
ART ATTACK	Permanently unfit.	
ART CONDITION	Consult Doctor or Sister. AABB.	N.B. Defer and obtain more information from the donor's G.P. A single episode of Rheumatic Fever or Pericarditis, a heart murmur, or repair of a congenital defect do not necessarily disqualify a donor, but this decision must be made in consultation with the donor's G.P. and B.T.S. Director.
ART OPERATION	See Heart Condition.	
ART PILLS	Defer - may be permanently unfit depending on underlying condition.	
PATITIS	Consult Doctor or Sister. NATS	Defer for one full year after recovery. Check if donor knows if he/she is a carrier for serum hepatitis, and if so, put off service. Otherwise, at their first donation 1 year after their recovery record "Hepatitis" on donor's name slip and inform Hepatitis Lab.
PATITIS CONTACT	Defer for 6 months after close contact, e.g. live together, using same towels, crockery, etc.	
PATITIS IMMUNSATION (globulin injection)	Acceptable after 24 hours.	
~~FORE TRAVEL ABROAD~~		

ATITIS IMMUNISATION LOWING EXPOSURE TO HEPATITIS MATERIAL	Defer for 6 months. Also record on donor's name slip and inform Hepatitis Lab. so that antibody can be looked for.	
NIA (HIATUS) OPERATION	Consult Doctor or Sister.	See under 'Operations'.
NIA (INQUINAL) REPAIR	Acceptable after 3 to 6 months if donor feels fit and has had no complications.	
PES SIMPLEX	See Cold Sore.	
ERTENSION	See Blood Pressure.	
ERTHYROIDISM	See 'Thyroid'.	
OTHYROIDISM	See 'Thyroid'.	
TERECTOMY	Consult Doctor or Sister.	See under 'Operations'. Acceptable 6 months or more after recovery depending on diagnosis.
LUENZA Edin.	Defer for 4 to 6 weeks depending on severity.	
LUENZA IMMUNISATION NBTS	Defer for 1 week. NB, AMBB suggest 2/52.	
URIES: MAJOR : MINOR WA Red cross. : TRIVIAL	Acceptable 6 months after full recovery. Acceptable after 3 months. Acceptable. Consult Doctor or Sister if in any doubt.	See Head injuries.
N TABLETS Edin.	Defer for 1 year after course is finished [illegible] donor's G.P. If taken [illegible]	

	self-medication and donor has no symptoms, accept if Hb is satisfactory.	
IRON INJECTIONS 7 days.	Defer.	
JAUNDICE	See Hepatitis.	
KIDNEY DISEASE	See Nephritis.	
LARYNGITIS 7 days.	Defer for up to 4 weeks depending on severity.	
MALARIA - HISTORY OF MALARIA	Accept 3 years after full recovery and stopping treatment for PLASMA only.	3yr malaria is WHB/AABB Plasma only is NBTS
MALARIA - RESIDENT IN MALARIAL AREA	Consult Doctor or Sister. NBTS	Provided no history of Malaria within last 3 years and donor has been in good health after arrival in U.K., accept for PLASMA only.
VISITOR TO MALARIAL AREA (up to 2 months)	Consult Sister or Doctor. NBTS.	Such a donor may give WHOLE BLOOD if he satisfies all of the following criteria:- (1) No suspect malarial infection when abroad (2) Donor has taken anti-malarial tablets for 4 weeks after return. (3) Donor has been well for at least 12 weeks after return. If in any doubt take for PLASMA only. H.B. Refer to Appendix II for Endermic Malarial Areas.

	Acceptable.	Malaria is not contagious. Take for WHOLE BLOOD donation.
[illegible] DISEASES	Permanently unfit. NABB.	N.B. Take donors with adequately Rx Basal Cell Carcinoma and adequately Rx Cervical Carcinoma in situ (see section on Cervical Ca).
ASTECTOMY	Consult Doctor or Sister. Sdlin.	Removal of benign breast lump defer for 3 to 6 months following recovery. If there is any doubt in diagnosis, defer and obtain more information from donor's G.P.
ASTOID OPERATION	Consult Doctor or Sister.	See under 'Operations'.
EASLES Sdlin. (WA Red Cross suggest 3/52)	Defer for at least 2 weeks after donor feels fit.	Hyperimmune donation may be taken up to 3 months after the onset of the illness. See hyperimmune donation form about plasmapheresis.
EASLES CONTACT	Acceptable if donor has had measles. Defer for 3 weeks after a clost contact if donor has not had measles.	? 7-14 days incubation period - check
EASLES IMMUNISATION : ACTIVE	Defer for 2 weeks. WHO.	Hyperimmune donation may be taken up to 3 months after the vaccination.
: PASSIVE (-globulin injection)	Consult Doctor or Sister.	Defer for a minimum of 2 weeks.
ENIERE'S DISEASE WA Red Cross.	Acceptable if symptom free and not on treatment.	

NINGITIS (Dr Gray CH - 3/12 (Canada PHS Red Cross suggest 6/12)	See Doctor or Sister.	Acceptable 3 to 6 months after complete recovery if no history of fits.
RAINE Edwin.	Consult Doctor or Sister.	Do not accept for at least 48 hours after an attack, or if attacks are frequent, severe and require regular treatment.
CARRIAGE : UNDER 3mnths PREGNANT]	Acceptable after 3 months.] If donor	WA Red Cross.
: OVER 3mnths PREGNANT]	Acceptable after 9 months.] feels fit.	
LTIPLE SCLEROSIS	Consult Sister or Doctor.	Permanently unfit. However, a keen regular donor, with only mild Multiple Sclerosis, can be accepted as serum for reagents at the Doctor or Sister's discretion. It should be explained to the donor that these donations are just as valuable and essential as for transfusion purposes.
MPS	Defer for at least 4 weeks after recovery. Dr Gray City H. '79	Hyperimmune donation may be taken up to 3 months after onset of illness.
MPS CONTACT	Acceptable if donor has had Mumps. Otherwise, defer for 3 weeks after a close contact.	
MPS PASSIVE IMMUNISATION (-globulin injection)	Consult Doctor or Sister.	Defer for a minimum of 2 weeks. Should be 3-4 wks as minimum 2-4 wks
OMECTOMY	See Fibroids - removal.	
PHRECTOMY	Consult Doctor or Sister.	Defer and obtain more information from the donor's G.P.

General policy Edwin.

CONDITION	ACTION	NOTES FOR SISTER OR DOCTOR
HRITIS 1SBT · 3	As for Nephrectomy.	N.B. Self-limited renal disease, e.g. single attacks of glomerulonephritis, pyelitis, from which recovery has been complete do not necessarily disqualify the donor but more information must be obtained. Donors with chronic renal disease are permanently unfit.
-SPECIFIC URETHRITIS 5d ii	Defer until cleared by hospital & G.P.	
E BLEEDS 5d iii.	Acceptable if not a severe and regular problem.	
RATIONS General classification of operations from NBTS, WARed Cross & Canada.	If a donor has had any recent major surgery, the Doctor or Sister should be consulted before they are accepted.	
: MAJOR	Consult Sister or Doctor.	Acceptable 6 months or more after recovery. e.g. Hysterectomy, Prostatectomy, Cholecystectomy, or 'minor' operations without complications such as transfusion, peritonitis, etc.
: MINOR	Acceptable 3 months after recovery.	e.g. Appendicectomy without complications.
: TRIVIAL	Acceptable after 72 hours or when healed.	e.g. Dental extraction without complications. N.B. It is the responsibility of the Doctor or Sister to decide the severity of an operation and to obtain further details from donor's G.P. (using relevant form) if in any doubt. Donors should not be accepted after surgery if: (1) the operation was for a malignant growth

CONDITION	ACTION	NOTES FOR DONOR OR DOCTOR
		(2) they are still attending hospital or their own G.P. for follow-up. (3) they are still having post-operative treatment.
STEOMYELITIS via Red Cross.	Consult Doctor or Sister.	More information should be obtained if necessary. Otherwise, may be acceptable 6 months after full recovery.
VARIAN CYST	Consult Doctor or Sister.	See under 'Operations'. May be acceptable 6 months after recovery depending on diagnosis.
AIN-KILLING TABLETS	See Analgesics.	
ELVIC FLOOR REPAIR Edin.	Acceptable 6 to 12 months after full recovery.	
EPTIC ULCER	Consult Doctor or Sister. Edin	Acceptable if donor has been free of symptoms and off treatment for 3 months longer, but action depends on the severi : cases should be assessed by the Doctor or Sister individually. See "Gastritis - chronic".
EPTIC ULCER - OPERATION	Consult Doctor or Sister.	See under 'Operations'.
ERICARDITIS - ACTIVE VIRAL	Consult Sister or Doctor	Defer and obtain more information from donor's G.P.

	ACTION	NOTES FOR SISTER OR DOCTOR
RICOS : NEW OR YOUNG DONORS : OLDER DONORS Edin.	Accept only near end of a light period. Defer during a very heavy period. Otherwise accept if they have previously given during a period.	N.B. Donors on contraceptive pill with light periods lasting 1-2 days may be accepted.
RITONSILLAR ABCESS	See Quinsy.	
RITONITIS WA Red cross.	Consult Doctor or Sister.	Acceptable 6 months after recovery but depends on cause.
ARYNGITIS Edin.	Defer for up to 4 weeks depending on severity.	
LEBITIS : ISOLATED ATTACK Edin.	Consult Doctor or Sister.	Check cause and site. Acceptable 6 months afte complete recovery.
LEBITIS : REPEATED ATTACKS	Permanently unfit.	
LES	See Haemorrhoids.	
EURISY Edin.	Acceptable 3 months after complete recovery. Consult Doctor or Sister if in doubt.	Check cause.
EUMONIA Edin.	Acceptable 3 months after complete recovery.	

CONDITION	ACTION	NOTE FOR SISTER OR DOCTOR
THORAX : TRAUMATIC : SPONTANEOUS	Consult Doctor or Sister.	Acceptable after a minimum of 6 months following recovery. Assess individual case.
	Acceptable if donor has been cleared by hospital. Seriously disabled donors should be assessed by Doctor or Sister.	
CONTACT	Accept.	
IMMUNISATION	Accept after 14 days.	
ANCY	Defer.	
ANCY : AFTER THE BIRTH	Acceptable 1 year after delivery for new donors or if mother has breastfed. Otherwise accept after 9 months.	
	N.B. If breast feeing has continued for more than 9 months accept 3 months after stopping breast feeding.	
ATECTOMY	Consult Doctor or Sister.	Acceptable 6 months or more after complete recovery depending on diagnosis. See under 'Operations'.
ASIS : MILD	Acceptable.	
: GENERALISED : SEVERE	Defer	
IATRIC PROBLEMS	Consult Doctor or Sister.	Check treatment, and assess individual case.

CONDITION	ACTION	NOTES FOR SISTER OR DOCTOR
NARY EMBOLISM	Consult Doctor or Sister.	Defer and obtain more information from donor's G.P. if necessary.
TIS/PYELONEPHRITIS	See 'Nephritis'	
IA OF UNKNOWN ORIGIN (P.U.O.)	Consult Sister or Doctor. NBTS.	Donors who have had P.U.O. during or after a visit to the tropics should be deferred for 3 months after the resolution of the pyrexia.
EVER ? NBTS.	Permanently unfit.	
Y Edin.	Defer for 4 weeks after recovery.	
IS IMMUNISATION : PRE-EXPOSURE Edin.	Consult Sister or Doctor.	Acceptable after 48 hours if donor feels well, or defer for 1 week if donor feels unwell. Hyperimmune donation may be possible up to 3 months after vaccination. Otherwise, for post-exposure, defer for 12 months after last injection.
: POST-EXPOSURE WHO.	Consult Dister or Doctor.	
. COLIC	Consult Doctor or Sister. NA Red Cross	Acceptable when symptom-free.
MATIC FEVER	Consult Doctor or Sister. International Policy.	May be acceptable. Doctor or Sister must assess donor or obtain details for further information from donor's G.P.
MATISM : ACUTE	Defer	
: CHRONIC (Mild)	Consult Doctor or Sister. International Policy.	Accept if donor feels well and is not taking regular tablets or other treatment.
: CHRONIC (Severe)	Defer	

WORM	Accept if mild, not affecting site of venepuncture, and not requiring treatment.	
LLA	Acceptable 1 month after recovery.	Hyperimmune donation may be taken up to 3 months following the onset of the illness.
LLA CONTACT	Acceptable if donor has had Rubella. Otherwise defer for 3 weeks.	
LLA IMMUNSATION	Defer for 3 months.	Do not take hyperimmune donation.
INGITIS	Consult Doctor or Sister.	Mild cases may be accepted 1 month after recovery.
OIDOSIS	Permanently unfit.	
-INFLICTED DRUGS	See 'Drug Abuse'.	
GLES (HERPES ZOSTER)	Consult Doctor or Sister.	Acceptable 2 weeks after donor feels fit. Hyperimmune donation may be given up to 3 months after the onset of illness.
GLES CONTACT	Acceptable	
SITIS : ACUTE : CHRONIC	Acceptable 4 weeks after recovery. Acceptable.	 Check treatment.
N DISEASES	See under specific disease, or consult Sister or Doctor.	As there are so many different skin diseases it is difficult to give specific directions. In general, the following points should be considered before deciding whether or not to accept a donor.

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CONDITION	ACTION	NO FOR SISTER OR DOCTOR
	Advice taken from French Canadian Red Cross criteria.	(1) If the skin disease is contagious, does it present a risk of infection to staff and other donors? (2) Does the skin disease affect the site of venepuncture? (3) Is the skin disease a manifestation of underlying illness? (4) Is the donor on treatment which might affect the blood donation?
PING SICKNESS	Consult Doctor or Sister.	Donors who have had Sleeping Sickness or who have lived in an endemic area accept as SERUM only. NBTS → ? Plasma only.
PING TABLETS Sdm. (WA Red Cross.)	Acceptable if taken as sleeping pills and for no other reason, i.e. no underlying condition that might render the donor unfit.	
LPOX IMMUNISATION NBTS.	Acceptable after 21 days.	Hyperimmune donation may be given up to 3 months after vaccination.
DYLOSIS (CERVICAL) Sdm -	Acceptable if donor is symptom-free.	
DYLITIS (ANKYLOSING) Sdm -	Consult Doctor or Sister.	Do not accept donors who have severe symptoms or who have had x-ray treatment.
:ILISATION Sdm.	Acceptable after next period.	

CONDITION	ACTION	NOTES FOR SISTER OR DOCTOR
DS : TABLETS Edin.	Consult Doctor or Sister.	In general, donors regularly taking steroid tablets are not accepted. Action depends on the underlying condition.
DS : CREAMS Edin.	Occasional use for minor dermatitis/eczema may be acceptable. Regular use over large areas of skin, defer.	
DS : INTRA-ARTICULAR INJECTIONS	Acceptable 1 week after injection. Check reason for injection.	WA Red cross
H ULCER	See Peptic Ulcer.	
Edin / NBTS.	Acceptable when healed or infection subsiding if donor feels well.	
LIS NBTS.	Permanently unfit.	
LIS CLOSE CONTACT	Do not accept.	
International	Acceptable after 6 months.	
JS IMMUNSATION : ACTIVE Edin.	Acceptable after 48 hours. If donor feels unwell after immunisation, defer for 1 week.	Hyperimmune donation may be given up to 3 months after immunisation.
US IMMUNISATION : PASSIVE (-globulin injection) Edin	Consult Doctor or Sister.	Acceptable after a minimum of 2 weeks.
H Edin	Acceptable once infection has cleared and not on treatment.	

CONDITION	ACTION	
IDS : TABLETS Edin.	Consult Doctor or Sister.	In general, donors regularly taking steroid tablets are not accepted. Action depends on the underlying condition.
IDS : CREAMS Edin.	Occasional use for minor dermatitis/eczema may be acceptable. Regular use over large areas of skin, defer.	
IDS : INTRA-ARTICULAR INJECTIONS.	Acceptable 1 week after injection. Check reason for injection.	WA Red cross
CH ULCER	See Peptic Ulcer.	
Edin / NBTS.	Acceptable when healed or infection subsiding if donor feels well.	
LLIS NBTS.	Permanently unfit.	
LLIS CLOSE CONTACT	Do not accept.	
International	Acceptable after 6 months.	
US IMMUNSATION : ACTIVE Edin.	Acceptable after 48 hours. If donor feels unwell after immunisation, defer for 1 week.	Hyperimmune donation may be given up to 3 months after immunisation.
US IMMUNISATION : PASSIVE (-globulin injection) Edin	Consult Doctor or Sister.	Acceptable after a minimum of 2 weeks.
H Edin	Acceptable once infection has cleared and not on treatment.	

CONDITION	ACTION	NOTES FOR DONOR OR DOCTOR
TRANQUILLISERS	See Valium.	
TROPICAL DISEASES NBTS.	Consult Doctor or Sister.	Donors who have been in Africa should be deferred for 12 weeks after returning: most tropical diseases do not prevent giving a donation. See Malaria, Sleeping Sickness.
TRYPANOSOMIASIS	See Sleeping Sickness.	
TUBERCULOSIS NBTS.	Consult Doctor or Sister.	Donors under treatment or regular surveillance should be deferred. Once clear of follow-up may be accepted. For B.C.G., Mear and Montoux tests see under respective entries.
TYPHOID IMMUNISATION Edin / NBTS.	Acceptable after 48 hours. If donor feels unwell defer for 1 week.	
ULCERATIVE COLITIS	See Colitis - chronic.	
VACCINATION	See under specific disease.	
VALIUM Edin w/ Red Cross (- general policy.)	Defer if taken as regular treatment. Acceptable if only an occasional tablet is taken. Consult Doctor or Sister if in doubt.	
VARICOSE VEINS OPERATION Edin.	Acceptable after 1 month, if no complications.	
VASECTOMY Edin.	Acceptable after 1 to 4 weeks, if no complications.	

CONDITION	ACTION	NOTE FOR SISTER OR DOCTOR
THROMBOSIS	See Phlebitis	
INFECTION (Unspecified) Edin.	Defer for 2 to 4 weeks after complete recovery.	
TABLETS : SELF MEDICATION Edin.	Acceptable if donor is well and free of symptoms.	
TABLETS : PRESCRIBED	Consult Sister or Doctor.	Defer and obtain further information from donor's G.P. if necessary.
INJECTIONS	Consult Sister or Doctor.	Defer and obtain further information from donor's G.P. if necessary
Edin.	Accept if not severe	
COUGH Edin.	Defer for 2 weeks after recovery.	
COUGH CONTACT	Acceptable.	
FEVER WA Red cross.	Acceptable 6 months after recovery	
FEVER IMMUNISATION NBTS.	Acceptable after 21 days.	

APPENDIX I

ONDITIONS RARELY ENCOUNTERED	ACTION	NOTES FOR SISTER OR DOCTOR
NTHRAX VACCINATION	Accept after 48 hours if donor feels well. Defer for 1 week if donor is unwell.	Can.
RTHROPOD-BORNE ENCEPHALITIDES	Acceptable after full recovery. See note on 'Tropical Diseases'.	NBTS '77
ILHARZIA	See Schistosomiasis.	
HAGAS' DISEASE	See Trypanosomiasis.	
OELIAC DISEASE	Permanently unfit.	Can.
ENGUE FEVER	Acceptable after full recovery.	NBTS (Canada - accept 3/12 after recovery.)
ILARIASIS	Acceptable after full recovery.	NBTS.
ERPES-GENITAL	Acceptable after recovery.	
YDATID DISEASE	Permanently unfit.	Canada
NGUINAL GRANULOMA	Permanently unfit.	Canada
ALA AZAR	Permanently unfit.	Canada.
ASSA FEVER	Acceptable after full recovery.	? NBTS.
EISHMANIASIS*		Canada suggests 3/12 after complete healing.
EPTOSPIROSIS	Acceptable 1 year after full recovery.	NBTS
ELAPSING FEVER	Acceptable 2 years after recovery.	NBTS
IFT VALLEY FEVER	Acceptable after full recovery.	NBTS
ANDFLY FEVER	Acceptable after full recovery.	NBTS
CHISTOSOMIASIS	Acceptable after full recovery.	WA Red Cross / NBTS
KIN CANCERS	Consult Sister or Doctor	MBB, WA Red Cross: Obtain details from donor's G.P. of diagnosis and treatment. Basal cell carcinoma of skin may not debar if it been adequately treated.
NAKE BITE	Acceptable after 3 months	WA Red Cross.
YPHOID FEVER		
EST NILE VIRUS FEVER	Acceptable after full recovery.	NBTS
AWS	Permanently unfit.	NBTS '83

APPENDIX II

MALARIAL COUNTRIES April 1982

Afghanistan
Algeria
Angola
Argentina
Bahrain
Bangladesh
Belize
Benin
Bhutan
Bolivia
Botswana
Brazil
Burma
Burundi
Cameroon
Cape Verde Islands
Central African Rep.
Chad
China
Colombia
Comoros
Congo
Costa Rica
Djibouti
Dominican Rep.
East Timor
Ecuador
Egypt
El Salvador
Equatorial Guinea
Ethiopia
Gabon
Gambia
Ghana
Guatemala
Guiana (French)
Guinea Bissau
Guyana
Haiti
Honduras
India
Indonesia
Iran
Iraq
Ivory Coast
Jordan
Kampuchea
Kenya
Korea (South)
Laos (Lao)
Liberia
Libya
Madagascar
Malawi
Malaysia
Madives
Mali
Mauritania
Mauritius
Mexico
Morocco
Mozambique
Namibia
Nepal
Nicaragua
Niger
Nigeria
Oman
Pakistan
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Qatar
Rwanda
Sao Tome and Principe
Saudi Arabia
Senegal
Sierra Leone
Singapore
Solomon Islands
Somalia
South Africa
Sri Lanca
Sudan
Surinam
Swaziland
Syria
Tanzania
Thailand
Togo
Tunisia
Turkey
Uganda
United Arab Republic
Upper Volta
Vanuatu (formerly New Hebrides)
Venezuela
Vietnam
Yemen Arab Rep. (North)
Yemen Democratic Rep. (South)
Zaire
Zambia
Zimbabwe

List Published by D.H.S.S., Leaflet SA35, 1982.

EDINBURGH / SOUTH-EAST SCOTLAND BLOOD TRANSFUSION SERVICE

NAME: _____

EALTH CHECK FOR NEW BLOOD DONORS

efore we can accept you as a blood donor we must make sure giving blood will do you no harm. We must also ensure the donation does no ontain anything harmful to the patient receiving it, e.g. medicines or viruses.

LEASE ANSWER THESE QUESTIONS BY RINGING YES OR NO AS APPROPRIATE. It will save you TIME when you are interviewed and have your aemoglobin checked to make sure that you are not anaemic.

A. GENERAL QUESTIONS

Have you ever given blood before? .. .. YES NO
Have you ever been rejected as a blood donor? .. .. YES NO
Are you under 18 or over 65 years of age? .. .. .. YES NO
Are you under 8 stones in weight? .. .. YES NO

B. SCREEN FOR GENERAL MEDICAL HEALTH

Have you been unwell recently?.. .. .. YES NO
Have you visited your doctor recently?.. .. .. .. YES NO
Have you ever had a serious illness or operation? .. YES NO
Do you suffer from chest pains?. .. .. YES NO
Do you have a persistent cough?. .. .. YES NO
Are you breathless on slight exertion?.. .. .. .. YES NO
Do you have any kidney trouble?. .. .. YES NO
Do you have diabetes? .. .. YES NO
Do you have asthma or any allergies? .. .. YES NO
Do you have fits or fainting spells? .. .. YES NO
Have you lost weight recently (not dieting)? .. .. YES NO
Do you take medicine or tablets? .. .. YES NO

Ladies:

Are you pregnant or do you have a child under 1 year?. .. .. YES NO

C. SCREEN FOR INFECTION

Have you been to the dentist in the last 72 hours? .. YES NO
Have you been in contact with any infectious diseases in the last three weeks?. .. .. YES NO
Have you received any vaccinations or injections in the last three months?. .. .. YES NO
Have you had malaria?. .. .. YES NO
Have you been abroad in the past three months? .. .. YES NO
Have you had jaundice or Hepatitis in the past twelve months? .. .. YES NO

D. SCREEN FOR HEPATITIS CONTACT - In the past six months have you:

Been exposed to, or lived in the same house as a hepatitis patient?.. .. .. YES NO
Had your ears pierced? .. .. YES NO
Received acupuncture?. .. .. YES NO
Been tattooed? .. .. YES NO

E. SAFETY FOR YOU AND OTHERS

Do you drive public service vehicles?. .. .. YES NO
Are you involved in unusual hazards of heights or depths? .. .. YES NO

Date: _____ Signature: _____

APPENDIX C

Post-Thaw Storage of Frozen Red Cells

The accepted criteria for optimal red cell storage are that the product is sterile and that more than 70% of red cells survive in a recipient 24 hours after transfusion.

For frozen red cells stored 5 days at 4 C in ACD-saline we have published data showing 88% survival of autologous red cells 24 hours after transfusion into normal volunteers (Amer, K.A., Pepper, D.S., Prowse, C.V. Brit. J. Haemat; 1980, 44 635-644). The biochemical characterisation of such cells is acceptable and we routinely check all units that outdate (5d) to provide ongoing assurance that this continues. For example the following represent data from 100 units after 5d storage.

pH	Supernarant K^+	Osmolarity	Supernatant Haemoglobin	Haematocrit
6.36 ± 0.13	14.0 ± 4.3mM	308±37mOsM	331 ± 133 mg%	47 ± 4%

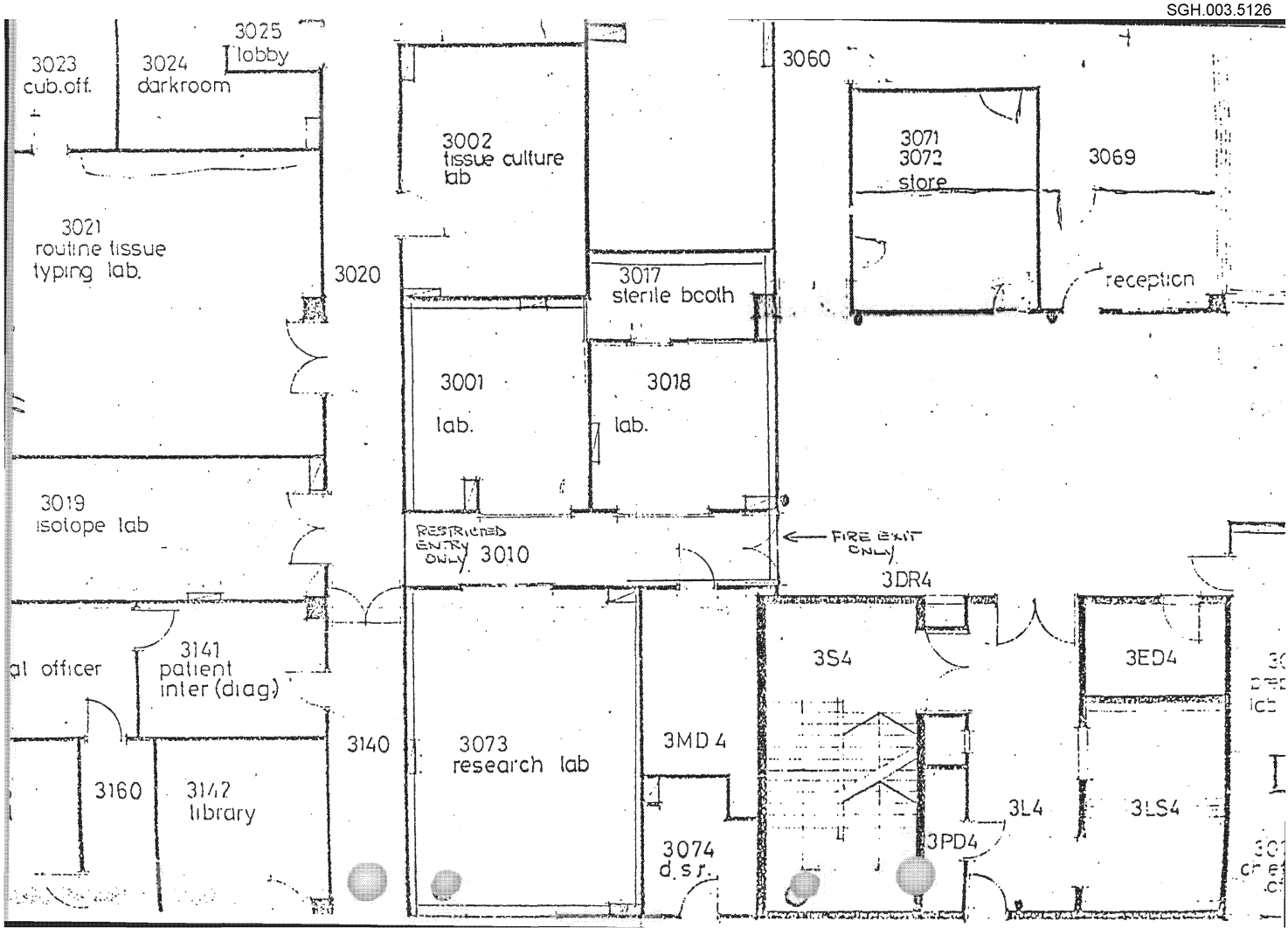
In addition every outdated unit is cultured under aerobic and anaerobic conditions to check sterility. Of 2,843 units tested only 2 (0.07%) have been confirmed as containing any bacterial contamination. This is less than we have observed in units of whole blood (0.5%) prepared in a closed system and is good evidence that no additional risk of contamination exists for units of red cells that have been frozen, thawed and stored for 5 days using the procedures established at this centre. During the same period 5,026 units of frozen-thawed cells were transfused without effect.

APPENDIX D

Planned modification to access to hepatitis testing laboratories.

APPENDIX E

Present and planned layout of blood bank, compatibility testing and issue area.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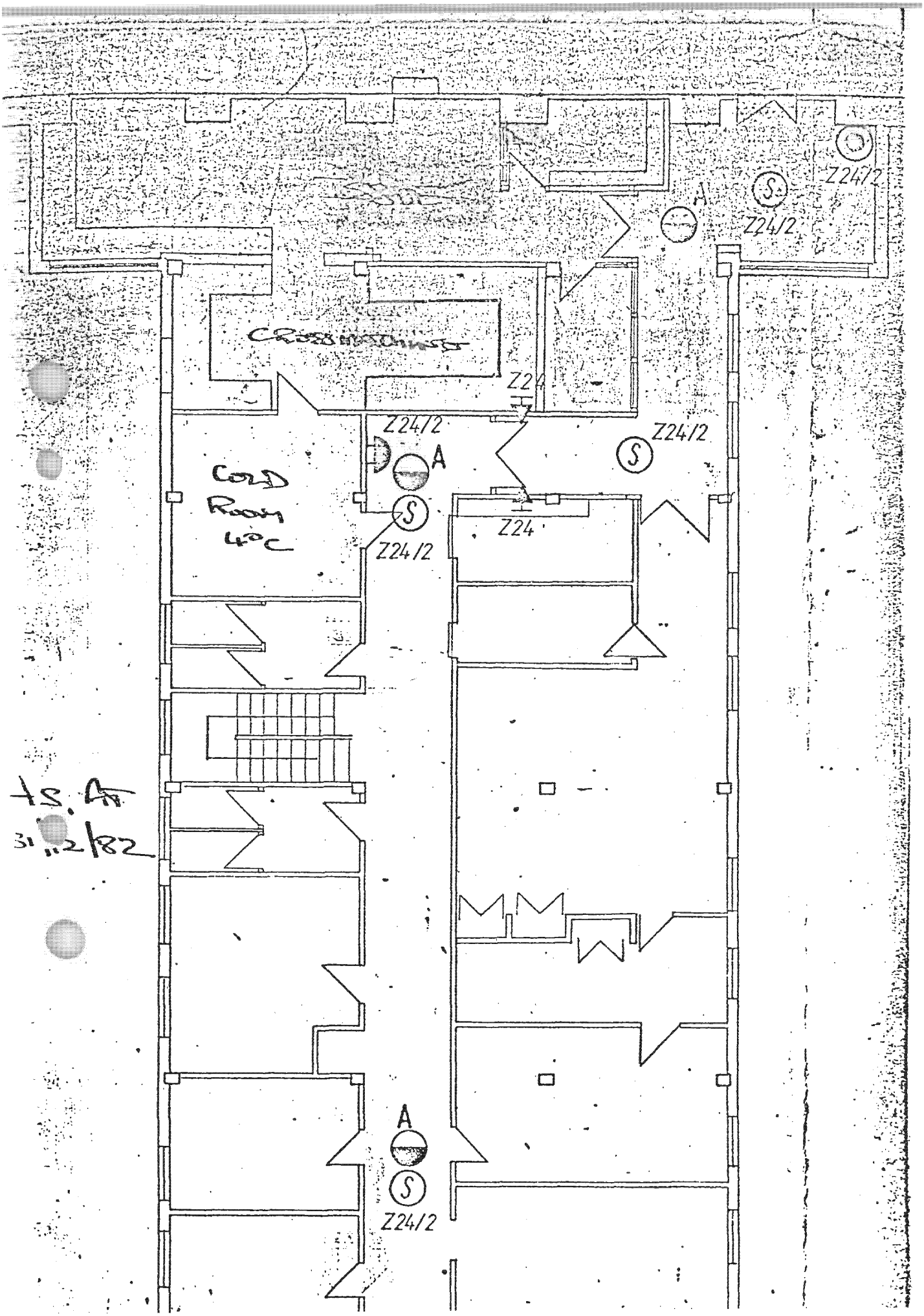
lobby
3023
cub.off.
3024
darkroom
3060
3002
tissue culture
lab
3071
3072
store
3069
3021
routine tissue
typing lab.
3020
3017
sterile booth
reception
3001
lab.
3018
lab.
3019
isotope lab
RESTRICTED
ENTRY
ONLY
3010
FIRE EXIT
ONLY
3DR4
al officer
3141
patient
inter (diag)
3S4
3ED4
3140
3073
research lab
3MD 4
3160
3142
library
3L4
3LS4
3074
d.s.r.
3PD4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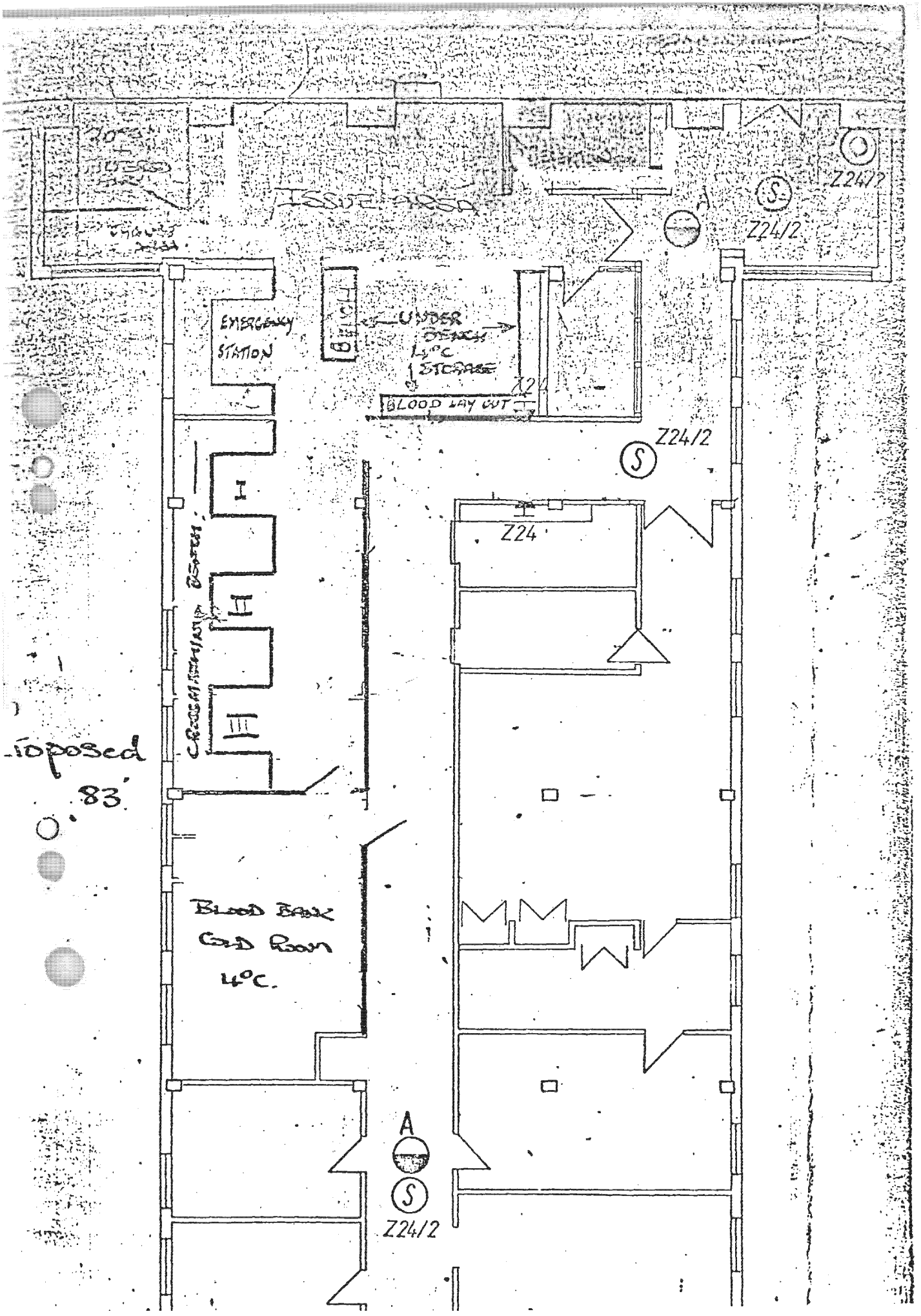
Cold Room 4°C
Z24/2
A
S
Z24/2


ISSUE AREA
Z24/2
EMERGENCY STATION
UNDER BENCH 4°C STORAGE
BLOOD LAY OUT
Z24
I
II
III
Blood Bank Cold Room 4°C
A
Z24/2

APPENDIX F

Sterility of Blood Components Prepared in the Pigtail System

The approach in Edinburgh to assure the safety of blood components prepared in pigtail packs under laminar air flow conditions has been to culture units at outdate (cellular components) or at the time of preparation (frozen plasma components) and to compare the results to those obtained for whole blood (prepared in a closed system) using the same procedures.

Results may be divided into those obtained for cellular components which do not pass through the pigtail connection (upstream) and those for plasma components prepared by pooling of plasma from more than one donation through the pigtail connection (downstream).

Units Confirmed to Contain Bacteria

	Pilot Studies	Routine Quality Assurance
Closed System		
Whole Blood	0.46% (5/1076)	0% (0/319)
Pigtail System (Upstream)		
Red Cell Concentrate	0.56% (6/1075)	0% (0/330)
Platelet Concentrate	0.3% (2/656)	0.67% (2/297)
Pigtail System (downstream)		
Thaw-siphon cryoprecipitate	(3 donor) - 0% (0/94)	0/94 <1 org/ml
Fresh frozen plasma	(2 donor) - 529/530	<1 org/ml
Bulk frozen plasma	(24 donor) - 5/191	>1 org/ml

Appendix F - Continued

Study of Microbial Contamination of Bulk Plasma Received by PFC

Data from Cuthbertson, B., 1932.

Bacterial cultures were made of core-samples of frozen plasma and pooled samples of thawed plasma. Tris extracts of thawed cryoprecipitate were also cultured.

Table I compared core samples of Edinburgh 5 litre plasma packs with earlier data from NBTS 2 li plasma packs and SNBTS packs which were not analysed by centre of origin.

Table II shows post thaw data on (i) all material recieved (ii) Glasgow plasma only (iii) batches comprised of Edinburgh & Glasgow plasma.

The conclusions of Mr P R Foster (PFC) and Mr Cuthbertson (PFC) are as follows: (i) contamination levels are better in Edinburgh 5 li pools and Glasgow "stripped single" pools than in the conventional single pack plasma (ii) contamination in thawed plasma is mainly introduced at the time of stripping the plastic from frozen plasma at the PFC.

TABLE 1

PLASMA CORE DATA

		Sample Source		
		EDINBURGH 5L	ALL SNBTS	ENGLISH 2L
1.	ALL DATA			
	a. Number tested	52	264	48
	b. Proportion <1CFU/ml	86.5%	81.8%	72.9%
	c. Range	0 - 88	0 - 429	0 - 21
	d. Mean	2.8	3.1	1.4
	e. Standard deviation	13.6	29.4	3.9
2.	DATA WITH COUNTS OF 25 OR ABOVE EXCLUDED			
	a. Number	50	262	
	b. Range	0 - 7	0 - 22	
	c. Mean	0.26	0.70	
	d. Standard deviation	1.1	3.0	

TABLE 2

POOL DATA (OCTOBER, 1981 - OCTOBER, 1982)

		Plasma Source	
	All Batches	Glasgow Only	Glasgow and Edinburgh
A. PRE-CENTRIFUGE			
Number of pools	72	21	10
Mean colony count	278	166	138*
Standard deviation	562	361	200
B. TRIS EXTRACT			
Number of pools	79	21	10
Mean Colony Count	3730	2955*	2402*
Standard Deviation	5216	2889	2024
Number >20,000	7	2	0

* Significance : $p < 0.10$ vs "all batches".

Appendix G

The Development of a Rational Blood Ordering Policy for Obstetrics and Gynaecology

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Summary

The relationship between quantities of blood ordered and quantities actually used for obstetrical and gynaecological diagnoses in one Scottish hospital was studied over a period of three months. It appeared that the amount of blood ordered as "cover" for many operative procedures and for patients under observation was, in many instances, uneconomically high. On the basis of this a "Maximum Surgical Blood Ordering Schedule" (MSBOS) has been proposed which would reduce the amount of blood crossmatched as "cover" by 65 per cent. Review of the circumstances of all transfusions given over the study period suggested that adoption of the proposed MSBOS would not be detrimental to patient safety.

Introduction

It is established practice in Obstetrics and Gynaecology, as in all surgical specialties, to request the crossmatching of blood to provide "cover" for major operative procedures (eg Caesarian section, hysterectomy) and for patients under observation with such diagnoses as placenta praevia or suspected ectopic pregnancy. It has been observed (Rauault and Gruenhagen, 1978) that the ordering of blood in such circumstances is often dictated only by habit and may be wasteful of personnel time, reagents and outdated units of blood.

Careful appraisal of the transfusion requirements for each procedure or diagnosis allows a "Maximum Surgical Blood Ordering Schedule" (MSBOS) to be drawn up which minimises unnecessary crossmatching. Such schedules for common surgical (including gynaecological) procedures have been proposed by several groups (Friedman et al, 1976; Rauault and Gruenhagen, 1978; Friedman, 1979) and all include a "Group and Screen" (G & S) procedure as an alternative to the crossmatching of blood for those diagnoses where the probability of transfusion is low. A G & S procedure such as that described by Boral and Henry (1976) is sensitive to more than 96 per cent of the antibodies which may occur in human sera and is calculated to be 99.9 per cent effective in preventing the selection of incompatible blood for transfusion.

The aims of the study described here were to present a "profile" of blood ordering and usage practices in the obstetrics and gynaecology unit of one Edinburgh hospital which is served by a full blood transfusion service located within the same building; to identify those diagnoses for which existing ordering practices seem excessive; to propose a MSBOS based on these findings and to illustrate, by review of the actual transfusions given over the study period, the lack of risk involved in implementing a system of this type.

Methods

All requests for compatibility testing (either crossmatching or G & S) originating in the obstetrical and gynaecological wards of the Simpson Memorial Maternity Pavilion and the Royal Infirmary of Edinburgh during the months of September, 1980, January 1981 and February 1981 were studied. These particular months were chosen in order to cover the tenure of three separate cohorts of junior medical staff and so minimise the effects of any idiosyncratic ordering practice. The indications for, circumstances of and outcome of each request were processed and analysed using the SPSS system of computer programmes on an ICL 2972 computer. The occurrence of a blood transfusion was deduced from failure of issued blood to be returned to the Blood Transfusion Centre and was confirmed by reference to the case records. The circumstances of each transfusion, with particular reference to the degree of urgency involved, were reviewed by one of us (GCP) by study of the case notes, operation notes and anaesthetic charts, as appropriate.

The proposed MSBOS was based on the recommendations of Mintz et al (1976) that a G & S provides adequate cover for procedures averaging less than 0.5 units of blood transfused per case and of Friedman (1979) that the recommended blood order for a procedure should provide for the transfusion needs of 90 per cent of cases.

Most of the diagnostic categories mentioned below are self-explanatory but it should be noted that the high risk labour category encompasses such conditions as previous Caesarian section, breech presentation, twins and prolonged labour. Also, patients undergoing Caesarian section because of known placenta praevia or abruption have been classified as ante partum haemorrhage rather than Caesarian section.

Results

Current Ordering and Usage Practice

During the three months of the study, 961 requests for compatibility testing were submitted. These related to only 871 patients as some clinical problems gave rise to multiple requests. Obstetrical problems accounted for 589 (61%) of the requests and gynaecological ones for 372 (39%). Details of all requests and of the use of the G & S facility, by month, are shown in Table I. Clearly, differences in junior medical staff had little influence on the overall pattern of ordering.

Of the 961 requests, 409 (43%) were for G & S rather than for crossmatching. Over half of the G & S requests were to provide "cover" for cases of spontaneous abortion. The only elective, operative procedure for which G & S was regularly used as the form of "cover" was termination of pregnancy. In only 14 of the G & S cases was a subsequent request for conversion to crossmatching submitted; in only six of these cases was blood actually transfused.

In all, 566 requests for crossmatching were submitted (552 plus 14 "conversions" from G & S). In response to these requests, 1402 units of blood were crossmatched. (In accordance with local blood issue policy, 89% of these were red cell concentrate as opposed to whole blood).* A <u>specific</u> need for blood transfusion (eg abruption, anaemia due to menorrhagia) prompted 63 of these requests. The remaining 503 requests (89%) were to provide "cover" for operations or diagnoses with a <u>potential</u> transfusion requirement. The provision of blood as "cover" accounted for 1213 of the total of 1402 units of blood crossmatched, 86% of the total workload.

/..

* Locally prepared "whole blood" comprises 450 mls of blood and 63 mls of anticoagulant and has a haematocrit of 38%. In contrast, red cell

Overall, 246 units of blood were transfused to 84 patients. Table II summarises the transfusion requirements for each diagnostic category in terms of the percentage of cases requiring transfusion and the average number of units of blood transfused. For many common, operative procedures (eg pelvic floor repair, Caesarian section, manual removal of placenta) less than 10 per cent of cases required transfusion and, on average, less than 0.5 units of blood were transfused per case (averaged over all patients undergoing the procedure; no transfused case actually received less than two units.

The alignment between blood ordered and blood used by a clinical practice of for an individual diagnosis can be assessed by consideration of the ratio between the number of units of blood crossmatched and the number actually used, the crossmatched : transfused (C:T) ratio. Rauault and Gruenhagen (1978) feel that a realistic level of this ratio for a hospital with a full range of clinical services is around 2.5:1. The overall C:T ratio for the Obstetrics and Gynaecology practice studied was 5.7:1 (1402 units crossmatched : 246 units transfused).

Study of the C:T ratios for individual diagnoses (Table III) highlights those for which ordering was particularly high compared with actual transfusion needs. Every operative procedure except termination of pregnancy was associated with a C:T ratio of greater than 2.5:1 and for five diagnoses the overall C:T ratio was greater than 10:1.

Proposed MSBOS

The maximum blood orders recommended in major studies for common operative procedures presently "covered" in this centre by crossmatching are shown in Table IV. The table also shows the transfusion rates/...

rates for the various procedures found in the present study and in the most recent of the large American studies (Friedman, 1979). For all procedures except vaginal hysterectomy, the local transfusion rates are comparable with those in Friedman's series and it therefore seemed reasonable to adopt his recommendations. The complete MSBOS, based on local transfusion data and on recommendations of the literature is presented in Table V.

Review of Transfusions

During the study period, 84 patients were transfused of which 39 (46%) received only blood crossmatched because of a specific transfusion requirement. The remaining 45 cases received blood which had been crossmatched as "cover". In these cases the availability of blood might have been reduced had the proposed MSBOS been operational and they are considered further. In 18 of the 45 cases, it was considered at the time of the case-note review that transfusion was required within minutes of the onset of the bleeding problem. The circumstances of these, the most urgent transfusions, and the anticipated outcome of each had the proposed MSBOS been operational are presented in Table VI. In 13 of the 18 cases, crossmatched blood would, in fact, have been available as "cover" under the MSBOS, in three cases it was considered that the degree of urgency was such that an emergency crossmatch could have been awaited and in only two cases did it seem that the transfusion of homologous, uncrossmatched blood would have been required.

this would represent a saving of some 3,000 crossmatches, around 65% of the "cover" crossmatching for obstetrics and gynaecology and around 55% of the total crossmatching workload for the specialty.

Review of the circumstances of the actual transfusions given during the study period was reassuring. Only two patients (2.4 per cent of the transfused patients and 0.23 per cent of all patients in the study) might have required transfusion with homologous, uncrossmatched blood under the proposed MSBOS. Since it has been shown (Boral and Henry, 1977) that the transfusion of homologous blood after a recipient's serum has been checked for unusual antibodies by a G & S is 99.9% safe, it is, perhaps time for a reappraisal of the view that a crossmatch is the only acceptable form of compatibility test.

Bear and Friedman (1977) have suggested that the most appropriate method for developing a MSBOS at the hospital level is to examine actual, blood transfusion requirements for that hospital's more common operations and to use these data, in conjunction with those in published studies, to arrive at a safe and equitable schedule which will decrease unnecessary crossmatching without jeopardizing patient welfare. We have attempted to do just that in the study presented here and would encourage clinicians in other centres to review their own practices and to collaborate with local transfusion services in ensuring optimal utilisation of donated blood, a unique therapeutic resource.

Acknowledgements

We would like to thank the South Lothian Division of Obstetrics and Gynaecology for allowing us to undertake this study. We would also like to thank the clerical and secretarial staff of the Simpson Memorial Maternity Pavilion and the technical staff of the Blood Transfusion Service for their co-operation in the locating of case records and in data collection. Thanks are also due to Dr D B L McClelland for helpful discussions and for reviewing the manuscript.

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Table I

Total Number of Requests for Compatibility Testing (Crossmatching plus G & S) and Number of Requests for G & S Only Submitted During Each of the Three Months of the Study

MONTH	JAN	FEB	SEP	TOTAL
Total No. Requests	322	339	300	961
No. G & S Requests	151	140	118	409
G & S as % of Total	47	41	39	43

Table II

Overall Transfusion Rates for O & G Operations and Clinical Problems

DIAGNOSIS	NO. CASES	NO. AND (%) TRANSFUSED	TOTAL UNITS TRANSFUSED	AVERAGE UNITS/CASE
[illegible] risk labour	67	0 (0)	0	0
[illegible]taneous abortion	213	2 (0.94)	4	0.019
Pelvic floor repair	47	1 (2.1)	6	0.13
[illegible]nation of pregnancy	59	2 (3.4)	9	0.15
Ectopic and ? Ectopic	52	4 (7.7)	9	0.17
Manual removal of placenta	26	2 (7.7)	5	0.19
Lower segment Caesarian section	107	10 (9.3)	22	0.20
Ante partum haemorrhage	50	5 (10)	19	0.38
Laparotomy	44	6 (13.6)	21	0.48
Abdominal hysterectomy	79	14 (17.7)	41	0.52
Post partum haemorrhage	34	9 (26.5)	22	0.65
Vaginal hysterectomy	9	3 (33.3)	8	0.89
Misc obstetrics	29	2 (6.9)	5	0.17
Misc gynaecology	39	9 (23.1)	30	0.77
Men[illegible]agia	8	7 (87.5)	22	2.75
Anaemia	8	8 (100)	23	2.9
TOTALS	871	84	246	

Diagnoses for which a MSBOS recommendation would seem appropriate are shown above the single line.

Diagnoses for which 10% of patients required transfusion and for which the transfusion rate was 0.5 units/case are shown above the double line.

Table III

Overall C/T Ratios for O & G Operations and Clinical Problems

DIAGNOSIS	NO CASES	C NO UNITS X-MATCHED	T NO UNITS TRANSFUSED	C/T
High risk labour	67	92	0	∝
Pelvic floor repair	47	102	6	17
Manual removal of placenta	26	63	5	12.6
Ectopic and ? Ectopic	52	108	9	12
Lower segment Caesarian section	107	250	22	11.4
Ante partum haemorrhage	50	137	19	7.2
Laparotomy	44	129	21	6.1
Spontaneous abortion	213	23	4	5.7
Abdominal hysterectomy	79	220	41	5.4
Vaginal hysterectomy	9	27	8	3.4
Post partum haemorrhage	34	38	22	1.7
Termination of pregnancy	59	12	9	1.3
Mis obstetrics	29	37	5	7.4
Misc gynaecology	39	112	30	3.7
Menorrhagia	8	29	22	1.3
Anaemia	8	23	23	1
TOTALS	871	1402	246	5.7

Diagnoses for which a MSBOS recommendation would seem appropriate are shown above the single line.

Diagnoses for which the present C/T ratio is 10:1 are shown above [illegible]

Table IV

Transfusion Rates and Recommended Maximum Blood Orders for Common O & G Operative Procedures Presently "Covered" by Crossmatching

	PRESENT STUDY			FRIEDMAN, 1979				FRIEDMAN ET AL, 1976	RAUAULT AND GRUENHAGEN, 1978
Procedure	No of Cases	% Trans	Average Units/Case	No of Cases	% Trans	Units/ Case	MSBO	MSBO	MSBO
Abdominal Hysterectomy	79	17.7	0.52	3,073	12.4	0.3	1 or GS&S	2	GS&S
Vaginal Hysterectomy	9	33.3	0.89	2,691	7.4	0.1	GS&S	1	GS&S
Pelvic Floor Repair	43	2.3	0.14	1,962	2.8	0.04	GS&S	GS&S	GS&S
Lower Segment Caesarian Section	107	9.3	0.2	8,931	8.5	0.2	GS&S	1-2	GS&S
Manual Removal of Placenta	26	7.7	0.19	-	-	-	-	1	-

Table V

Proposed MSBOS for O & G

OBSTETRICS

2 Units of Blood X-Matched

1. Caesarian Section or EUA for known or suspected placenta praevia or after trial of forceps.
2. Active ante or post partum haemorrhage.
3. Twin deliveries (abdominal or vaginal).
4. (Any form of shock or anaemia requiring transfusion).

G & S

1. Uncomplicated Caesarian Sections.
2. Manual removal of placenta.
3. High risk labour, eg Breech, foetal distress etc.
4. Spontaneous abortion.
5. Termination of pregnancy.
6. Small ante partum haemorrhage including placenta praevia under observation.

GYNAECOLOGY

2 Units of Blood X-Matched

1. Cancer surgery.
2. Ectopic pregnancy for operation.
3. Vaginal hysterectomy.
4. Myomectomy.
5. (Any form of shock of anaemia requiring transfusion)

1 Unit X-Matched

1. Abdominal hysterectomy for benign conditions.

G & S

1. Pelvic floor repair (including Marshall Marchettie procedures).
2. Spontaneous abortion.
3. Termination of pregnancy.
4. Suspected ectopic under observation.
5. Laparotomy for minor, benign conditions, eg ovarian cyst.

NB - Procedures such as sterilisation and dilation and curettage for which no compatibility procedure is presently undertaken are excluded, as no change of practice is indicated.