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Donor Care and Selection Chapters to replace Chapters 3 to 6

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom – 7th Edition 2005 (Red Book)

The JPAC Standing Advisory Committee on Care and Selection of Donors has redrafted chapters 3, 4, 5 & 6 of the Red Book. The 4 chapters have been rewritten into 3 more focused chapters reflecting the fact that care and selection of donors is similar whether they are whole blood or component donors. Outdated prohibitions have been removed. The repetition of the Donor Selection Guidelines (DSG) in the chapters has also been removed as the DSG is an appendix to the Red Book.

Other changes reflect an updated understanding of apheresis, actual adult blood volumes and the new technology now being used. This results in changes to a reduced safe Extra Corporeal Volume (15% rather than 20%) and improved charts and appendices. Following legal advice on Consent, more information on competence (following the Mental Capacity act 2005), confidentiality and Donor Adverse events has been added.

Please replace chapters 3, 4, 5 and 6 with the attached:

- Chapter 3 Care and selection of whole blood and component donors (including donors of pre-deposit autologous blood)
- Chapter 4 Premises and quality assurance at blood donor sessions
- Chapter 5 Collection of a blood or component donation



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Chapter 3

Care and selection of whole blood and component donors (including donors of pre-deposit autologous blood)

3.1 Introduction

All blood donors in the United Kingdom are non-remunerated volunteer donors. These guidelines relate to the collection of a) whole blood and b) components by automated apheresis. Their purpose is to:

ensure the safety of volunteer donors and to ensure the quality of collected components.

to protect recipients of blood transfusions from adverse effects, such as transmission of infectious diseases or other medical conditions and unwanted effects caused by any medications taken by the donor.

They relate only to whole blood collection and the apheresis of healthy volunteer donors and not to the clinical use of cell separators for plasma exchange and other therapeutic procedures.

A medically qualified consultant must be ultimately responsible for the selection, health and welfare of the donors. He or she should ensure that all staff are appropriately trained and that clinical standards are maintained. Extreme care should be taken to ensure that undue pressure is not put on persons to donate.

The criteria for selecting blood donors are laid down in the current Joint UKBTS/HPA Professional Advisory Committee's (JPAC) Donor Selection Guidelines.⁽¹⁾ These apply to donors of a) whole blood and of b) components (cells and/or plasma) collected by apheresis. Other than in exceptional circumstances (to be decided by a designated medical officer), donors for apheresis procedures shall meet the usual criteria for ordinary whole blood donations. First-time donors may give components by apheresis. Donors who will be giving platelets should have given at least one sample for mandatory infection screening within the last two years and at least 8 weeks prior to their platelet donation. In addition the following criteria should be observed for apheresis donors:

for donors between 50 and 60 kg in weight, the extra-corporeal volume (ECV) must be calculated and never exceed 15 % (see Appendix I)

the minimum pre-donation platelet count must be $150 \times 10^9/L$

the predicted post procedure platelet count must not be less than $100 \times 10^9/L$

deferral periods for platelet donors following ingestion of drugs affecting platelet function (e.g. aspirin or non-steroidal anti-inflammatory drugs) should be in accordance with the JPAC Donor Selection Guidelines.⁽¹⁾

For the collection of double units of red cells by apheresis, special considerations apply. Male and female donors must be greater than 70 kg in weight.

The haemoglobin level to donate double units of red cells must be 140 g/L for both males and females.

Guidelines for donors of pre-deposit autologous donations are outlined in Section 3.16. The criteria for donors of stem cells and tissues are found in Chapters 24 and 22.

More detailed and frequently updated criteria are found in the Joint UKBTS/HPA Professional Advisory Committee's (JPAC) Donor Selection Guidelines⁽¹⁾ which form a constituent part of this chapter and must be consulted.

3.2 General principles

Only persons in good health shall be accepted as donors of blood or components for therapeutic use.

A prospective donor's medical history must be evaluated on the day of donation by a suitably qualified person who has been trained to utilize the JPAC Donor Selection Guidelines.⁽¹⁾

If there is any doubt about the suitability of a prospective donor, a donation should not be taken and the details referred to the designated clinical support.

Each blood establishment responsible for the collection of blood should include a medical consultant (with responsibility for donors) who will take professional responsibility for the care and selection of donors. The immediate responsibility is that of the clinician in attendance at the session. Patients referred for therapeutic venesection shall not be accepted at donation sessions (but see Section 3.9 on donors with genetic haemochromatosis).

Donors with hazardous occupations or hobbies

Occupations where a delayed faint may present a hazard either to the donor or to others can be accepted only when the individual is going off duty. This would apply, for example, to train, HGV or bus drivers; heavy machine or crane operators; work involving climbing ladders or scaffolding; miners working underground.

'Hazardous' hobbies should not be undertaken on the day of donation, e.g. gliding, powered flying, car or motor cycle racing, climbing, diving, etc.

3.3 Assessment of fitness to donate

The combination of assessing each donor clinically (at every attendance) and testing each donation for markers of infection is essential to maximize donor and recipient safety.

Each donor must undergo an assessment based on the JPAC Donor Selection Guidelines⁽¹⁾ to determine their eligibility to donate. This requires each donor to complete a questionnaire and answer a series of standard questions relating to their general health, lifestyle, travel history, past medical history and medication.

In addition on entry to the apheresis programme as a minimum requirement for all donors the pulse and weight must be assessed and recorded.

If necessary, with the donor's consent, his/her General Practitioner may be contacted for further information.

3.4 Informed consent

For consent to a procedure to be legally valid the donor must as a matter of good principle have been told the nature and purpose of the procedure as well as being warned of any substantial or unusual adverse event risk. Therefore informed consent must be obtained by a trained person, fully conversant with the procedure. A consent form must be signed by each donor before donation.

Leaflets (nationally, locally or commercially produced) about donation appropriate to the procedure should be available at the session and studied by prospective donors to assist in the process of obtaining fully informed consent. In obtaining donor consent, the consentor must satisfy themselves that the donor has read the leaflet and has understood the following information:

- the purpose of the donation and the use of the product (clinical, research or other)

- a description of the procedure and its likely duration

- an explanation that a voluntary donor can withdraw consent at any stage of the procedure or of an apheresis programme

- a description of the common risks and discomfort involved in the procedures. These include:

- for all donors:-

 - dizziness and fainting

 - haematoma formation

- for donors of components by apheresis:-

citrate toxicity

red cell loss if the procedure has to be aborted and it is considered unsafe to return the red cells

chilling on reinfusion.

If the donor asks further questions relating to more remote hazards, they must be answered truthfully, however unlikely these hazards may be.

It is the responsibility of session staff to ensure that donors clearly understand the nature of the donation process and the associated risks involved as explained in the available literature. The donors must also understand the health check and other medical information presented to them. Donors are asked about confidential and sensitive aspects of their medical history and lifestyle. It is therefore important that blood collection sessions have facilities that offer privacy for donor interviews and that donors are assured of the confidentiality of any information they provide. For the donor's consent to be valid the donor must have capacity to consent. Capacity is defined in the 2005 Mental Capacity Act⁽³⁾. The five principles of this act state that:

The person must be assumed to have capacity unless you can establish that they have not.

No-one should be treated as being unable to make a decision unless we have made all practical steps to ensure that they are able to make that decision without success.

The person may not be deemed unable to make a decision just because they appear to make an unwise decision.

Any act done or decision made under the Act on behalf of a person who lacks capacity must be done in the best interests of that person.

One must always consider whether you can do the same thing in a way that is less likely to infringe that person's rights and freedom of action.

We must therefore presume that every donor that we deal with has capacity to make decisions. To have capacity the person must, with the appropriate help and support, be able to understand, retain, use and or weigh up the information they are given to make the decision or to communicate their wishes. Just because a person is of a certain age, has a disability, communication difficulty or medical condition we cannot assume that they lack capacity. Thus staff who consent donors must understand and apply these principles, all donors be they 17 or 70 should have capacity when they sign their consent and it is the duty of the attending carers and health care professionals at the session to ensure that they do have that. Since the Family and Law Reform Act 1969 children have capacity to give consent in medical matters from the age of 16. Third-party interpreters should not be used except as laid down in the current Joint UKBTS/HPA Professional Advisory Committee's (JPAC) Donor Selection Guidelines⁽¹⁾ as there is no guarantee of understanding or of truth telling to the interpreter, particularly if they are a friend, family member or are otherwise known to the donor. Blood service staff gain sensitive medical and personally identification information about donors. They must not disclose information about a donor without their consent to a third party. This includes members of their family and includes the fact that they have attended for donation. Should a family member ring up to make an appointment or to ask a specific question, that specific factual question may be answered but further information about the donor should not be disclosed, e.g. "My husband has started on treatment for high blood pressure, can he donate?" Answer – "Yes, once he has been on the treatment for four weeks and as long as he has no other problems."

Should third party information be given to members of the blood service staff it must be handled as per an appropriate procedure to ensure that the information is acted on in an appropriate fashion and verified if at all possible regardless of the source of that third party information, i.e. even if it is from an internal NHSBT source. All members of staff should be very clear that they have a duty to protect a donor's personal information and the only people who they should disclose this to are people who have a legitimate right to know and that should include not disclosing unnecessarily within the organisation.

Potential donors who are unable to read the literature should be informed of its contents by a suitably trained member of staff.

3.5 Donor age

Donors shall be between the ages of 17 and 65 years; i.e. from their seventeenth to sixty sixth birthday inclusive. Regular and returning donors may be allowed to donate beyond their 66th birthday with permission of the physician in the blood establishment, given annually.

It is normal practice to set an upper age limit of 60 years (up to 61st birthday) for first-time donors. However, older donors may be accepted at the discretion of the physician in the blood establishment.

3.6 Frequency of donation:

Whole Blood An interval of 16 weeks between donations of whole blood is reasonable. The minimum interval is 12 weeks. Normally, no more than three donations should be collected from a female donor during any 12-month period and four from a male donor.

Plasma and Plateletpheresis: A donor should not undergo a total of more than 24 plasma/plateletpheresis procedures per annum including not more than 12 leucapheresis procedures per annum. There should normally be a minimum of 2 weeks between plateletpheresis procedures. There should normally be a minimum of 48 hours between leucapheresis procedures and a donor should not normally undergo more than two procedures within a seven-day period.

Not more than 15 litres of plasma should be donated by one donor in a year.

Not more than 2.4 litres of plasma should be donated by one donor in any one-month period.

After a whole blood donation, or the loss of an equivalent number of red cells during an apheresis procedure, a donor should not normally donate plasma, platelets or leucocytes for a period of four weeks.

Double red cell donations: The interdonation interval for regular donation of double red cells by apheresis should not be less than 26 weeks (6 months) in the absence of iron supplementation. A shorter interval may be acceptable only if confirmation of iron-replete body stores can be accurately demonstrated and monitored.

3.7 Volume of donation

Whole Blood: A donation of 450 mL±10% is required to ensure the final red cell component meets specification. No more than 15% of the estimated blood volume should be taken during any one donation. In general 470–475 mL of blood, excluding samples, is collected into the main pack.

Attention must be paid during apheresis to the extra-corporeal volume (ECV) in order to avoid rendering the donor significantly hypovolaemic. Consideration must be given to the following factors:

donor weight and estimated blood volume

type of apheresis procedure: intermittent flow or continuous flow

donor's haematocrit: this influences volume of plasma collected during any one cycle of an intermittent flow procedure (see Appendix III).

For any single apheresis procedure, the final collection volume should not exceed 15% of the total blood volume (TBV) excluding anticoagulant (see Appendix I).

During apheresis procedures the ECV should not exceed 15 % TBV (excluding anticoagulant). Some procedures may result in a total ECV of as much as 1 litre. The procedure may need to be adjusted to suit each individual donor's safety tolerance limits. Special considerations should be given during intermittent flow apheresis procedures (see Appendices I, II and III). TBV can be estimated using the Nadler formula (see Appendix I) ⁽⁴⁾.

ECV is the total volume of blood and plasma removed from the donor at any time. It includes all blood and plasma in collection packs and contained within the machine harness (volumes contained within collection harness can be obtained by reference to manufacturers' manuals).

Anticoagulant ratio during collection influences the volume of anticoagulant in collected plasma, e.g. anticoagulant in 1:12 ratio forms 14% of the final volume collected in a donor with haematocrit of 45% (see Appendix II).

3.8 Medical history of donors

General considerations

All donors should clearly understand any information and questionnaire presented to them and must sign an appropriate document which also attests to their consent for the blood to be taken, tested and used for the benefit of patients. Any condition declared shall be discussed with the clinician in attendance at the blood collection session unless clear, unequivocal instructions regarding the responses are available to the member of staff conducting the questioning.

For the details of information to be supplied to and obtained from donors see Chapter 5.

Donors whose serum or plasma or cells are to be used for laboratory, as opposed to therapeutic, purposes shall be submitted to the same routine as other donors, but some decisions regarding their suitability to donate may be different (e.g. treatment with certain medications, or on the basis of their medical history). When this is the case, secure mechanisms must be in place to ensure that the donation cannot be released for clinical purposes.

Individuals currently undergoing medical investigations or who have been referred for a specialist opinion or are on a hospital waiting list should normally be deferred. If, however, the condition or potential condition concerned would not of itself be a contraindication to donation they may be able to donate.

Donors taking part in clinical trials cannot be accepted until their involvement in the trial has finished, or the designated clinical support team member has examined the trial protocol and agreed that donors participating in that trial can be accepted. A 'clinical trial' normally implies that the donor is participating in an intervention programme – usually taking a drug or a potential drug which may be either active or a placebo. Participating in questionnaires does not constitute a clinical trial.

All donors should be made aware that recipients are at risk from transfusion, and shall be asked to report any illness that develops within 14 days of donation.

Information about either the donor or the donation which becomes available after the blood or any derivative has been issued or transfused, and which is, or may be, relevant to the safety of that blood for transfusion, should be reported to the appropriate individual e.g. consultant in charge of the hospital blood transfusion laboratory. Donor confidentiality must be respected.

The member of staff carrying out the donor assessment must confirm they have done so by signing the donation record. Any reason for deferral, whether temporary or permanent, must be explained to the donor and recorded.

3.9 Genetically determined conditions

An increasing number of genetically determined conditions that potentially affect donor health are being identified, and some donors have had specific tests which confirm that they possess variant genes. These include not only the haemoglobinopathies and thalassaemias, but also more recently discovered conditions such as the thrombophilias (e.g. factor V Leiden). Mere possession of such genetic variants does not debar from donation if the donor is otherwise healthy and fulfils all other selection criteria.

Genetic haemochromatosis

This is a special case. Blood from individuals with genetic haemochromatosis (GH) who have no symptoms arising from their GH is intrinsically safe for transfusion. However, before patients with GH who require continued venesection for the maintenance of their health are accepted as blood donors, the consultant with responsibility for donors must ensure that the following criteria are met:

the selection criteria/methods for all donors with GH preserve the principles of altruism

blood donated for therapeutic use by any donor known to have GH meets all other criteria (except donation frequency) in the JPAC Donor Selection Guidelines.⁽¹⁾ If it is clinically appropriate for individuals to donate more frequently than the minimum donation interval, specific permission must be obtained from the designated medical officer

the donor is under the continuing care of a physician who is able to offer alternative venesection facilities whenever, for any reason, the donor does not meet all other criteria in the JPAC Donor Selection Guidelines.⁽¹⁾

3.10 Donors on treatment with medications (drugs)

Donor deferral for most drugs is based on the underlying illness suffered by the donor rather than for the properties of the drug itself, e.g. cardiovascular disease, diabetes, anaemia and malignancies. Since, in general, traces of drugs in blood and blood components are believed to be harmless to patients, many people taking medications – even when prescribed – are acceptable as blood donors so long as the reason for which the medication is taken is acceptable.

A pragmatic view should be taken of treatment of infections with antimicrobials. Providing the donor is in good health, deferral is limited to two weeks from full recovery and one week after cessation of antimicrobial therapy, whichever is the longer. This is based on what may be regarded as a reasonable recovery period for the infection and is not related to the antimicrobial therapy itself.

Donors taking drugs which are proven or potential teratogens (e.g. vitamin A derivatives) or who are taking drugs that accumulate in tissues over long periods, should not be accepted for blood donation. Some such drugs may be taken to prevent diseases to which the donor – though currently healthy – is prone. A decision to accept should be taken after considering the pharmacodynamics of the specific drug, and its mode of action. The period of deferral after finishing a course of treatment is set out in the JPAC Donor Selection Guidelines.⁽¹⁾

The current JPAC Donor Selection Guidelines⁽¹⁾ must be referred to for all donors who have had immunizations.

Sporadic self-medication with some drugs (e.g. vitamins, aspirin, sleeping tablets) need not prevent a donation being accepted, providing the donor is in good health.

If the donor has taken drugs affecting platelet function (e.g. aspirin) within either the last two or five days the donation shall not be used for preparing platelets. A list of such drugs is in the JPAC Donor Selection Guidelines.⁽¹⁾ Other drugs or tablets may be acceptable. However the taking of some drugs may indicate a disease which would automatically make a donor ineligible.

3.11 Transfusion transmissible infectious diseases

Every effort is made to prevent transmission of disease by careful and appropriate selection of donors. This includes ensuring that the donor is provided with clear, understandable and up to date information and also ensuring that the donor has understood this information (see Chapter 5).

Donors must be assessed for their exposure to any risk of acquiring a transfusion transmissible infection. The latest JPAC Donor Selection Guidelines⁽¹⁾ should be consulted for any donor with a relevant exposure history.

3.12 Travel history

Increased and rapid travel of the population may lead to asymptomatic people donating infectious blood. A clear and detailed travel history must be obtained from all donors to minimize the risk of transmission of malaria, T. cruzi and emerging diseases such as West Nile Virus and Chikungunya virus.

The latest JPAC Donor Selection Guidelines⁽¹⁾ should be consulted for any donor with a relevant travel history.

The Blood Services and JPAC maintain close links with the WHO and the UK Health Protection Agency and base the donor deferral criteria on the advice obtained. Any changes to current selection guidelines need to be rapidly communicated and this will happen through Change Notifications and the website www.transfusionsguidelines.org.uk

3.13 Prion-associated diseases including sporadic Creutzfeldt-Jakob Disease (CJD) and variant CJD (vCJD)

Individuals who are identified as having an increased risk of developing a prion-associated disease must be permanently excluded from donation. This includes

individuals who have received human pituitary-derived hormones

patients who have received grafts of human dura mater or cornea, sclera or other ocular tissue

persons identified as being members of a family at risk of inherited prion diseases

persons who are known to have received an allogeneic tissue or blood transfusion since 1980. For these purposes, a transfusion is defined as any product containing red cells, platelets, granulocytes, fresh frozen plasma, cryoprecipitate depleted plasma, buffy coat preparations and intravenous or subcutaneous human normal immunoglobulin. This includes mothers whose babies have required intra-uterine transfusion

persons who have been told that they have been put at increased risk from surgery, transfusion or transplant of tissues or organs.

persons who have been told that they may be at increased risk because a recipient of their blood or tissues has developed a prion related disorder.

The current edition of the JPAC Donor Selection Guidelines⁽¹⁾ provides detailed advice and should be consulted.

3.14 Physical examination of donors

General considerations

A detailed medical assessment procedure must be conducted on all donors, as referred to above, i.e. based on the JPAC Donor Selection Guidelines.⁽¹⁾ Particular attention is required for the assessment of first time or 'returning' donors. Returning donors are defined as those who – although formerly registered as a blood donor with one of the four National Blood Transfusion Services – have not been assessed for donation for two years or more.

Assessment of blood pressure is not recommended because the circumstances at blood collection sessions are not conducive to obtaining meaningful measurements. Routine measurement of blood pressure could also give the impression that blood establishments offer a general health screening service which might be construed as an inducement to donate.

Inspection of the donor: the donor should be in good health. Note should be taken of poor physique, debilitation, under-nutrition, plethora, jaundice, cyanosis, dyspnoea, intoxication and mental instability. When in doubt the donor should be deferred until further advice has been obtained from a designated medical officer.

Weight: the minimum weight for donation is 50 kg (7 stone 12 lb). Those who weigh less than 50 kg are more likely to suffer adverse reactions, in particular dizziness and fainting, after a standard donation. This is because the volume taken represents a greater proportion of their blood volume. It should be noted that donors who are obese but are towards the lower weight limit may not have a sufficient blood volume to ensure a safe donation.

3.15 Blood tests

Estimation of the concentration of haemoglobin (Hb) in donor blood

The Hb concentration should be determined each time a potential donor presents. The acceptable lower limits for venous blood are 125 g/L for female donors and 135 g/L for male donors. This should be assessed using a validated test system (see Chapter 5).

The precise method of screening donors for their blood Hb concentration may be determined by the consultant with responsibility for donors. An acceptable strategy is to apply the gravimetric method using solutions of copper sulphate on blood samples obtained by fingerprick. Alternatives which can be considered are capillary sampling with spectrophotometric devices or validated non invasive technology.

A donor whose fingerprick sample fails the gravimetric screen should be offered a test on a sample of venous blood for accurate determination of their Hb concentration. This is to enable the donor to receive appropriate advice either from the consultant with responsibility for donors or the donor's general practitioner. The Hb concentration in the venous sample may be determined immediately at the session if a suitably validated haemoglobinometric device capable of rapid and accurate analysis is available. If the concentration so determined is at or exceeds those quoted above the donor may be invited to give a full donation.

Donors whose Hb concentration is below the minimum values should not be bled. The reason for deferral should be explained and the donors advised to see their own general practitioner if this is considered to be appropriate.

If a quantitative method of Hb determination is employed, before or after the donation, individuals found to have a concentration of Hb above the normal upper limit should be referred for further investigations.

In addition component donors should have the following tests:

At the initial visit, the following blood tests should be performed:

full blood count for all donors

serum albumin and total serum protein levels for plasma donors (total serum protein has no relevance to platelet donors).

The lower limit of acceptability for haemoglobin level should be as for normal whole blood donation. Special considerations as above apply to red cell donation by apheresis.

The platelet count should be performed at each visit for plateletpheresis donors.

The full blood count must be carried out at least annually for all donors and serum albumin and total serum proteins must be measured at least annually for plasma donors. A system must be in operation for regular review of these results, together with a documented protocol of the action to be taken in the light of any abnormal findings.

3.16 Donors of pre-deposit autologous donations

Autologous pre-deposit donations must be collected according to the same requirements as allogeneic donations but the deferral criteria vary. These donations must be clearly identified as such and kept separate from allogeneic donations.

Deferral criteria

The deferral criteria for donors of autologous pre-deposit donations in the UK, originally agreed by the British Committee for Standards in Haematology Blood Transfusion Task Force were updated in 2007.⁽²⁾

The two main deferral criteria are serious cardiac disease (where the clinical setting of the blood collection must be taken into account) and active bacterial infection.

3.17 Donors of immune plasma

Recruitment of donors for specific immune globulins has been suspended in the UK until such time as the UK government decision to use only non-UK source plasma has been rescinded.

References

1. Joint UKBTS/NIBSC Professional Advisory Committee's (JPAC) Donor Selection Guidelines available at www.transfusionguidelines.org.uk.
2. British Committee for Standards in Haematology Blood Transfusion Task Force (2007) Guidelines for policies on alternatives to allogeneic blood transfusion. 1. Predeposit autologous blood donation and transfusion *Transfusion Medicine*, 2007, 17, 354–365
3. The Mental Capacity Act 2005 available at www.legislation.gov.uk
4. Nadler S B, Hidalgo J U, Block T. Prediction of blood volume in normal human adults. *Surgery* 1962 51:224-32

Appendix I

Extra-corporeal volume tables

To avoid symptomatic donor hypovolaemia, ECV and final collection volume in ml should not exceed 15% TBV (excluding anticoagulant) the maximal safe volume is indicated in the tables below, after Nadler et al⁽³⁾

MALE												
	Weight											
Height	50	55	60	65	70	75	80	85	90	95	100	Kg
150	518	542	566	590	614	638	663	687	711	735	759	4'11
153	522	546	570	594	618	642	666	691	715	739	763	5'
155	525	549	574	598	622	646	670	694	718	743	767	5' 1
158	529	553	577	602	626	650	674	698	722	746	771	5' 2
160	533	557	581	605	630	654	678	702	726	750	774	5' 3
163	537	561	585	609	634	658	682	706	730	754	778	5' 4
165	541	565	589	613	638	662	686	710	734	758	782	5' 5
168	545	569	593	617	642	666	690	714	738	762	786	5' 6
170	549	573	597	622	646	670	694	718	742	766	791	5' 7
173	553	577	602	626	650	674	698	722	746	771	795	5' 8
175	557	582	606	630	654	678	702	726	751	775	799	5' 9
178	562	586	610	634	658	682	707	731	755	779	803	5' 10
180	566	590	614	638	663	687	711	735	759	783	807	5' 11
183	570	595	619	643	667	691	715	739	764	788	812	6'
	7.9	8.7	9.5	10.2	11	11.8	12.6	13.4	14.2	15	15.7	Stone

FEMALE												
	Weight											
Height	50	55	60	65	70	75	80	85	90	95	100	
150	456	481	505	530	555	580	605	630	654	679	704	4'11
153	460	484	509	534	559	584	608	633	658	683	708	5'
155	463	488	513	538	562	587	612	637	662	686	711	5' 1
158	467	492	517	541	566	591	616	641	665	690	715	5' 2
160	471	495	520	545	570	595	620	644	669	694	719	5' 3
163	475	499	524	549	574	599	623	648	673	698	723	5' 4
165	478	503	528	553	578	602	627	652	677	702	726	5' 5
168	482	507	532	557	582	606	631	656	681	706	730	5' 6
170	486	511	536	561	586	610	635	660	685	710	734	5' 7
173	490	515	540	565	590	614	639	664	689	714	738	5' 8
175	494	519	544	569	594	618	643	668	693	718	742	5' 9
178	499	523	548	573	598	623	647	672	697	722	747	5' 10
180	503	528	552	577	602	627	652	676	701	726	751	5' 11
183	507	532	557	581	606	631	656	681	705	730	755	6'
	7.9	8.7	9.5	10.2	11	11.8	12.6	13.4	14.2	15	15.7	

Appendix II

Citrate anticoagulants and the avoidance of citrate toxicity

Based on studies undertaken in 1989-90 the following recommendations can be made to avoid citrate toxicity during apheresis procedures.

Intermittent flow cell separator machines

The reinfusion rate of citrated blood or plasma should not exceed 0.015 mmol citrate/kg/min.

Continuous flow cell separator machines

The continuous reinfusion rate of citrated blood or plasma should not exceed 0.01 mmol citrate/kg/min.

Maximum acceptable reinfusion rates (mL/min for a 70 kg donor)

For the four citrate anticoagulants listed that are commonly used in the UK, the above recommendations are represented in the table below:

Citrate anticoagulants

AC	AC:blood ratio	Average plasma citrate mmol/L	AC volume in collected plasma %	Plasma		Whole blood	
				Int.	Cont.	Int.	Cont.
CPD-50	1+15(1:16)	17	11	60	33	100	60
Acid CPD	1+11(1:12)	19	14	55	29	90	50
ACD-A	1+11(1:12)	16	14	60	33	100	55
ACD-A	1+7(1:8)	23	20	45	24	75	40

AC = Anticoagulant

Int. = Intermittent flow cell separator

Cont. = Continuous flow cell separator

Packed cells may be reinfused as quickly as the characteristics of the return system and the viscosity will allow, but not normally faster than 130 mL/min.

NB – For donors weighing less than 70 kg, these reinfusion rates need to be suitably adjusted downwards to avoid citrate toxicity occurring. They may also be adjusted upwards for donors above 70 kg in weight.

If different anticoagulant formulations or ratios are used other than those represented above the procedure should be validated:

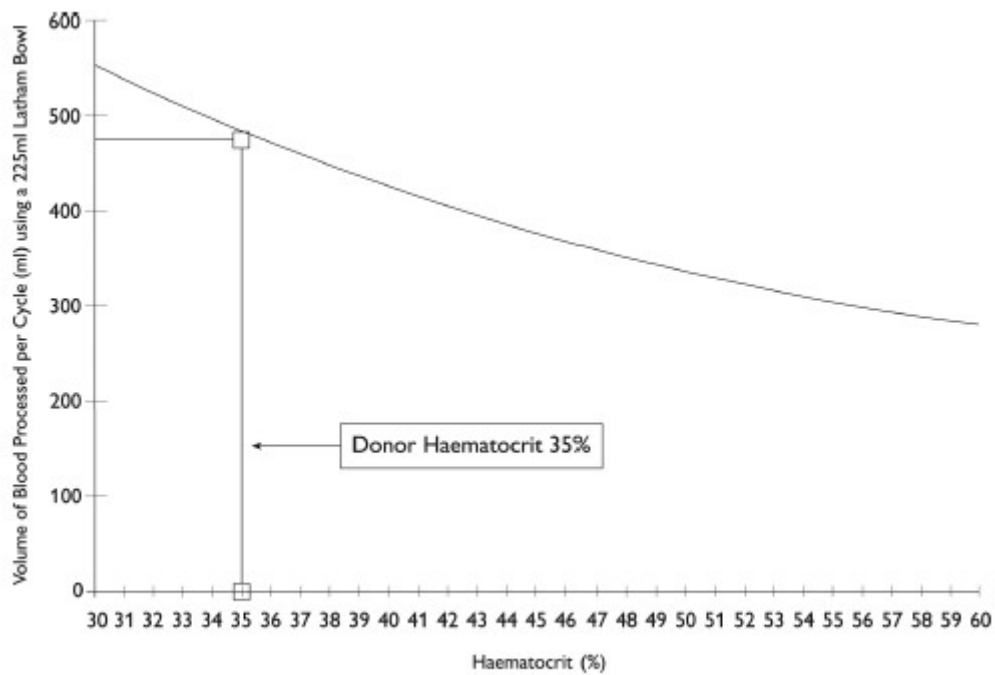
to ensure plasma citrate levels are within the required range for fractionation purposes, i.e. 15–25 mmol/L

to ensure the citrate molar reinfusion rate does not exceed these recommended maximum acceptable limits.

Final collection volume must not exceed 15% TBV (excluding anticoagulant).

Appendix III

Volume of blood processed per pass



Source: Haemonetics Corporation

Volume of blood processed per cycle vs donor haematocrit

Based on haematocrit of 0.80 in bowl and a flow rate of 60–80 mL/min. Includes harness volume of 35 mL.

These figures draw attention to the fact that for donors with a low haematocrit an increased volume of blood is processed at each pass. This will influence the ECV accumulating throughout the procedure and this particular group of donors may become symptomatically hypovolaemic.

Chapter 4

Premises and quality assurance at blood donor sessions

This section applies to the collection of donations of whole blood and components at permanent sites or by mobile blood collection teams.

4.1 Premises

Premises used for the preparation of components from blood and plasma are subject to scrutiny by the Competent Authority, the Medicines and Healthcare Products Regulatory Agency, since 2005. Such facilities must comply with the principles embodied in the Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007.⁽¹⁾

Notwithstanding the fact that premises used for mobile donor sessions may often be accepted, from necessity, as the only local venue available, they must be of sufficient size, construction and location to allow proper operation, cleaning and maintenance in accordance with accepted rules of hygiene and in compliance with WHO Expert Committee on Biological Standardisation 43rd Report, Technical Report Series No. 840 1994.⁽²⁾

The designated person in charge of the blood collection team should in all cases be provided with a written plan of action appropriate to each venue. This can be used if conditions on arrival are not found to be acceptable. Care must be taken to avoid disturbances of any other activities within the venue if it is being shared.

Selecting a venue

Whole blood and donor component procedures for the collection of plasma, platelets, red cells or combinations of these may be carried out at fixed or mobile collection sites.

Leucapheresis procedures to collect, e.g. granulocytes, lymphocytes, peripheral blood progenitor cells, should only be performed at fixed component units.

In any apheresis unit, or at any blood donor session a telephone must be immediately available so that the emergency services can be called at any time.

Resuscitation equipment as required by local and National Guidelines for blood donor sessions must be available at all sessions undertaking routine component procedures.

Account must be taken of the following activities/requirements when selecting a venue:

- registration of donors and all other necessary data processing.

- appropriate facilities to assess the fitness of individuals to donate

- withdrawal of blood from donors without risk of contamination or errors

- flooring should be non-slip

- social and medical care of donors, including those who suffer reactions. Sufficient seating should be provided for donors and staff, with allowance made for possible queues during busy periods

- storage of equipment, reagents and disposables

- storage during the session of blood and components, if they are not to be transferred immediately to the blood processing centre or to appropriate storage in the team vehicle

- access to an adequate electrical supply to support all electrical equipment used for the session

- the space required for these activities will depend on the anticipated workload.

Health and safety factors

The requirements of the Health and Safety at Work Act must be taken into account when selecting sessional venues. Each organization has the responsibility to ensure that venues comply with the Health And Safety at Work Act and that staff are fully aware of their responsibilities under this legislation. It is the responsibility of all staff with supervisory or line management responsibility to ensure that safe systems of work are in place at all times. All venues should be formally assessed for suitability with an appropriate plan to manage risks. Premises should be safe, clean and comfortable for donors and staff. In particular, the following points should be borne in mind:

The venue should be as close as possible to the centre of population being served. It should be possible for the sessional vehicle(s) to park in close proximity to the access doors, to facilitate off-loading if required. The ground to be covered by staff carrying equipment shall be even and well lit. The space to be used should preferably not entail carriage of equipment on stairs. A similar safe approach should be ensured for donors, with as much provision as possible for car parking. Notices should be displayed, directing donors to the appropriate entry point of the building, and to the room being used.

Furniture and equipment within the available space should be arranged to minimize crowding (with the increased risk of mistake or accident), enabling adequate supervision and ensuring a smooth and logical workflow.

Fire exits must be unobstructed and operational. All sessional staff must be aware of the location of the fire extinguishers and exits.

Lighting should be adequate for all the required activities. Provision should be made for the use of emergency lighting in the event of interruption of the electricity supply.

Environmental control may not be within the power of a mobile team, but every effort should be made to ensure that the space does not become too hot, cold or stuffy. Subsidiary cooling fans and heating should be carried on sessional vehicles, and used as necessary. This equipment should be subjected to a planned maintenance programme.

Facilities for the provision of refreshments for donors and staff should be separated from the other activities of a donor session whenever possible. Every effort should be made to ensure that equipment used in this area poses the minimum threat of danger to all persons.

Toilet facilities for male and female donors and staff should be provided.

Separate washing facilities are desirable for those staff involved in 'clean' procedures.

Adequate facilities must be available for the disposal of waste. On mobile sessions, all waste should be collected and contained in a suitable manner for subsequent disposal in accordance with relevant regulations.

4.2 Staffing and training principles for donation sessions

The medical consultant with responsibility for the donors in consultation with nursing and operational managers should ensure that there are adequate staffing levels and ensure that staff are properly trained. This consultant may delegate day-to-day clinical responsibility to appropriately trained clinical staff. When donors are undergoing leucapheresis procedures (e.g. granulocyte, lymphocyte, and peripheral blood progenitor cell collections) a suitably trained doctor must be immediately available to attend to the donor.

At sessions where component collection is performed one or more suitably trained doctors or registered nurses must be responsible for supervising the performance of venepunctures and for the supervision of machine procedures.

The administration of drugs, e.g. local anaesthetic and citrate, must be supervised by a registered professional in accordance with Guidelines for Administration of Medicines (October 1992)⁽³⁾. During donation, donors should never be left in a room without the presence of an appropriately trained doctor or registered nurse.

Training and certification of registered nurses undertaking donations procedures including training and monitoring of staff, performing venepunctures and obtaining informed consent, must be in accordance with the current Nursing and Midwifery Council (NMC) Code of Professional Conduct.⁽⁴⁾

The consultant in consultation with the nurse manager must ensure that there is an appropriate staffing level and skill mix to ensure donor safety and adequate monitoring of the equipment in use. They must ensure that, as a minimum requirement, all healthcare professionals involved with component procedures receive basic life support training annually.

At sessions where component collection is performed planned staffing levels should ensure that normally there is at least one member of suitably trained staff present for every two machines in use. For leucapheresis procedures, higher staffing ratios are required. A programme should be established for initial and continued training to ensure an appropriate level of proficiency.

The consultant with responsibility for donors must ensure that a manual of standard operating procedures (SOPs) is compiled in accordance with local quality assurance systems for whole blood collection and each type of component collection procedure. These SOPs must be regularly reviewed and updated and must take into account the machine manufacturer's operating instructions. A current copy of the relevant manufacturer's manual for each type of machine in use must be available on site.

4.3 Collection of the donation

The ultimate responsibility for ensuring that every unit of blood and blood components has been collected in accordance with the Blood Safety and Quality Regulations (2005) rests with the "Responsible Person" for the Blood Establishment. The advocacy and guardianship of high quality care for donors is the responsibility of the designated clinical lead in attendance and that must be a registered nurse or medical practitioner.

Guidance for whole blood and component donation procedures is given in Chapter 5. Guidance for laboratory testing procedures is given in Chapters 10 and 13.

4.4 Donor identification

Donors must positively identify themselves at registration by volunteering their name, date of birth and permanent address. Once registered for subsequent identification their name and date of birth is sufficient. The identity of the donor must be recorded and linked to the donation record.

4.5 Labelling

Session staff must ensure that a set of labels with a unique number is assigned to each donation and that the same unique number appears on the donor session record, the primary and secondary collection packs and all the sample tubes used. Great caution is necessary to avoid crossover or duplication of numbers. The working practice should be designed to minimise the risk of error. Arrangements should be such as to avoid the possibility of errors in the labelling of blood containers and blood samples. The blood or component bags and corresponding samples must not be removed from the donor's couch until a satisfactory check on correct labelling has been carried out. It is recommended that each donor couch has its own individual facilities for the handling of samples during donation and labelling.

Packs, sample tubes and the donor session record must never be relabelled. Unused sets of numbers must be accounted for. Labels which have been discarded must not be retrieved.

4.6 Records

It is strongly recommended that all records pertaining to donor and donation identity be entered and maintained in an electronic format which can be accessed readily by approved and qualified personnel, and in a manner which preserves donor confidentiality in accordance with legal requirements. Machine-readable systems for identifying donors and donation derivatives are also recommended. Initial documentation – for example, on session records – may be taken manually and archived for the required period in law, with relevant portions transcribed electronically whenever convenient operationally.

Donor session records

A record of the sessional venue, the date, the donation number and the identity of all donors attending must be maintained. For any donors who are deferred, rejected or retired, the full details must be recorded and the reasons given for the action taken.

The records of blood donation sessions should allow identification of each important step associated with the donation. All donations must be recorded; the reason for any unsuccessful donations must be recorded. All

adverse reactions must also be recorded together with the action taken. Full details of any other incidents, including those only involving staff must be recorded.

These records should be used for the regular compilation of statistics which should be studied monthly by those responsible for activities concerned with the organization and management of blood collection sessions.

4.7 Control of purchased material and services

Specification and inspection of blood bags

Blood collection shall be by aseptic techniques using a sterile closed system and a single venepuncture. The integrity of the system must be checked prior to use and measures must be taken to prevent non-sterile air entering the system.

Blood shall be collected into containers that are pyrogen-free and sterile, containing sufficient licensed anticoagulant for the quantity and purpose of blood to be collected.

The container label shall state the kind and amount of anticoagulant, the amount of blood that can be collected, and the required storage temperature.

Manufacturers' directions regarding storage, use and expiry dates of the packs whose outer containers have been opened and resealed must be adhered to.

Batch numbers of the blood packs used shall be recorded.

The donation number on the pack sample tubes should be checked at the end of the donation to ensure that those for a given donation are identical i.e. the donation number on the donor health and lifestyle questionnaire, the primary and secondary collection packs and the sample tubes must all be identical.

Prior to release from the blood collection session the pack and its associated tubing should be reinspected for defects and its integrity should be checked by applying pressure to the pack to detect any leaks. Any defective pack should be marked for disposal and held separately from intact packs. Details of the defect(s) should be recorded for future analysis and action (see Section 5.11).

Specification of apheresis sets

Blood components must be collected by apheresis using sterile, single use, disposable items that are licensed and CE marked. The apheresis set for collection of components for direct clinical use must have a pre-connected access needle to ensure a sterile pathway, and incorporate a bacterial filter in all nonpre-connected fluid lines (e.g. saline, SAG-M, and the anticoagulant line [not required if anticoagulant bag is pre-connected]). For dual needle procedures a pre-connected needle is only essential for the access venepuncture.

A record must be kept of all lot and/or batch numbers of all the apheresis set components and injectable materials used, in accordance with local quality systems.

Specifications for automated donor apheresis machines (see also Section 9.5)

Machines must be correctly installed and commissioned according to each manufacturer's instructions. They must be CE marked.

The environment and operating area for each machine employed and the power supply available, must conform to the manufacturer's recommendations for satisfactory machine performance.

Machines must comply with the relevant aspects of the Health and Safety at Work Act 1974,⁽⁵⁾ and Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture⁽⁶⁾.

Automated apheresis machines must have the following features:

- a manual override system so that the operator can stop the automatic cycle at any time during the procedure

a blood flow monitor, to monitor blood flow during blood withdrawal and return. The purpose is to ensure that the selected donor flow rate does not cause collapse of the donor's vein and to monitor the venous pressure during the donor blood return cycle such that if any obstruction to flow occurs, the blood pump will automatically reduce speed and/or stop. In either event a visual and audible alarm system should operate

an in-line air detector to protect the donor from air embolism. In the event of air entering the extra-corporeal circuit a visible and audible alarm must be activated, the return blood pump must automatically stop and the venous return line must automatically be occluded

a blood filter integral with the harness to prevent any aggregates formed during the procedure from being returned to the donor

an anticoagulant flow indicator, providing a visible means of monitoring anticoagulant delivery throughout the procedure, and ideally an audible alarm if no anticoagulant is flowing

a device for pre-setting the collection volume, monitoring the collection volume during the procedure and automatically ending the procedure. A system with a visual and audible alarm to notify the operator of the completion of the procedure may be provided

in the event of a power failure the machine must automatically enter a standby mode once power returns.

Apheresis machines must be serviced in accordance with the manufacturer's instructions. A planned maintenance scheme should be followed. Machine maintenance and servicing must be documented and be in accordance with the procedures outlined in the appropriate Medicines and Healthcare Products Regulatory Agency publications: DB 9801, DB 9801 Supplement 1 and DB 2000(02).⁽⁷⁾

Apheresis machines must be routinely cleaned with a suitable decontaminating agent on a daily basis. A standard procedure for dealing immediately with blood spillage must be in operation.

Anticoagulant

A licensed citrate anticoagulant must be used at a ratio which achieves a final plasma citrate concentration of 15–25 mmol/L in the collected component (see Chapter 3 Appendix II).

The anticoagulant must be in date, with no evidence of particles or leakage. Any suspect unit must not be used. The batch number must be recorded on the session record and any defect reported in accordance with local quality systems.

4.8 Protection and preservation of product quality

All whole blood and apheresis components must be transported, tested and stored in accordance with the specifications for blood components in Chapters 7 and 8.

References

1. Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007, available at <http://www.mhra.gov.uk/Publications/Regulatoryguidance/Medicines/Othermedicinesregulatoryguidance/CO N2030291>
2. World Health Organization (1994) WHO Expert Committee on Biological Standardisation. World Health Organ. Tech. Rep. Ser., 840, pp1–218.
3. Standards for Medicines Management (2007) available at www.nmc-uk.org/publications/standards
4. Nursing and Midwifery Council (NMC). Code of Professional Conduct, available at www.nmc-uk.org.
5. Health and Safety at Work Act 1974, available at www.legislation.gov.uk
6. Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture available at www.ispe.org.

7. Medicines and Healthcare Products Regulatory Agency publications available at www.mhra.gov.uk:
DB 9801 Medical Device and Equipment Management for Hospital and Community-based Organisations.
DB 9801 Supplement 1 Checks and Tests for Newly Delivered Medical Devices.
DB 2000(02) Medical Device and Equipment Management: Repair and Maintenance Provision.

Chapter 5

Collection of a blood or component donation

Introduction

This chapter describes the steps involved in the collection of a blood or component donation from the information to be provided to a donor to the information required from the donor post-donation.

Sections 5.1 and 5.2 are taken from the Blood Safety and Quality Regulations 2005.⁽¹⁾

5.1 Information to be provided to prospective donors of blood or blood components

Accurate educational materials, which are written in terms which can be understood by members of the general public, about the essential nature of blood, the blood donation procedure, blood components, and the important benefits to patients

For both allogeneic and autologous donations, the reasons for requiring a medical history, the testing of donations and the significance of informed consent

For allogeneic donations, the criteria for self-deferral, temporary and permanent deferral, and the reasons why individuals are not to donate blood or blood components if there could be a substantive risk for them or the recipient

For autologous donations, the possibility of deferral and the reasons why the donation procedure would not take place in the presence of a health risk to the individual whether as donor or recipient of the autologous blood or blood components

Information on the protection of personal data, including confirmation that there will be no disclosure of the identity of the donor, of information concerning the donor's health and of the results of the tests performed, other than in accordance with the requirements of these Regulations

The reasons why individuals are not to make donations which may be detrimental to their health

Specific information on the nature of the procedures involved either in the allogeneic or autologous donation process and their respective associated risks. For autologous donations, the possibility that the autologous blood and blood components may not suffice for the intended transfusion requirements

Information on the option for donors to change their mind about donating prior to proceeding further, or the possibility of withdrawing or self-deferring at any time during or after the donation process, without any undue embarrassment or discomfort

The reasons why it is important that donors inform the blood establishment of any subsequent event that may render any prior donation unsuitable for transfusion

Information on the responsibility of the blood establishment to inform the donor, through an appropriate mechanism, if test results show any abnormality of significance to the donor's health

Information explaining why unused autologous blood and blood components will be discarded and not transfused to other patients

Information that test results detecting markers for viruses, such as HIV, HBV, HCV or other relevant blood transmissible microbiologic agents, will result in donor deferral and destruction of the collected unit

Information on the opportunity for donors to ask questions at any time

If the donated blood is to be used for purposes other than clinical transfusion specific information must be provided.

5.2 Information to be obtained from donors by blood establishments at every donation

Donor identification

Donors must positively identify themselves by volunteering their name, date of birth and permanent address. The identity of the donor must be recorded and linked to the donation record.

Health and medical history of the donor

Health and medical history, provided on a questionnaire and through a confidential personal interview performed by a qualified health professional, must be assessed. This will include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or health risks to themselves. Donors must be selected in accordance with the current JPAC Donor Selection Guidelines⁽²⁾ which form a constituent part of Chapter 3.

Signature of the donor

The donor must sign the donor questionnaire, countersigned by the qualified health professional responsible for obtaining the health history confirming that the donor has

read and understood the educational materials provided

had an opportunity to ask questions

been provided with satisfactory responses to any questions asked

given informed consent to proceed with the donation process (see Chapter 3)

been informed, in the case of autologous donations, that the donated blood and blood components may not be sufficient for the intended transfusion requirements

acknowledged that all the information provided by the donor is true to the best of their knowledge.

5.3 Haemoglobin screening

The objective is to ensure that prior to each donation the donor has a minimum acceptable haemoglobin concentration (currently at least 125 g/L in females and at least 135 g/L in males). In the UK, testing using the gravimetric method is widely used for blood donor screening, usually backed up by a second level (spectrophotometric) test. Several non-invasive techniques are currently being evaluated.

Copper sulphate haemoglobin screen

Aqueous copper sulphate, coloured blue, with a specific gravity of 1.053, equivalent to 125 g/L haemoglobin is normally used to test female donors. Copper sulphate, coloured green, with a specific gravity of 1.055, equivalent to 135 g/L is normally used to test male donors. These stock solutions should be colour-coded and labelled accordingly.

Copper sulphate storage

Stock solutions shall be stored at room temperature in tightly capped, dark glass containers to prevent evaporation and contamination. Copper sulphate solutions must not be frozen or exposed to high temperatures. The specific gravity of each batch in the stock solution should be checked at least weekly by designated staff with a calibrated hydrometer. The date, the result and the name of the individual who carried out the check must be recorded on the bottle. Alternatively, copper sulphate solutions of required standards may be obtained in individually labelled containers, predispensed in 25 to 30 mL aliquots direct from manufacturers.

Copper sulphate for routine use

Designated staff shall be responsible for dispensing the stock solutions for sessional use. The solution shall be well mixed before dispensing the required amount of each solution into appropriately labelled, clean, dry tubes or bottles. These solutions shall be changed daily or after 25 tests, depending on the volume of

solution dispensed, otherwise contamination of the solution will affect the accuracy of the test. Any used solution at the end of a session shall be discarded in accordance with relevant regulations. The calibration temperature of the copper sulphate must be that specified by the manufacturer to provide the correct specific gravity, e.g. cupric sulphate MAR, (material conforming to the AnalaR specification) has the correct specific gravity for Hb estimations at 15.5 °C. If kept chilled, the copper sulphate solutions must be given time to warm to ambient temperatures prior to use. When dispensed or kept in plastic containers, care must be taken to avoid accumulation of electrostatic charge, as this can interfere with penetration by blood drops.

Procedure for estimating Hb concentration on a fingerprick blood sample using copper sulphate

1. The skin at the chosen site on the finger must be cleaned with antiseptic solution and wiped clean with sterile gauze or cotton wool. The skin must be punctured firmly, near the end but slightly to the side of the finger, with a sterile disposable lancet, or spring loaded disposable needle system. A good free flow of blood must be obtained
2. The first drop of blood should be discarded and the finger should not be squeezed repeatedly as this may dilute the blood with tissue fluid and give falsely low results
3. Blood from earlobe puncture should not be used as it has a higher haemoglobin and haematocrit than blood from a fingerprick sample and may allow donors with unsuitably low levels to give blood
4. The blood is collected into a pastette without any air entry as this may prevent or delay the delivery of the drop
5. One drop of blood is allowed to fall by unassisted gravity from the tube from a height of 1 cm above the surface of the copper sulphate solution. The drop is observed for 15 seconds. If the drop of blood has a higher specific gravity than the solution, it will sink within 15 seconds. If not, the sinking drop will hesitate, remain suspended, or rise to the top of the solution
6. Results are recorded as pass or fail.

Spectrophotometric method for Hb concentration screening

1. If a haemoglobin photometer (or other validated method) is used to provide a quantitative measurement of Hb at the donor session, standard operating procedures for the use of the instrument must be available in the session procedure manual
2. They should include a technique whereby the performance of the meter is validated by the regular use of appropriate calibration working standards
3. In addition, a system of regular and frequent assessment of the accuracy of performance of any equipment must be established.

5.4 Preparation of the venepuncture site

Blood must be drawn from a suitable vein in the antecubital fossa in an area that is free of skin lesions. The veins can be made more prominent by using appropriate means of venous occlusion.

Although it is not possible to guarantee sterility of the skin surface for venepuncture, a strict standardized and validated procedure for the preparation of the venepuncture site should be in operation to achieve surgical cleanliness and thus to provide maximum possible assurance of a sterile product.

The antiseptic solution used must be allowed to dry completely after application to the donor's skin, or the skin wiped dry with sterile gauze before venepuncture. Thereafter, the prepared area must not be touched with fingers before the needle is inserted.

5.5 Preparation of the blood pack

Whole Blood pack

The blood collection set must be in date and inspected for any defects. These are sometimes obscured by the label attached to the container, so careful inspection is required.

Moisture on the surface of a plastic pack after unpacking should arouse suspicion of a leak and if one or more packs in any packet is found to be abnormally damp, none of the packs in that container can be used. The solution in the set should be checked for clarity and must be clear before accepting the packs for use.

The blood pack is positioned below the level of the donor's arm and the blood collection tube must be clamped off.

The method used for monitoring the volume of blood removed shall be checked to be in working order and the pack placed in the correct position for the method to be effective.

Apheresis Sets

The complete apheresis set and individual packaging must be thoroughly inspected for faults prior to use and during the setting up procedure. The set must be in date and a search made for set faults such as kinks, occlusions, points of weakness or leaks that may only become detectable during the setting up and priming procedure before the donor is attached to the set.

If an occlusive kink that cannot be remedied or a leak becomes apparent during a procedure then that procedure must be abandoned and any blood constituents remaining in the disposable must not be returned to the donor.

Any faults detected before or during a procedure must be recorded in accordance with local quality systems. Any defects must be reported (see Section 5.11).

If there is any doubt about the integrity of any set, it must not be used but retained for inspection and returned to the manufacturer if deemed necessary.

Labels

Labelling: whole blood and apheresis packs and donor sample tubes must be labelled in accordance with local SOPs.

All donors' records and labels should be checked for printing errors. Duplicate number sets shall not be used and these and missing numbers shall be reported via a designated senior manager to the printer concerned and to the Chairman of the National Working Party or equivalent on machine-readable labels.

5.6 Performance of the venepuncture

Venepuncture should only be undertaken by authorized and trained personnel. If local anaesthetic is used, this should be a licensed medicinal product and injected in a manner which avoids any chance of donor-to-donor cross-infection (e.g. using individual disposable syringes and needles). A record of the batch number(s) should be made at each blood collection session and be capable of being related to individual donors.

Containers of local anaesthetic should be inspected for any leakage and if glass, inspected for cracks. Any suspect containers should be rejected.

Unused material must be discarded at the end of each donor session.

An aseptic technique must be used for drawing up the local anaesthetic into the syringe and the needle changed prior to the injection of the local anaesthetic.

Items used for venepuncture must be sterile, single use and disposable. If the dry outer wrapping of sterile packs becomes wet the contents must not be used. Prior to use, session staff must ensure that the materials used for venepuncture are sterile, in date and suitable for the procedure to be undertaken. The sterile donor needle should not be uncovered and its tamper-proof cover checked for integrity immediately prior to the venepuncture.

As soon as the venepuncture has been performed, the clamp on the bleed line must be released.

It is important that a clean skilful venepuncture is carried out to ensure the collection of a full, clot-free unit of blood suitable for the preparation of labile blood components.

The tubing attached to the needle should be taped to hold the needle in place during the donation.

Sample collection

At the start of the donation 30 ml (up to 45 mL in some circumstances) of blood should be diverted into a pouch. It is recommended that this pouch has a means of access opposite the entry line which allows blood to be sampled for haematological and serological testing without compromising the environmental integrity of the blood in the main pack.

5.7 Whole Blood donation

If necessary, the donor should be asked to open and close his/her hand slowly every 10-12 seconds to encourage a free flow of blood.

The donor must never be left unattended during or immediately after donation and should be kept under observation throughout the phlebotomy.

Blood anticoagulation

The blood and anticoagulant should be mixed gently and periodically (at least every 60 seconds) during collection. Mixing should be achieved by manual inversion of the blood pack, or automatically by placing the blood pack on a mechanical agitator or by using a rocking device.

Blood flow

Blood flow should be constantly observed to ensure that the flow is uninterrupted. Blood should be mixed regularly during the period of donation which should not exceed 15 minutes.

Blood volume monitoring

The volume of blood withdrawn must be controlled to protect the donor from excessive loss of blood and to maintain the correct proportion of anticoagulant to blood.

The most efficient way of measuring the blood volume in plastic bags is by weight. The mean weight of 1 mL of blood is 1.06 g; e.g., a unit containing 470 mL of blood should therefore weigh 470×1.06 g plus the weight of the pack(s) and the anticoagulant.

If it is not possible to adjust the weighing device in use for the tare weight of the container and anticoagulant solution it is advisable to record the minimum and maximum weight for the brand of pack in use as products from different manufacturers may vary considerably.

Several kinds of weighing equipment are available and such devices should be used according to the manufacturer's instructions for weighing blood into its plastic pack and periodically calibrated by appropriate techniques.

Completion of the donation

The pressure cuff must be deflated and the needle then removed from the arm. Immediate pressure must then be applied to the venepuncture site through a suitable clean dressing.

The needle must be discarded into a special container designed to minimize risk to personnel.

The pack must be inverted gently several times to ensure the contents are thoroughly mixed.

For pack systems designed for in-line leucodepletion in which the donor line becomes detached from the final red cell pack, and hence unavailable for compatibility testing, the line should be sealed close to the collection pack, according to clearly defined procedures. This sealing may be done without expressing the contents of the line into the main pack if the contents of the line are deemed to be of no further use.

The arm and general well-being of the donor should be checked before the donor leaves the session venue.

5.8 Component Donation by Apheresis

Guidance for collection procedures is identical to that for normal whole blood donations except for the following points:

Performance of the venepuncture: once the venepuncture is performed subsequent procedures such as releasing clamps on the bleed line should follow the protocol for the particular type of apheresis procedure being undertaken.

Anticoagulation: occurs automatically in apheresis, but instructions are needed to ensure apheresis machine operators monitor flow of anticoagulant.

Consideration should be given to withdrawing donors who repeatedly show signs and/or symptoms of citrate toxicity from the apheresis panel. The practice of prophylactic oral supplementation with calcium should be discouraged.

Blood flow and monitoring: blood flow occurs automatically in apheresis, unless a satisfactory flow rate cannot be maintained.

Instructions are needed for the apheresis operator in the event of a low flow or no flow situation. Particular care is needed when monitoring the return flow rate since most apheresis procedures operate with a pumped red cell return such that haematomas can rapidly form unless appropriate action is taken to prevent this from occurring.

Sample collection: in apheresis sampling should take place at the beginning of a donation. The methods employed shall ensure an aseptic technique with no risk of contamination and be clearly defined in the sessional procedures SOP manual.

Completion of the donation and quality control samples: a length of tubing should be left attached to the collection pack(s) as required for laboratory testing purposes. All used disposable equipment must be discarded in such a way as to prevent any risk to personnel, according to Health and Safety regulations.

Final donation inspection: the collected apheresis components must be inspected routinely for the presence of haemolysis, unwanted red cell contamination, other abnormal appearance or evidence of clotting. Such changes may require a review of the apheresis procedure and/or equipment. Any suspected apheresis component abnormality must be recorded, the donation identified and reported in accordance with local quality systems.

5.9 Information to be provided to the donor post-donation

The donor must be provided with information on care of the venepuncture site and requested to report any illness occurring within 14 days of donation. They will already have been made aware of the importance of informing the blood establishment of any event that may render their donation unsuitable for clinical transfusion.

5.10 Adverse reactions in donors

The care of all donors at blood collection venues should incorporate research-based therapeutic interventions to reduce the risk of adverse events of donation. An example of the preventative measures that can be implemented are described in 'Points of Care' used within one UK Blood service (see Appendix I). This is a donation care pathway designed to minimise vasovagal events, bruising and re-bleeding from the venepuncture site.

All adverse reactions in donors should be documented and reported according to standard protocols. It is recommended that as a minimum data is collected and reviewed on all Donor Adverse events of donation using the International Haemovigilance Network (IHN) definitions of DAEDs (Appendix II) or similar and a standard data set for Serious Adverse Events of Donation (SAEDs) that is in line with the IHN definitions of SAEDs (Appendix III). This will allow comparison over time and between services of event rates, and monitor the effectiveness of any interventions to reduce event rates. SAEDs should all be fully investigated with a root cause analysis or similar tool to ensure that proper preventative and corrective actions are implemented.

Serious adverse reactions occurring in donors during or post donation must be reported to the Competent Authority according to the blood establishment protocol.

5.11 Adverse events

All adverse events must be documented and reported according to standard protocols.

All bag/harness defects, e.g. pinhole leaks, must be recorded and all defects should be reported to the Quality Assurance Manager. If the defect appears to be batch-related, all packs and blood collected in them must be set aside for further investigation.

Any safety-related defects in equipment, including single use items, must be reported via the head of department to the Department of Health in accordance with the requirements of the Competent Authority, currently the Medicines and Healthcare Products Regulatory Agency.⁽³⁾

Serious adverse events must be reported to the Competent Authority according to the blood establishment protocol.⁽³⁾

5.12 Donor compensation

The Transfusion Services should have established procedures to ensure that any claim by a donor for compensation for any injury or loss allegedly attributable to having donated by apheresis will be considered sympathetically and decided promptly. A system of ex gratia payments and compensation operates throughout the UK Blood Services on an individual donor basis within a legal framework.

References

1. Statutory Instrument 2005 No. 50. The Blood Safety and Quality Regulations 2005. ISBN 0 11 051622 2 available at www.legislation.gov.uk
2. Joint UKBTS/NIBSC Professional Advisory Committee's (JPAC) Donor Selection Guidelines available at www.transfusionguidelines.org.uk
3. Online reporting is available at www.mhra.gov.uk

Welcomer
<ul style="list-style-type: none"> • A principle role of the Welcomer is to reduce potential anxiety in the donor. Observe for donors in a 'hyper vigilant' state and refer where appropriate. • Professionalism, including appearance, is crucial in order to assure the donor of a safe and positive experience. • Greet the donor with a warm welcome and thank them for attending the session and giving up their time to donate blood. • The Welcomer needs to promote drinks to the donors. Offer the donor 500mls of fluid to stretch the stomach (gastric dilation) and raise blood pressure (BP), reducing the risk of vaso vagal (VV) episodes. This offer or promotion of drinks must be emphasised quite strongly in order for the donor to understand the importance of taking the fluid. Ideally the fluid should be drunk over 5 minutes rather than sipped, and should be taken no longer than 30 minutes prior to donation for best affect. The nurse or supervisor may wish to change the position of the water area on session in line with donor waiting times. An information leaflet for donors is available. • If possible, donors who are queuing to give their details should be offered fluids along with an explanation of why there is a delay. • Donors who are waiting to be screened must not be sat facing the pods. The eyes of all waiting donors ideally need to be focused away from clinical activity. • Ensure all donors are given the Welcome information to read prior to screening.
Screening
<ul style="list-style-type: none"> • Enquire as to whether the donor has had any previous problems when donating blood and try to relieve any anxiety. • Ask the donor about their preparation for giving blood e.g. have they had something to eat before attending the session / have they avoided doing any strenuous activity or exercise regime that may increase their risk of an adverse event. • If a previous adverse event is identified or the donor has an increased risk of an adverse event, a nurse should be asked to speak to the donor. The nurse will also instruct the donor on how to do applied muscle tension (AMT) exercises to raise the BP if appropriate. • Ask the donor if they have drunk the recommended volumes of fluid prior to the screening. If they have not, it needs to be explained to the donor why drinking fluids is important and offer again. If the donor agrees to drink, give the fluids whilst talking. • Ensure new donors and those with a previous history or higher risk of VV episode/s are indicated in some way. This will help easily identify those with a higher risk of complication or adverse event. • Once screening is complete, show the donor to the waiting area, which must not have chairs facing the beds. Magazines and reading material should be available as a method of distracting the waiting donors from focusing on the clinical area. It is important to reduce tension and anxiety that will be experienced by many first time donors and those who may have had a problem donating or an adverse event in the past. Additional fluids could be offered at this point too.
Beds
<ul style="list-style-type: none"> • Prioritise donors and provide appropriate therapeutic attention. Talking to donors will allow you to recognise their coping strategies and how best to put them at their ease. • If required, in order to raise the donor's BP, once they are on the bed, ask the donor to commence AMT exercises. This keeps their mind occupied as they are counting and their focus away from the venepuncture (VP). • Where donation chairs are used the donor should be reclined at an angle of 45degrees from the hip. • Do not leave the donor before starting VP. Aim to have the pack labelled and VP started promptly to prevent the donor's BP from being affected. • If an adverse event occurs, a nurse should decide if it is clinically necessary to screen off the donor to ensure privacy for the person involved and to avoid raising anxiety levels in those who are waiting. Screens should be placed around the donor, but initially if necessary, place your body between the donor and the waiting donors to block their view until screens arrive. Donors should never be left unattended behind a screen. • Non donating family/friends are welcome, but must sit by the donor and not stand by the bed.

- Once the donation is complete, remove the needle and cover the VP site with gauze, asking the donor to apply firm pressure with 3 fingers to the dressing.
- Sit the donor up, extending their legs out in front of them if possible.
- Stay with the donor until they leave the bed. Use the time to complete any observations, give advice to the donor, assess pallor and ensure the donor is applying the correct pressure to their arm.
- After 1 minute the donor can move their legs over the side of the bed. After a further minute if the site is observed, do so by lifting the gauze without removing it, to protect the donor from any blood splash. This also shields the donor from seeing the VP site, if there is no new bleeding, apply the dressing.

Appointments & Teas

- Ensure the computer does not obscure your direct vision of the donors.
- Ensure there is adequate space around the tea table and chairs in case of falls and potential head injury.
- Stress to donors who refuse a drink, the importance of having a post donation drink to replace fluid depletion.
- Encourage new donors and those with a previous VV episode to have cold drinks.
- Deal with re-bleeds promptly. Try to ensure nearby donors see as little as possible.
- If a donor becomes unwell, stay with them and call for assistance.
- When giving post donation advice, take care not to embarrass donors or trigger other donors to listen in to the conversation

Appendix II

International Haemovigilance Categories for Donor Adverse events

A. Complications mainly with local symptoms.

A 1. Complications mainly characterized by the occurrence of blood out-side the vessels.

Haematoma

A haematoma is an accumulation of blood in the tissues outside the vessels.

Arterial puncture

Arterial puncture is a puncture of the brachial artery or of one of its branches by the needle used for bleeding of donor.

Delayed bleeding

Delayed bleeding is spontaneous recommencement of bleeding from the venepuncture site, which occurs after donor has left the donation site.

A 2. Complications mainly characterized by pain

Nerve irritation

Irritation of a nerve by pressure from a haematoma.

Nerve injury

Injury of a nerve by the needle at insertion or withdrawal.

Tendon injury

Injury of a tendon by the needle.

Painful arm

Cases characterized mainly by severe local and radiating pain in the arm used for the donation and arising during or within hours following donation, but without further details to permit classification in one of the already more specific categories mentioned above.

A 3 Other kinds of categories with local symptoms

Thrombophlebitis

Inflammation in a vein associated with a thrombus

Allergy (local)

Allergic type skin reaction at the venepuncture site caused by allergens in solutions used for disinfection of the arm or allergens from the needle.

B. Complications mainly with generalized symptoms.

Vasovagal reaction

A vasovagal reaction is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (faint).

Immediate Vasovagal reaction

Symptoms occurred before donor has left the donation site

Immediate Vasovagal Reaction with injury

Injury caused by falls or accidents in donors with a vasovagal reaction and unconsciousness before donor has left the donation site

Delayed Vasovagal Reaction

Symptoms occurred after donor has left the donation site.

Delayed Vasovagal Reaction with injury

Injury caused by falls or accidents in donors with a vasovagal reaction and unconsciousness after donor has left the donation site.

C. Complications related to apheresis

Citrate reaction

Haemolysis

Generalised allergic reaction

Air embolism

D. Other complications related to blood donation

Appendix III

International Haemovigilance Definition of Severe Donor Adverse Events

Conditions which define a case as severe are:

Hospitalization: If it was attributable to the complication.

Intervention: To preclude permanent damage or impairment of a body function
To prevent death (life- threatening)

Symptoms: Causing significant disability or incapacity following a complication of blood donation and persisted for more than a year after the donation (Long term morbidity)

Death: If it follows a complication of blood donation and the death was possibly, probably or definitely related to the donation.

For the purpose of consistent reporting of Serious Adverse Events of Donation the UKBTs have adopted these categories:

SAED Category
Death within 7 days of donation
Hospital admission within 24hrs of donation
Injury resulting in a fracture within 24 hrs
Road Traffic Collision (RTC) within 24hrs of donation
Acute Coronary Syndrome (ACS) diagnosed within 24hrs of donation
Problems relating to needle insertion persisting for more than a year
Anaphylaxis, haemolysis or air embolism (CD)