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Glasgow and West of Scotland Blood Transfusion Service
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1. INTRODUCTION

Glasgow and West of Scotland BTS serves a population of approximately three million and has its Regional Headquarters and Laboratories at Law Hospital in Carluke. (The Regional Donor Centre is at St Vincent Street in Glasgow.) The Carluke building was erected in 1956. Approximately 150,000 donations are collected annually and around 140 staff are employed at the Centre, which was last inspected in July 1986. Since then, a new sterile suite has been commissioned and brought into use.

2. SCOPE

The inspection covered the manufacture and control of the products listed in Section 4. Clinical matters, eg clinical apheresis, tissue typing and testing relating to patients, were not included. On this occasion, a visit was not made to the Regional Donor Centre in Glasgow.

3. SENIOR STAFF LIST

Dr R Mitchell	Director
Dr D Hopkins	Consultant in Transfusion Medicine
Dr R Crawford	Consultant in Transfusion Medicine
Dr G Gabra	Consultant in Transfusion Medicine
Dr M Inskip	Consultant in Transfusion Medicine
Dr M Peterkin	Senior Registrar
Mr M Muir	Principal MLSO
Mr A Barr	Senior Chief MLSO, Microbiology, Plasma Processing and Cryogenics
Mr R Sheridan	Senior Chief MLSO, Donor Grouping
Mr K Leitch	Senior Chief MLSO, Blood Group Serology and Immunology

4. LIST OF MEDICINAL PRODUCTS

Product	Produced and placed at issue 1 April 1987 - 31 March 1988
Whole blood	1584
Red cell concentrates	118108
Washed red cells	170
Filtered red cells	3
Frozen red cells	206
Platelet concentrates	27769
Platelet concentrates (pheresis donors)	121
Buffy coats	165
Cryoprecipitate	12314
FFP, clinical units (60ml)	843
FFP, clinical units (200ml)	8167
FFP, 8 hour, for fractionation at PFC (kg)	16897.9
FFP, 18 hour, for fractionation at PFC (kg)	4816.8
Time-expired plasma for PFC (non-fresh plasma)(kg)	1904.9
Cryosupernatant for PFC (kg)	3124.8
Hyperimmune plasma for PFC (kg)	532.2

5. INSPECTION

5.1 Blood Collection and Receipt

Visits were made to two mobile donor sessions in Paisley, one in the Town Hall and one in the BTS blood collection bus. Procedures at both sessions are essentially the same except that conditions on the bus are considerably more cramped and the proportion of "walk-in" donors is much higher for the bus.

No donor records are available at sessions. When a donor presents, the Reception Clerk fills out a "K Form" (registration form) with details provided by the donor, either verbally or from their personal donation record cards. Any queries at this point are referred to the MO and/or the Sister. Donors are then given a haemoglobin check using the copper sulphate method, the limit of acceptance being 125g/litre for all donors. If a donor fails the copper sulphate test, then a repeat test is performed using a manual haemoglobinometer (American Optical). If donors fail this test, they are not bled for a donation but a further small venous sample is taken for haemoglobin quantitation back at the laboratory. (These samples also serve as controls for the machines.)

A set of eight bar-code numbers is issued for each accepted donor, and this is stapled to the back of the K Form. The labels are only attached to the bags when venepuncture is completed and blood collection has started. Two Vacutainer sample tubes (one anticoagulated, one dry) are also given bar-code labels and attached to the bags with elastic bands. One per cent Lignocaine without adrenaline is routinely used in donors, ten syringes at a time being pre-filled and held available. The batch number of the Lignocaine is recorded back at the Donor Centre.

At the end of collection, the Vacutainer tubes are filled. The dry tube is filled first with blood from the pig-tail, then the anticoagulated tube is filled, via the pigtail, with blood from the bag. This procedure obviates the need for stripping the packs. The pigtail is then clip-sealed at the pack-end and segmented by heat-sealing. Should a sample tube be dropped and broken while connected to the pack (and before it has been sealed off) the pack is marked "contaminated", and this is also recorded on the K Form and the Donor Record Sheet, which is a sheet on which the details of all the donations at the session are manually recorded.

Periodically, crates of donations are removed and put into a refrigerated van for storage prior to transportation back to the BTS. (Blood for platelet preparation is not refrigerated.) The van temperature (nominally 4°C) is digitally displayed in the cab. Drivers are instructed to check and record the temperature at regular intervals. At the time of inspection (4pm), the van refrigeration was not switched on but the temperature record had been completed in advance, 4°C being recorded for 6pm. (Apparently, temperature chart recorders used to be fitted to the vans but had recently been removed.)

New donor attendants receive a four weeks' training course at the Donor Centre, followed by training at sessions with a Senior Team Leader. A visit to the Carluke Centre also forms part of the training process. There is a Training Manual but this was being revised at the time of inspection to take account of altered procedures.

5.2 Blood Products

The main centrifuging laboratory is equipped with 10 IEC DPR-6000 centrifuges and two IEC 6000 B machines. All these machines are water-cooled, so air-conditioning of the laboratory has not been considered necessary. However, at the time of inspection, the door was jammed open.

The main laboratory, where closed processing takes place, in general is rather cluttered, the bench tops being covered with old record sheets and cardboard boxes containing more record sheets are stacked under the benches. At the time of inspection, a window to the outside was open. In one corner of the laboratory there is a sink which, at the time of inspection contained a quantity of burst plasma packs and blood bags. Such packs are put in this sink where they remain for some days until the microbiology results on the donations are available, when they are discarded either by emptying the contents down the sink or by disposal via the Microbiology department. However, there is no record kept of the disposal nor a signature of the person responsible. There is a log book for recording the sink-contents but this is inadequately completed. One pack in the sink was not listed in the log book.

An adjacent room houses a liquid nitrogen blast-freezer; for staff safety reasons, the main door to this room is open to the outside, only being covered by a coarse wire grating. As a consequence, when the door between the processing laboratory and the blast-freezer room is opened, gusts of wind carrying leaves, dust and other debris blow through the laboratory.

Blood donations are brought back to the Blood Products department from the session, together with the K Forms and the Donor Record Sheets, which carry the donors' names and the donation numbers (applied manually with an ink-stamp). This information is transferred (again using a manual ink-stamp) to a Plasma Processing Work Sheet. This is subsequently filled in with the products made from each donation, checked against the actual donation numbers on the packs. Worksheets for platelet testing are photocopied, stamped as platelet release sheets and sent to Microbiology, the original going to Donor Grouping. All results come back to Blood Products.

Quarantined platelets are stored at 22°C in a Helmer Platelet Shaker in the processing laboratory. When the platelets are cleared for issue, group labels are stuck onto the packs and these labels are then checked by eye against a printed list. Unlike red cell preparations, there is no facility for a computer verification that the correct group label has been applied to platelet packs. When platelets are pooled and issued, this is recorded in the Platelet Issues Book. Staff are supposed to record the time of pooling and by whom it was done but there is little space in the book to record this information and it is often omitted.

There is a full set of SOPs for production procedures available in the processing laboratory but none for cleaning procedures. Centrifuge buckets and bowls are cleaned weekly with Vantrolpol FH bactericidal detergent but there is no environmental monitoring to demonstrate the effectiveness of this or other cleaning procedures in the area.

Open processing is performed in the sterile suite. The main activity is the pooling of platelets, with between 10 and 20 pools of (usually) five concentrates being pooled daily. The other, much less frequent, uses of the sterile suite are freezing and washing red cells by the Cryogenics department.

The sterile suite consists of two Class 100 rooms off a common change and entrance area. Each room is supplied with terminally HEPA-filtered air and is equipped with laminar air-flow cabinets. The suite is on a positive pressure cascade from the sterile rooms to the change room to the corridor. The HEPA-filters are not alarmed but are checked (including DOP-testing) on a six-monthly basis by outside contractors (Crowthorne). The differential air-presssures are monitored and recorded daily. Preparation rooms adjacent to the clean rooms have interlocked pass-throughs.

Staff entering the clean rooms put on full, sterilised clean room clothes but the gloves currently in use are powdered. A Malvern Laser Particle Counter has recently been acquired and is being used occasionally to monitor the air-quality when the rooms are in use. A slit sampler is normally used to monitor the environment of the empty rooms on a weekly basis but at the time of inspection it was under repair. Settle-plates are used routinely in all open procedures.

The department is equipped with a Dent and Hellyer autoclave which is used to sterilise the clean room clothing, donor session equipment and laboratory reagents and equipment. The clean-room garments are washed and dried on the premises and are prepared for autoclaving in the autoclave room, although there are plan to install a small LAF cabinet next to the washing machine for this purpose.

The autoclave has two cycles, the porous load cycle being 134°C for four minutes and the fluid cycle consisting of 25 pulses followed by 121°C for 15 minutes. The machine has a controller probe in the drain and a recording probe in the centre of the chamber. The run records are not checked and signed as indicating a successful cycle after each run.

Vacuum leak tests are performed weekly by BTS engineers but Bowie-Dick tests are not carried out. The machine was commissioned in 1981 and has never been validated since. An attempt at revalidation by a CSA engineer in 1986 failed due, it was said, to the steam supply being wet. Sterilising runs and maintenance works are supposed to be recorded in the autoclave log-book but many entries are missing.

5.3 Donor Grouping

Donor Grouping is carried out in a large, open-plan laboratory in which all the BTS serology work is performed. It is equipped with two Technicon Autogroupers.

Samples from the previous day's donor session are brought from the reception cold-room overnight by a laboratory assistant and put in the fridge in the Grouping laboratory. The K Forms and Donor Record Sheets are brought from Blood Products and left on the clerical area bench in the laboratory. If the previous grouping history has been written onto the K Forms at the session, this is now re-written on a different position on the form and any remarks on the K Form are transferred to the Donor Bleed Sheets.

Samples are checked (first and last numbers and total count) against the Plasma Processing Work Sheet (from Blood Products), un-stoppered in a safety cabinet, centrifuged and loaded onto the Autogrouper in numerical order. VDRL testing for syphilis is done on the Autogroupers and the results are included with the grouping results.

A list of new donors is generated in the computer room and delivered to the Grouping Laboratory. After the corresponding samples have been machine-grouped once, they are picked out and are manually grouped. The results are then compared by a single person, the comparison not being double-checked.

The Autogroupers do not have the facility of directly comparing grouping results with the donors' previous history. Known donors are machine-grouped once and the results are compared by eye with the previous grouping history as written on the K Forms at the session. However, in many cases, the previous history is not known at the session and so is not entered on the K Form. As the donor records are held at the Donor Centre in Glasgow, the comparison of new results with previous history does not take place in such cases until the K Forms reach St Vincent Street, often some days later. This arrangement gives rise to the possibility that if, for example, sample tubes are mixed up at the session or if the Autogrouper makes an error, such events would not be picked up before products are issued.

In fact, examples of both types of error have occurred within the previous two years. In one case, a donor was grouped erroneously by the machine as A Rh-positive, whilst his previous 15 donations had been grouped as A Rh-negative. The donor records showing up the mistake were not checked until ten days later, by which time the donations had gone through the system.

The Autogroupers print out their results onto hard-copy in addition to a disc. If the machine gives no result, then the sample is put through again. If there is still no result, the sample is manually grouped. The hard copy is then compared with the K Forms for previous history. One person calls out the donation number and grouping result and a second person enters the group on the Donor Record Sheet. They then change over, the second person calling out the numbers and groups and the first person entering the group on the K Forms. The Donor Record Sheets and the K Forms are then compared to ensure correct transcription. A hold-list of blood which is not to be issued is compiled.

The next stage is the editing of the disc by up-dating the information on it to include results of manual grouping, "flags", remarks etc. This is done in a separate, quiet office area. When completed, an edited hard-copy is printed out and is checked by eye against the manually-amended original hard-copy which was used for editing. Although this involves comparing two long printed lists, it is only checked by one person, not double checked. The checker signs the form on completion. The information on the edited disc is copied onto the main copy disc and is retained by the computer staff for three months; the edited disc goes to the Blood Bank for use in labelling.

Labelling of packs is performed by Blood Bank staff, who collect the unlabelled blood from the quarantine store, together with a supply of group labels, which have been prepared in advance by Grouping staff and carry dates of collection and expiry. The edited disc is entered into the computer and one person wands the donation number on the pack; the grouping result appears on the screen. A second person affixes the appropriate group label on the pack, initials the label and hands it to the first person who wands the group label for computer verification. This person also initials the label. (The system of both labelling staff signing the label is laborious but was recently introduced when a pack was found to have gone through the system with the wrong group label, ie it had obviously not been computer-verified.)

Labelled blood is returned to the quarantine cold-room. Virology reports are sent to Grouping staff, who are responsible for releasing blood to stock. (Virology staff are responsible for removing HBsAg + ve and HIV antibody + ve donations.) Grouping staff check the quarantine list, ensure that all "holds" are identified and present and compile a Donor Grouping Blood Banking Report, which is signed and check-signed, giving final clearance for issue. Grouping staff then transfer the released blood to the Blood Bank fridge.

5.4 Virology

The tests done here on all donations are for HIV antibody (Wellcome ELISA) and HBsAg (Abbot AUSRIA II). For HIV antibody testing, the Wellcome test has been slightly modified by introducing a one minute mix after serum addition prior to addition of the conjugate. This has been shown to increase sensitivity and reduce any possibility of missing weak positives.

Serum samples are brought to Virology at 7am each day by a laboratory assistant, who also performs a preliminary check that all samples are present, spins them down and sets them out in numerical order in rows of 10. The laboratory assistants also make out a work-sheet and, in the case of HBsAg assays, prepare the plates by writing the first and last numbers on them and dispensing the beads. Virology staff then check the first and last numbers on the work-sheet and the running order of the samples.

For HBsAg, 200 µl quantities are pipetted into each well. As each tube is sampled, it is moved in the rack one place to the left. Standards used are the manufacturer's (seven negatives and three positives) and an in-house "go - no go" control of 0.5 iu/ml. In addition, a range of standards from 10 ng to 0.3 ng is used as a daily QC control and a 0.3 ng/ml control is included at the end of each session. The manufacturer's cut-off point is defined as 2.1 x the mean of the seven negative controls. Here, a local cut-off of 1.5 x negative mean is used.

For HIV antibody testing, the plate wells are in rows of eight, not 10, so pipetting samples from 10-row racks is more complicated and open to error. Standards used are the manufacturer's controls (on every plate) and the Scottish/Irish standard weak positive for every session. In addition, weak positive and negative in-house controls (supplied by Ruchill Hospital) are included when wells are available and controls from CPHL, Colindale, are included as a daily check. The test cut-off is 10 per cent of the negative mean but in addition, all results falling between 10 per cent and 20 per cent of the negative mean are here regarded as equivocal, as are samples less than 3.2 standard deviations of the negative samples on each plate.

The procedure for dealing with equivocals and positives is the same for both HBsAg and HIV antibody. Initial screen positives are not issued. Virology staff remove all packs the same evening and sign and countersign the Plasma Processing Work Sheet certifying that this has been done. (Plasma is removed by Blood Products staff the following morning.) The original serum sample is then re-tested, along with a plasma sample (obtained from Donor Grouping) and a sample from the original pack pigtail. If any of these test positive or borderline, the samples are referred to the Hepatitis Reference Laboratory at Ruchill Hospital; if all are negative, then the donor is "flagged" and three negative donations are required in a six month period before a donation will be used. (For equivocal results, the test is repeated; if repeat is equivocal or positive, the procedure is the same as for initial screen positives.)

All results are double-checked and signed. A report is written out in a duplicate book, signed and countersigned. The top copy is sent to Donor Grouping. Results are kept as hard copy for four weeks and are then microfiched. All serum samples are being stored as library samples indefinitely.

5.5 Quality Assurance

At present there is no Quality Assurance Manager. The Senior Chief MLSO currently responsible for QA also has responsibility for Virology, Plasma Processing, Bacteriology and Cryogenics. The appointment of a full-time QA manager, independent of production, is being considered.

The QA procedures currently carried out are split between Bacteriological monitoring (of products and of the environment) and non-bacteriological quality monitoring of blood and its components.

Bacteriological monitoring of products involves sterility-testing by direct innoculation into TSB and Thioglycollate. TSB agar pour-plates are also used, with incubation at both room temperature and 35°C. In-coming media are tested to prove that they will support growth.

Products tested are red cell concentrates (10-20 outdated packs per week), FFP (10 packs per week), cryoprecipitate, washed red cells (routinely) and platelets (six out-dated packs per week). Platelet pools are now also monitored: when pooling is completed, a small sample of the final (mixed) pool is pushed back into the last pack before being clipped off; this sample is held at room temperature for about one week and then sterility tested. So far, about five out of 1000 pools tested have shown contamination but the evidence suggests that contamination occurred at the time of blood collection rather than during platelet pooling.

Environmental monitoring involves the weekly checking of the sterile suite when it is in use, using a slit sampler. (This was under repair at the time of inspection.) Limited use is also being made of a recently-acquired Malvern Laser Particle Counter. Settle-plates are used during all open-processing. On an experimental basis, donor sessions are being visited and swabs are being taken of donors' arms pre-clean, post-clean and post-donation.

Non-bacteriological quality monitoring of blood and products is co-ordinated by a Senior MLSO in the Donor Grouping Laboratory, the testing being done either in Donor Grouping or in Haematology. Products checked are whole blood, concentrated red cells, platelet concentrates, FFP and cryoprecipitate.

Whole blood is checked for volume by weight, with a target of 476 g. ± 10% per donation. 60 units a week are check-weighed as they come into the Blood Products Department.

Concentrated red cells (30 out-dated units per week) are tested for pH (target > 6.0) and haematocrit (target 65 -75 per cent) in the Haematology laboratory.

Platelet concentrates (six out-dated packs per week) are tested for platelet count, pH, volume, red cell and white cell counts. Platelet counts are done manually with a target of 75 per cent having a count greater than 5.5×10^{10}. The target volume is 40-60 ml and the pH should exceed 6.0.

FFP is tested for Factor VIII:C activity and platelet count. The Scottish National Target for VIII:C in FFP is for 70 per cent of packs to exceed 0.7 iu/ml. The target here is for 80 per cent of packs to exceed 0.5 iu/ml, the mean being greater than 0.7 iu/ml. Two samples daily are tested.

Cryoprecipitate is tested (one unit from each batch prepared) for VIII:C (target of more than 80 iu/pack) and fibrinogen (target of more than 140 mg per pack)). FVIII:C assays are carried out using a one stage assay on a Coagulometer with Diagen FVIII-deficient plasma as substrate and the 15th British Standard supplied by NIBSC.

All the QC test results are collected and filed but are not reported in a formal way unless there are some obvious deviations from targets. Three monthly summary reports are prepared for the Senior Chief MLSO and these are sometimes passed on to the Director.

5.6 Blood Bank and Issue

The Blood Bank has freezers for FFP and Cryoprecipitate, a 22°C incubator for platelets and a 4°C cold room for whole blood, red cell products and PFC products. Each is fitted with a high/low alarm. The temperatures of these stores are checked and recorded each morning, each night and three times at weekends by Despatch staff.

Orders are generally received by telephone and a laboratory assistant writes the request onto a triplicate "Order and Issue Record" Form. There is one version of this form for BTS products and another for PFC products. The order is then put together and the donation numbers of the units (or the batch numbers of PFC products) are written onto the form. In the case of BTS products, the numbers are wanded prior to issue to verify they are cleared. When the order goes out, the top copy of the Issue Record form is retained while the second and third copies accompany the order.

Records of issues are kept in a "Bible" made up of the Donor Record Sheets. The destinations of the various components are hand-written into this book and ultimately transferred (manually) to the mainframe computer in Edinburgh. A daily stock sheet of packs for issue is written out in pencil from a physical stock-check. As the day's issues proceed, the stock figures on this sheet are altered by erasing the old figures and pencilling in new ones. PFC products are under computer stock control, every issue being manually keyed-in. There is also a daily physical stock check.

Blood and products are delivered to hospitals in BTS vans on a daily "milk round" basis. However, the drivers take not only blood which has been ordered and issued but they also take extra supplies in case a hospital has had an additional requirement after the van has left the Centre. In such cases, it is left to the receiving hospital to select packs, after telephoning the Regional Centre to be given the necessary authorisation, and be responsible for recording correctly the appropriate donation numbers.

6. FUTURE PLANNED CHANGES/DEVELOPMENTS

A full-time Quality Assurance Manager may be appointed.

BTS delivery vans are to be fitted with telephones, enabling drivers to keep in contact with the Centre and take responsibility for recording the issue of extra blood to hospitals.

The Donor Centre in St Vincent Street, Glasgow, is being re-furbished with a view to expanding the activities carried out there to include, for example, the emergency pooling of platelets. An inspection visit to the Centre, which was not seen on this occasion, will be made when the re-fitting is complete.

7. MATTERS OF CONCERN

(a) The temperature of the refrigerated vans used to store and transport blood at donor sessions is inadequately monitored. At the time of inspection (4pm) the 6pm temperature had been recorded as 4°C; in fact, the refrigeration system was not switched on.

(b) The main laboratory for closed-system processing is cluttered, with record sheets and cardboard boxes stored on and under benches. Windows and doors are kept open and when the door to the blast-freezer room is opened, gusts of wind bring in leaves, dust and debris.

(c) An open sink in the processing laboratory is used to store burst packs of blood and components for several days at a time. A log-book recording the sink contents is inadequately filled in. There is no signed record of the ultimate disposal of the burst packs.

(d) When platelets are pooled and issued, the signature of the pooler and the time of pooling are not always recorded in the Platelet Issues Book.

(e) There is no environmental monitoring of the closed-system processing laboratory or the equipment. The effectiveness or otherwise of the cleaning procedures used has not been demonstrated.

(f) The autoclave has not been validated since it was commissioned in 1981, the last attempt in 1986 having failed. Bowie-Dick tests are not carried out and the log-book is only haphazardly completed. Print-out records of autoclave runs are not checked and signed each time to confirm that a satisfactory cycle has been completed.

(g) The gloves worn by staff carrying out open-processing in the sterile suite are powdered.

(h) When new donors are manually-grouped, the comparison with the machine result is not double-checked by two people.

(i) Known donors whose groups are not known at the session are machine-grouped once only, the result not being checked against their previous history (held on records at St Vincent Street) until some days later, by which time the donation will have been released.

(j) The checking of the hard-copy print out of the edited grouping results against the amended original copy is a single check by one person.

(k) The Despatch procedure is exceedingly manual, involving a triple transcription of donation numbers and manual recording of destinations.

(l) Currently, delivery vans carry extra supplies of blood in case hospitals need more than they have ordered; the receiving hospitals, having telephoned the Regional Centre for authorisation, are given the responsibility of removing packs and recording the donation numbers (but see Section 6, above).

8. POST-INSPECTION SUMMARY

After the inspection, a discussion took place with Dr Mitchell, Dr Crawford, Dr Hopkins (part-time), Mr Muir and Mr Barr. The inspector welcomed the possible appointment of a full-time Quality Assurance Manager and expressed surprise at the amount of manual data handling still in use, particularly in Donor Grouping and the Blood Bank/Despatch department.

The points noted above (Section 7) were listed and discussed.

9. CONCLUSIONS

1. The facilities for open-processing are of a high standard and are well maintained. However, the autoclave should be re-validated as a matter of urgency and the procedures governing its use reviewed.

2. Urgent steps should be taken to reduce the amount of manual data handling, particularly in the Donor Grouping and Blood Bank/Despatch departments.

3. The system of checking grouping results with donors' previous history should be changed from the present retrospective procedure.

4. Although much valuable quality monitoring is being done at present, the appointment of a full-time Quality Assurance Manager, independent of production, who can collate QC results, issue regular reports, take and follow-up corrective action, co-ordinate documentation production and carry out QA audits, should be expedited.