SECTION 8.1

ADVERSE EVENTS AND REACTIONS DURING BLOOD DONATION

8.1.1 Introduction

Donor safety is of paramount importance during blood sessions and is assured, in so far as it can be, by donor selection guidelines, SOPs, adequately trained staff and appropriate facilities. Despite these measures, various adverse events and reactions can and do occur during and after blood donation. These complications can be a negative experience for donors. Preventing them must be a priority.

Blood establishments have a duty of care to minimise the risks to donors. This is particularly so, as donating is of no proven health benefit for donors (other than for those who have haemochromatosis). The uneven risk-to-benefit ratio for blood donors also places an ethical responsibility on health care givers, the users of blood donations, to avoid wastage and unnecessary use of blood transfusions.

When donor complications do occur, it is essential that they are managed appropriately. It is also essential that blood establishments analyse their complication rates and compare their data with those of other blood services, so as to promote best practice.

This section will categorise types of complications, identify guidelines for managing and preventing complications, describe the effect of complications on donor motivation, and provide information on haemovigilance, notification and monitoring.

8.1.2 EU definitions

Accidents and errors may occur at any stage in the process that starts at blood collection and ends after transfusing a blood component to a patient. Serious adverse events and serious adverse reactions are defined by the European Union as follows [1].

Serious adverse event

Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.

Serious adverse reaction

Any unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.

Distinction between serious and non-serious

Adverse events and adverse reactions range in severity from mild to moderate to severe. The EU mandates that blood establishments notify the competent authority in their country of any serious adverse events or serious adverse reactions which may have an effect on the quality or safety of blood or blood components [1]. Subsection 8.1.4 deals with levels of severity in a more detailed way. More information on notification to competent authorities can be found in subsection 8.1.9.

8.1.3 Types and prevalence

This section focuses on adverse events and reactions that take place during and after blood donation. Section 8.2 will describe adverse events and reactions in other situations in the donor management process.

Description and classification: Adverse events and reactions can manifest themselves in several ways. To facilitate benchmarking, internationally accepted description and classification of adverse events and reactions was required. The *Working Group on Complications Related to Blood Donation*, a joint working group of the *International Society of Blood Transfusion* and the *European Haemovigliance Network* was established for this purpose. In the public arena, the group uses the term 'complication related to blood donation' in preference to 'adverse event or reaction'. However, the *Working Group* defines complications related to blood donations as 'adverse reactions or incidents related in time to a blood donation (whole blood or aphaeresis)' [2]. They classify complications into two main categories: those with predominantly local symptoms and those with predominantly generalized symptoms (the categorisation is shown in Box 1). The term 'complication related to blood donation' will be used in this entire section.

Complication statistics: Complications related to blood donation occur in about 1% of all whole blood donation procedures [3]. A higher frequency (3.5%) has been estimated from a donor haemovigilance programme on more than 6 million whole blood donations procedures in 2006 [4]. The differences in definitions most probably explain these different estimates of donor complication frequencies, but in any case donor reactions are relatively frequent. It is well recognised that certain categories of donors have higher reaction rates [5-8]. Young age and first-time donor status have been associated with higher reaction rates in many studies. Eder reported a complication rate of 10.7% in 16 and 17 year olds, 8.3% in 18 and 19 year olds and 2.8% in donors aged 20 years and older [5]. She also found a higher incidence of donation relation injury (particularly physical injury from syncope-related falls) in 16 and 17 year olds compared with older donors[5]. Wiltbank, and later Kamel in an extended study from the same group, found that compared to donors with no reactions, the strongest predictor of a reaction was a donor's blood volume of less than 3,500 ml [6, 8]. In addition, Kamel et al. showed that 24% of the moderate and severe vasovagal reactions of the study were delayed, occurring more than 15 minutes after the collection. These delayed reactions were significantly associated with female sex. Off-site delayed reactions (12% of the delayed reactions) were more likely to be associated with a fall, with head trauma, with other injury, and with the use of outside medical care [8].

Reporting limitations: It is also accepted that the reported rate of reactions is much less than the true reaction rate. Newman solicited information from 1,000 randomly selected donors three weeks after donation [9]. He found that 36% of donors had had one or more adverse events. The most common systemic adverse events were fatigue (7.8%), vasovagal symptoms (5.3%), and nausea and vomiting (1.1%). The most common arm findings were bruise (22.7%), arm soreness (10%) and haematoma (1.7%) [9].

Causes: Jorgensen found that approximately one-third of complications were caused by inserting the needle and two-thirds were vasovagal in nature [3]. He comments that 99% of all complications collated by the EHN/ISBT common working group for 2005 belonged to 4 common categories; vasovagal reactions (86% of all complications), haematomas (13%), nerve injuries (1%) and arterial punctures (0.4%). The other reported complications together account for 1% of all complications.

Specific complications: Some complications are specific to aphaeresis donations, e.g. citrate reactions, haemolysis, air emboli, allergic reactions to ethylene oxide used in the sterilisation of the harness, and thrombocytopenia and protein deficiency from excessive platelet or plasma donations respectively [10]. The majority of aphaeresis donors experience some mild citrate related side-effects e.g. metallic taste in the mouth and / or tingling around the lips. This is an accepted occurrence and is considered to be a physiological effect of the anti-coagulant used in aphaeresis donations. Most blood establishments will only report citrate related complications if they are moderate or severe or if they result in the donation being discontinued. Donors who donate granulocytes by aphaeresis may also experience allergic reactions to the sedimenting agent that is used and may report steroid or growth factor related side-effects.

Potential adverse long term consequences of donation, such as iron depletion with or without associated anaemia [11, 12] or increased bone resorption, as has been reported in aphaeresis donors [13], are not currently reported as complications of donation. However, this may change, given time.

Box 1. Description of categories of complications related to blood donation Source: Working Group on Complications Related to Blood Donation [2]

A: Complications mainly with local symptoms. These complications are directly caused by the insertion of the needle.

A1: Complications mainly characterized by the occurrence of blood outside the vessels
- haematoma
  accumulation of blood in the tissues outside the vessels
- arterial puncture
  puncture of the brachial artery or one of its branches
- delayed bleeding
  spontaneous recommencement of bleeding from the venepuncture site, which occurs after the donor has left the donation site

A2: 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
  severe local and radiating pain in the arm arising during or within hours following the donation, different from the other A2 categories

A3: Other kinds of categories with local symptoms
- thrombophlebitis
  inflammation in a vein associated with a thrombus
- allergy (local)
  allergic skin reaction at the venepuncture site caused by allergens in solutions used for disinfection of the arm, allergens from the needle, or from the band-aid

B: Complications mainly with generalized symptoms
- vasovagal reaction
  general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (fainting)
  - immediate vasovagal reaction symptoms occurred before the donor has left the donation site
  - immediate vasovagal reaction with injuryinjury caused by falls or accidents in donors with a vasovagal reaction and unconsciousness before the donor has left the donation site
  - delayed vasovagal reaction
    symptoms occurred after the 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 the donor has left the donation site

C: Complications related to aphaeresis
- citrate reaction
- haemolysis
- generalised allergic reaction
- air embolism

D: Other complications related to blood donation

8.1.4 Serious and non-serious; severe and non-severe

Complications range in severity from mild to moderate to severe. The European Union uses the term 'serious adverse events and reactions'. The EU compels blood establishments to notify serious complications that may influence the quality or safety of blood or blood components to their competent authorities. Subsection 8.1.8 will deal further with this notification. The term 'serious' used by the EU is comparable to that of 'severe' as defined by the *Working Group on Complications Related to Blood Donation* [2]. Non-severe complications are further classified as either 'mild' or 'moderate'. Box 2 gives an overview of the levels of severity as described by the working group.

Severity: The vast majority of all complications are mild. However, some rare complications are severe, such as accidents related to vasovagal reactions and nerve injuries with long-lasting symptoms [3]. These can have serious consequences for the donor and can impact on his or her daily life. Vasovagal reactions that occur after the donor has left the donation session are of particular concern, due to the potential for the donor to come to harm. These are called delayed reactions. It is believed that delayed vasovagal reactions account for 10% of all vasovagal reactions. Occasional deaths have occurred as a result of accidents following delayed vasovagal reactions [3]. Sorensen carried out a retrospective analysis of Danish data relating to 2.5 million donations [14]. He found that severe complications occurred with an incidence of 19 per 100,000 procedures; two-thirds of these were due to vasovagal reactions with loss of consciousness and one-third due to needle insertion.

Box 2. Severity of complications.
Source: Working Group on Complications Related to Blood donation [2]

Level of severity	Specification
Severe complications	Conditions which define a case as severe: - **Hospitalization:** if 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
Non-severe complications	Complications which do not satisfy any of the requirements for severe complications Non-severe complications may be subdivided into mild and moderate complications, for instance for the following categories: - **Haematoma** · mild: local discomfort during phlebotomy only minor pain or functional impairment · moderate: as mild but with major discomfort during normal activities - **Arterial puncture** · mild: no symptoms or local discomfort during phlebotomy or haematoma · moderate: local discomfort continuing after the collection was terminated - **Painful arm** (subcategory specified or not) · mild: symptoms for less than two weeks · moderate: symptoms for more than two weeks but less than 1 year - **Vasovagal reaction** · mild: subjective symptoms only · moderate: objective symptoms

8.1.5 Prevention strategies

Several strategies can be used to reduce the risk of complications occurring during and after blood donation.

Prevention of type A complications

Needle techniques: Good needle insertion techniques reduce the frequency and severity of Type A complications. Jorgensen and Sorensen give the following advice on needle insertion techniques [3].

- Always move the needle forward in a slow ongoing movement.
- If the needle is not inserted in the vein at the first attempt, it is not advisable to do a second try by moving the needle a little bit backwards, change direction, and then move forward again in a new direction, as this will increase the risk of injuries and occurrence of haematoma, and thereby the risk of a severe complication.
- Never try to insert the needle twice, using the same puncture site. Instead try the other arm.
- Never ask for or give help if insertion was not a success, as this will always include a try in a new direction.

Prevention of type B complications

Type B complications, characterised predominantly as generalised symptoms such as vasovagal reactions, require different precautionary measures. Jorgenson and Sorenson identify the following generally accepted, but not evidence-based, practices [3].

- **Gentle treatment** of the donor, providing refreshments before and after donation to reduce the risk of vasovagal reactions.
- **Observing the donor** during and after donation, treating the donor if a complication occurs and making sure the donor feels absolutely well before leaving the blood session.
- **Giving advice** to the donor on secondary bleeding, driving, rest and return to work after the donation. Asking the donor to contact the blood establishments if symptoms reoccur.
- **Applying pressure** to the venepuncture site and if necessary a pressure bandage if a haematoma is developing.

The prevention techniques for type B complications listed below have been suggested in several studies.

- **Muscle tension:** when a donor makes repeated and rhythmic contractions with the major muscle groups in his arms and legs, the blood flow to the brain can be increased in order to prevent fainting.[15, 16]
- **Distracting the donor** during the bleeding procedure. Watching a movie could reduce stress in a donor [17].
- **Water or caffeine loading.** Several studies have reported fewer complications when donors drink water or coffee before their donation [18, 19].

8.1.6 Management

Adequate management of complications during blood sessions serves several goals. First, it is essential for the health and wellbeing of donors. Second, proper management of complications helps to alleviate the negative effects complications may have on donor motivation and on donor return rates. Employees must be prepared and equipped to handle the most frequent complications. Protocols, training, first aid equipment and donor counselling are imperative.

Standard Operation Procedures

The management of complications must be clearly documented in Standard Operating Procedures (SOPs). The role of different professions e.g. medical doctors, nurses and donor attendants must be clearly outlined in these procedures. The SOPs must contain comprehensive information on the sequential steps that must be taken in the initial management of each complication and on the follow-up of donors after they have left the donation session. The indications for referring donors for further medical assessment or treatment e.g. to an Accident and Emergency Department must be clearly defined. The standard advice that is given to donors who have had complications must be specified. Some donors who have had severe complications may be advised not to donate again, e.g. a donor who had lost consciousness and suffered a head Injury. The type and severity of complication that will lead to a donor being advised not to donate again must be clearly defined.

Furthermore, the SOPs will give guidance on how to register the complication in the blood bank information system. It is also advisable to develop an SOP for volunteers. Volunteers, especially when they are assigned the task of observing donors after donation, must be informed of their responsibilities in case of a complication and must receive explicit instructions on the management of complications and on when to turn to blood bank staff for assistance. Volunteers must be happy to take on these duties and must be deemed competent to do so.

Training

Staff must be able to manage complications that occur during and after blood donation sessions. Frequent refresher instruction and training are recommended.

First aid equipment

Basic first aid equipment must be available at each blood session. Blood establishments vary in their practice with regard to the sophistication of the available equipment. For example, some blood services routinely carry Automated Emergency Defibrillators (AEDs) on all blood sessions, others do not.

Staff training: It is recommended that staff receive frequent refresher training and instruction on the use of the equipment that is available on their sessions. Providing effective, life-saving initial care for an illness or injury that can follow blood donation requires instruction and practical training. This is especially true where it relates to potentially life-threatening complications, such as those that require cardiopulmonary resuscitation.

AEDs: The use of AEDs does carry a risk of injury to the donor, if used inappropriately. Training is essential prior to use and only those who are competent in their use should use the equipment. Training is generally provided by attending a course, typically leading to certification. Due to regular changes in procedures and protocols, based on updated clinical knowledge, and to maintain skills, attendance at regular refresher courses or re-certification is necessary. First aid training is often available through community organisations such as the Red Cross or through commercial providers. This commercial training is commonly used for training of employees to perform first aid in their workplace.

Managing emergencies: Each blood establishment must have clearly defined procedures for managing emergency situations. These will include prior arrangements with local hospitals, medical doctors and the emergency services in order to assure the best possible and prompt care for donors in emergency situations.

Donor counselling

It is an essential element of good donor care that each donor who suffers a complication of donation be given specific advice about the complication. This advice should include information on the nature of the complication and on what the donor should expect over the course of the complication. If, for example, the donor has a haematoma he/she may expect bruising and discolouration that may be distal to the site of the venepuncture. Many donors are surprised and concerned when they experience bruising distal to the venepuncture site; thus, an adequate explanation of what to expect can alleviate unnecessary concern.

Donor advice: Donors should be advised on measures they should take to prevent the complication from getting worse. For example, it is worthwhile to inform donors not to use the donation arm for carrying heavy items such as bags of groceries if they have had a haematoma. They should also receive advice on how to prevent the complication from recurring at the next donation. If necessary, the donor can be referred to a General Practitioner or to an Accident & Emergency Department. Ideally, the verbal information given to the donor should also be available in a written format, such as a leaflet that the donor can take home.

24 hour access: It is also critical that blood services provide 24 hour access to advice for donors after donation. The 24 hour number should be readily available and all donors should be advised of its existence after donating, as some complications of donating only become apparent after the donor has left the blood session.

Donor follow-up: If donors have had a complication, the blood service should make every effort to contact the donor in the days after his/her donation to enquire as to how the donor is progressing. This is not only an essential element of good donor care, but is basic 'good customer relationships.' As the complication may have a negative effect on a donor's motivation to make a subsequent donation (Subsection 8.1.7), the follow-up of the donor and the provision of adequate information play an important role in encouraging the donor to continue to donate. (Section 8.3 contains a comprehensive description of the donor counselling process).

8.1.7 Effect on donor motivation - next donation

A negative experience during blood donation can have a negative effect on donor motivation. Several studies have shown that experiencing a complication during the bleeding procedure is an important factor that prevents donors from making a subsequent donation [20, 21]. France et al. [22] found that for light vasovagal reactions in whole blood donors the likelihood of returning for a next donation reduced by 20% for first time donors and by 33% for experienced donors. For moderate and severe vasovagal complications, return rates reduced by 50%. Gorlin and Petersen found that the more severe a complication, the lower the return rate [23]. Adequate handling of a complication, therefore, serves multiple goals: ensuring the donor's health and retaining the donor for a subsequent donation.

8.1.8 Haemovigilance and monitoring

Haemovigilance comprises a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in blood donors or recipients and the epidemiological follow-up of donors [1]. It is a system of surveillance and alarm, from blood collection to the follow-up of the recipients, gathering and analysing untoward effects of blood transfusion in order to correct their cause and prevent recurrence [24]. For blood donor management, haemovigilance related to complications occurring during and after blood donation is particularly relevant. Haemovigilance in relation to adverse patient outcomes is also important but lies outside the scope of this manual.

Ongoing complications monitoring: Most adverse event systems focus on severe complications. It is highly recommended that data on non-severe complications is also retained, in order that appropriate corrective and preventative action can be taken. Both severe and non-severe complications can be investigated, analysed and monitored so as to determine the root cause thereof. The resulting corrective and preventative actions taken will improve processes and procedures.

The use of a system to monitor adverse events in blood donors may be a useful adjunct to monitoring donor deferral rates. Used in conjunction with deferral codes, the information can be used to assess the impact of any changes to procedures or selection criteria. A useful example would be a change in the upper or lower age limit. When assessing the impact of this change, it would be useful to observe adverse event rates to ensure that there was no increase thereof. In addition, the availability of this data is useful to benchmark against the experiences of other organisations that apply different selection criteria. The data can help support the evidence base to change donor selection criteria, obviously within the limits set by the EU in Commission Directive 2004/33/EU [25].

8.1.9 Notification to competent authorities

Complications during blood donation occur in different grades of severity, as described in subsection 8.1.3. Articles 5.1 and 6.1 in EU Commission Directive 2005/61/EC [26] compel European member states to notify the competent authority in their country in cases of serious adverse events or reactions. In the DOMAINE survey on donor man-

agement, European blood establishments have reported that the average number of serious adverse reactions in donors in 2007 ranged from 0 to 0.06% of all blood donors.

Blood establishments are compelled to notify only the serious adverse events and reactions that influence the quality and safety of the blood components to their national competent authority. Directive 2005/61/EC [23] provides further specifications on the notification. All national competent authorities have to send an annual report on the notifications to the European Commission. Additional legislation on notification of complications during blood donation may be present at national level. Some European countries require notification of all serious adverse events and reactions, including the cases that did not affect the quality and safety of blood products.

8.1.10 Insurance

Donors who have suffered physical or material damage, related to a blood donation, may file a claim with the blood establishment. Blood establishments need to have a relevant insurance policy in order to cover the costs.

SECTION 8.2

ADVERSE EVENTS AND REACTIONS: OTHER SITUATIONS

8.2.1 Introduction

Besides complications during blood donation, as described in the previous section, several other adverse events may occur. This section concentrates on adverse events that also have an effect on donor management: post-donation infection or other information with consequences for blood safety and material damage.

8.2.2 Post-donation infection or safety information

This class of events relates to developments in relation to the donor that become apparent after the donation and blood screening results.

Post donation illness: Donors should be encouraged to report any illness, such as a viral infection, that occurs shortly after donation. Depending on the circumstances, it may be appropriate to recall blood components manufactured from the donation or to defer the donor temporarily or permanently.

Late donor information: This is where a donor gives information relevant to blood safety that they did not give at the interview, such as when they remembered that they had taken medication; had contact with someone suffering from an infection; or, for other reasons, had withheld personal information. Again, depending on the circumstances, it may be appropriate to recall blood components manufactured from the donation or to defer the donor temporarily or permanently.

Reactive screening tests: A blood sample that reacts in a screening test will typically be retested. A reactive laboratory test generally leads to discarding of the donated unit. Repeated reactive laboratory tests may lead to permanent deferral of the donor, referral for diagnostic confirmatory testing and counselling. Because of the risk of late seroconversion, a look-back procedure may be appropriate and the recipients of components manufactured from earlier donations identified. The look-back period will be determined by the window period for seroconversion associated with the specific infection.

8.2.3 Damage to donors and insurance

During a donation session accidents or serious events may happen, which may cause damage to a donor's possessions or loss of income. For example, spots of blood can accidentally fall on a donor's clothing, bag or other belongings, resulting in cleaning bills or replacement costs, while fainting could lead to work absenteeism or direct loss

of income. Donors who have suffered damage may ask the blood establishment to reimburse them for the costs involved. These costs are usually for nominal sums and most blood establishments are happy to do so, but may want to arrange a relevant insurance policy.

Insurance policies: Blood establishments need to have relevant insurance policies in place to cover the more unusual situations where larger amounts of money are involved e.g. if a donor was unfortunate enough to crash his/her car due to a delayed vasovagal. In this case the donor himself/herself may have been severely injured and the claim could be for a substantial amount for both personal injury, loss of earnings and damage to the donors' property.

SECTION 8.3

ESTABLISHING DONOR COUNSELLING SERVICES

8.3.1 Introduction

When significant results become evident or adverse events take place during any of the stages in the donor life cycle, counselling of the donor becomes important. A blood establishment can counsel adequately if one knows when to counsel and what outcomes to expect. Systems should be set in place to provide the ideal conditions for successful counselling.

To ensure that a donor receives proper counselling, a Blood Collecting Team, BCT, or blood establishment should have sufficient personnel and equipment, an adequate infrastructure and, above all, adequate time. However, what is meant by sufficient or adequate? This section outlines these aspects in more detail. Figure 1 shows in a flow chart what is basically happening.

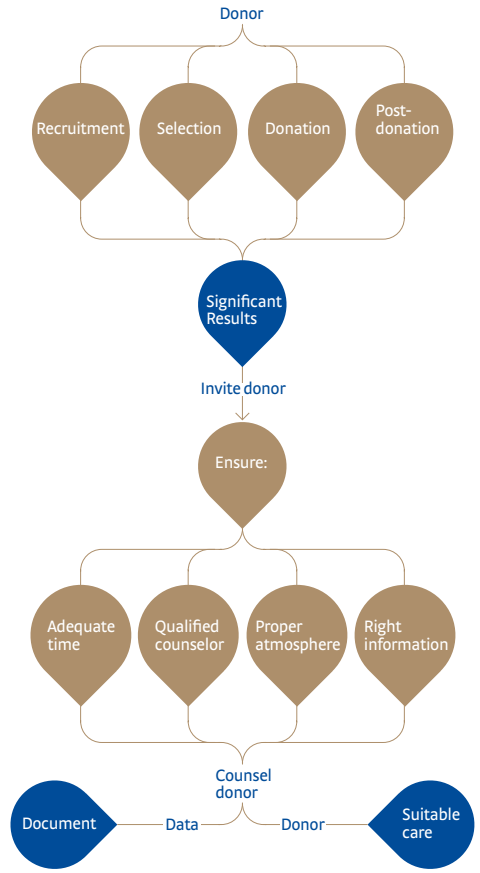

Figure 1. Counselling at a glance.

8.3.2 Categories of conditions requiring counselling in a blood establishment setting

Many conditions occur during everyday practice for which a blood establishment will have to counsel the donor. Important conditions include the following.

- Conditions disclosed by the donor resulting in temporary or permanent deferral (see Section 7.5 on donor selection and Section 7.6 on deferrals)
- Conditions identified during pre-donation health check
  - Anaemia resulting in temporary or permanent deferral
  - Hypertension resulting in temporary or permanent deferral
- Conditions observed during or after donation
  - Fainting/syncope: Managed according to SOP
  - Venepuncture-related problems: Managed according to SOP
- Conditions identified following blood tests
  - Serological findings: Irregular antibodies
  - Transfusion Transmittable Infections, TTIs: HBV, HCV, HIV, HTLV, Syphilis, Chagas' disease and other transmissible (infectious) diseases of regional importance
- Other conditions
  - Motivation of donors with special or rare phenotypes to get enrolled in a rare donor panel or aphaeresis programme
  - Donors who seek TTI testing and other health check-ups
  - Donors who ask for post-donation self-exclusion

8.3.3 Counselling process, basic elements

Regarding counselling requirements, one may distinguish two levels: basic elements and additional elements. Basic elements, or prerequisites for the donor counselling process, without which donor counselling could do more harm than good, are self-evident. In fact, analogous to the description of managerial targets, counselling must be SMART: Specific, Measurable, Accepted, Realistic, and Time-bound.

- **Specific:** When counselling takes place, no matters should be discussed other than the issue of immediate concern. Only then can successful counselling be envisaged. Discussing more than one topic almost unavoidably will result in confusion.
- **Measurable:** All counselling should be both consistent and accurate, leaving no doubt on the content of the message. The message must also be reproducible, meaning that the message, when given twice, should have the same content.
- **Accepted:** The counsellor should fully accept the donor and the donor's feelings, irrespective of their circumstances. Responses to the donor's needs must not be affected by the counsellor's feelings.
- **Realistic:** Counselling should be appropriate to the cultural settings and should preserve confidentiality boundaries at all times (see section on Ethics and legal considerations).
- **Time-bound:** Adequate time should be taken to counsel donors. Many times, the message will change the donor's life perspective. In taking adequate time, trust can be developed and the information is more likely to come across.

Fulfilling the criteria for SMART counselling can be achieved by making proper, preferably written, agreements with the staff of the blood establishment.

8.3.4 Counselling process, additional elements

Additional requirements for counselling relate to available staff, infrastructure, information, communications and documentation.

Staff

Sufficient and sufficiently trained personnel for counselling are of paramount importance, particularly when information of a sensitive (and potentially life-changing) nature is to be conveyed to unsuspecting donors. A blood establishment must take care of both these aspects.

- **Appointed counsellors** should be available in each BCT and at each blood collecting session. Almost any member of a BCT or any member of blood establishment-personnel, including blood establishment-volunteers, may face a donor in need of counselling. Nevertheless, it seems prudent to limit the number of counsellors. Preferably, in each BCT, trained counsellors should be present: one physician and one nurse. In addition, each blood establishment should appoint administrative personnel, trained to do counselling in straightforward, non-complex cases. However, in such a case, a trained counsellor (physician/nurse) must be available for back-up.
- **Background training**
  - **Physician-counsellor:** If a physician is part of the BCT, he/she could be the team counsellor. Also, when the physician is the only staff member to perform donor selection, he/she will be the obvious person to act as counsellor. However, in other cases, a physician could act as the back-up counsellor.
  - **Nurses** can also be counsellors, provided they are adequately trained. Depending on their background training they may treat more or less complex cases.
  - **Appointed administrative members** of the blood establishment may deal with straightforward donor eligibility queries, for example, when a potential donor phones asking how long he/she has to wait before donating after returning from a tropical holiday.

Infrastructure

The only physical requirement for the infrastructure where donor counselling takes place is that it should ensure adequate privacy, whether in a fixed location or mobile setting. This should be done in a friendly atmosphere and in a separate area where the counselling session is not overheard. Therefore, any part of a room, provided there is the possibility of avoiding direct contact with others, can be satisfactory. Preferably, each blood collecting site should have at its disposal a separate room that guarantees privacy and that has the right, clean atmosphere to maximize the possibility of getting a difficult message across.

Information and information systems

Language and phraseology of the written information available to hand over to donors after counselling must be easily understood by the target audience. This will ensure that the correct information is at hand when the donor returns home. The information should include important addresses and telephone numbers, in case the donor is in need of extra help.

Websites: Computerised information systems are an important tool in preventing mistakes and guaranteeing that the right information is available at each stage of the donation process. If available, internet facilities will greatly assist and speed up information transfer. To this end a blood establishment website that includes information on negative aspects of blood donations would be very helpful. Negative aspects, preferably with relevant links to other websites include the following elements.

- Risks in the blood transfusion chain from donor to patient
- Non-compliance with selection criteria
- Deferrals for negative medical findings
- Unintended effects of blood donation
- Untoward (laboratory) test results

Communication

At times the counsellor will want to refer the counselee to health care institutions. Moreover, some of the information is important for recipients of blood products, while authorities may want to be informed as well. Therefore, the blood establishment staff must have all the addresses and telephone numbers available of the following organisations.

- Local/regional health care facilities
- Users/receivers of blood products
- Authorities/government

Documentation

A donor management information system (donor registry), electronic or manual, to facilitate the counselling of the right donor at the right time must be in place. (See also Chapter 12 on Information Technology).

8.3.5 Possible outcomes of donor counselling

The content and outcome of the counselling session varies according to the issue to be addressed during the session. Table 1 lists the different outcomes of donor counselling in different situations.

The counselling or discussion objectives with the donor or potential donor vary and determine the content and the approach of such counselling. For example, counselling a donor with a rare blood group and convincing him to get enrolled in a rare donor panel to give more donations and save more lives initiates positive emotions. A donor receiving bad news about having tested positive for HIV will feel very differently. Therefore, it is very important to understand the different aspects of donor counselling and to identify the key elements to make such counselling sessions successful and beneficial to both the donor and the transfusion service.

Situation	Condition	Life-style issues	Psycho-social referral	Medical referral	Other actions, remarks
Temporary or permanent deferral					
Failure of donor selection criteria	Anaemia	Yes	No	?	Nutritional Advice, Iron status assessment
	Hypertension	No	No	Yes	Nutritional advice
	Other medical conditions requiring follow up	?	No	Yes	
	Risk factors for receiver	Yes	No	No	
Positive TTI screening test results	Hepatitis B	Yes	Yes	Yes	Alcohol/drugs, 3rd parties
	Hepatitis C	Yes	No	Yes	Alcohol/drugs, 3rd parties?
	HIV	Yes	?	Yes	3rd parties
	Syphilis	Yes	No	Yes	Medical referral depending on local practice, 3rd parties
	Chagas' disease	No	No	Yes	Medical referral depending on local practice
	Other TTI	?	?	?	WNV, Dengue, Malaria, SARS, Flu, ...?
Healthy donors					
Abnormal results	Donation related reactions: syncope, venepuncture	No	No	?	
	Abnormal test results interfering with the blood bank tests	No	No	No	Re-entry sometimes possible
	Previous donations resulted in serious complication for the recipient (e.g. TRALI)	No	No	No	
Donation related anxiety	Recruitment	No	No	No	
	First time donors	No	?	No	
Special Situations					
Donors with special features	Motivation of donors with special or rare phenotypes to get enrolled in a rare donor panel and/or aphaeresis programme	?	No	No	
	Donors who seek TTI testing and other health check-ups	Yes	No	?	
	Donors who ask for post-donation self-exclusion	?	?	?	Cultural aspects need consideration

Table 1. Different outcomes of donor counselling in different situations
? = to be determined

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MULTIPLE TRANSFUSED PATIENTS

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CHAPTER 09

SECTION 9.1

MULTIPLE-TRANSFUSED PATIENTS

9.1.1 Introduction

This section describes patients who constitute the multiple-transfused or special patient groups. In addition, it covers issues dealing with the procedures that blood establishments have implemented in order to cover needs in blood and blood products of the various groups of multiple-transfused patients identified in the DOMAINE survey. The focus is on blood collection and processing. All other processes dealing with screening for infectious diseases are beyond its scope.

One of the aspects of this section is the identification of 'Good Donor Management' practices that blood establishments have devised in order to manage donors and cover the needs for multiple-transfused patients, especially relating to rare blood types.

First, a brief description is given of some groups of the multiple-transfused patients, highlighting patients with haemoglobin disorders, who are now presenting a challenge to blood establishments across Europe. A short summary follows on the special processes implemented by blood establishments in donor management, identified by the survey, in order to cater for special groups of patients.

9.1.2 Multiple-transfused patients

Several patient groups form a special category of individuals who have long-term and special transfusions needs: multiple-transfused patients. To cover their needs, many blood establishments across Europe have developed various methods to recruit new and retain regular donors, especially donors with rare blood types. This practice has become of critical importance since the progress of medical science has introduced new therapies, allowing longer survival in chronic disorders, extending such patients' lives.

A significant number of such patients depend on blood-transfusions. In addition, the influx of migrant populations across Europe, from countries that are highly affected with haemoglobin diseases, not indigenous in Northern European populations, accentuates the need for good donor management of rare blood phenotypes. Examples of such diseases are thalassaemia and sickle sell disease. Their therapy requires life-long safe and adequate blood supply.

Each of the major medical conditions that require long-term blood transfusion is briefly described below, highlighting only the haemoglobin disorders which are rapidly becoming a challenge to European blood establishments.

- Thalassaemia major and intermedia
- Sickle cell disease
- Diseases of the newborn
- Stem cell transplantation - heterologous or autologous - for malignant or non-malignant disorders
- Leukaemias and myelodysplastic syndromes
- Immune deficiencies
- Coagulation disorders, such as haemophilia

Each of these groups requires different quantities and types of blood product, and puts a particular strain on the blood transfusion chain.

Epidemiology of haemoglobin disorders

Globally, it is estimated that more than 500,000 children with haemoglobin disorders are born every year, 30% of whom are in middle- and high resourced countries [1]. Of these children, 40% are born with thalassaemia and 60% with sickle cell anaemia. About 50-80% of children with sickle cell anaemia and about 20-40% of children with thalassaemia major die every year. In the last 10 years, haemoglobin disorders are slowly emerging as a serious public health priority, whose prevalence has significantly increased for two reasons: the influx of migrant populations from highly affected developing countries, and the development of improved diagnostic technologies and care of patients.

It is estimated that, in order to keep alive 500,000 new affected transfusion-dependent patients worldwide, many more additional units of blood will be required. This number of units cannot be specified with accuracy, since the new cases will have different requirements in red blood cells (RBCs) depending on the severity of their condition to the already existing requirements are needed. It is estimated that about 20,000 living transfusion-dependent patients reside in Europe, and an additional 1,500-2000 babies with these disorders are born each year. The latter is, in part, due to the circumstance that in many European countries, no comprehensive control programme or national prevention strategies yet exist [2]. As a result, the blood supply needs to increase each year, to cover the needs of these patients.

Thalassaemia

Thalassemia is particularly demanding in terms of quantity of blood, especially for patients with thalassaemia major. These patients have a hereditary disorder: their need for RBC transfusions starts from early infancy and continues throughout life. With comprehensive medical care, their life-span is now over 50 years in developed countries.

RBC transfusions are required to increase the haemoglobin level, but also to suppress non-effective red blood cell formation and non-effective red cell producing tissue in bones. In this way, vitality, normal growth and avoidance of deformity are achieved [3]. Apart from all the potential dangers of blood transfusion, these multiple-transfused patients are especially vulnerable to antibody formation, reactions to blood compo-

nents, transmission of infectious agents and iron overload. For these reasons, they require both a constant supply of adequate and safe blood to maintain their haemoglobin levels (above 9g/dl)[3] and special attention needs to be paid to the following issues.

- Exact compatibility with the patient, which requires extensive phenotyping
- Appropriate processing, storage and transport
- Quality laboratory screening and other procedures for reducing the risk of transmission of pathogens

All these safety measures require meticulous quality control of blood establishments and donation policies based on regular voluntary, non-remunerated collection of blood.

Sickle cell disease

Most sickle cell patients maintain an acceptable haemoglobin level and do not require life-long blood transfusions. However, during vaso-occlusive crises and infections, periodic transfusions may be needed. In some circumstances, more regular transfusions are needed to relieve anaemia and improve blood flow, and prevent new complications. Such circumstances include the following.

- Haemolytic episodes and severe anaemia
- Prevention and treatment of stroke
- Prolonged priapism
- Lung infarction or pneumonia
- Frequent and severe outbreaks of pain

These may be treated by simple transfusions or by regular exchange transfusion which may better increase blood flow. The risks to these patients then become the same as those faced by regularly transfused thalassaemia patients. This includes iron overload and, when overt, iron chelation should be considered.

Diseases of the newborn

Neonates in intensive care may require blood products to support them. Examples of dispositions and disorders, requiring transfusions include the following.

- **Anaemia,** premature babies are particularly susceptible and may require several 'top-up' transfusions. The blood product required in this situation is pure RBC.
- **Babies with haemolytic disease**, such as caused by Rhesus (Rh) incompatibility, may require exchange blood transfusions, not only to increase the foetal haemoglobin, but also to reduce the bilirubin levels which may cause brain damage. In specialised centres, these transfusions may also be performed intrauterinely in the yet unborn child.
- **Serious neonatal infections** may require the support of another blood product (usually immunoglobulin IgG). This product may also be used in another condition which affects premature and low-birth weight babies, such as necrotising enterocolitis.

Stem cell transplantation

Patients in need of stem cell transplantation are a group of individuals with severely, medically-induced immuno-suppression. Their endogenous haematopoiesis has been destroyed and replaced with donor stem cells. For prolonged periods of time, the patient may need to be supported by the following blood products.

- **Red cell concentrates** to maintain the haemoglobin level
- **Platelet concentrates** to prevent bleeding from thrombocytopenia, derived from several donors
- **White cell concentrates** administered usually in acute infections
- **Immunoglobulins (IgG)**

Infections, whose treatment requires blood products derived from pooled donor blood, render these patients particularly vulnerable to complications and infectious agent contamination.

Leukaemias and myelodysplastic syndromes

Leukaemia patients face serious haematological disorders. They often have their endogenous haematopoiesis suppressed by chemotherapeutic agents and irradiation. They require comparable blood product to the previously described group of transplant patients. In fact, these patients may also be candidates for stem cell transplantation. Patients with myelodysplastic syndromes may need regular blood transfusions for several years.

Immune deficiencies

Patients with congenital immune deficiencies need protection with immunoglobulin preparations throughout their lives in order to be free from life-threatening infections. IgG preparations are derived from pooled plasma. This pooling process harbours risks of contamination from infected donors, especially with HIV and HCV.

Coagulation disorders

Patients with coagulation disorders have a deficiency in one of the blood clotting factors, mainly Factors VIII and IX. Replacement therapy is required regularly in most patients with severe deficiency: milder cases can be dealt with through periodic replacement to prevent bleeding. Blood clotting factors can be derived from human blood serum or from recombinant industrially manufactured ones. In the past, HIV infection was transmitted by clotting factors derived from pooled plasma. Strict donor selection is necessary to avoid such tragic consequences.

9.1.3 Dealing with multiple-transfused patients with special transfusion requirements

Even though data is missing from non-responders, especially from private blood establishments, the general trend that the DOMAINE survey has revealed on donor management for multiple-transfused patients is that blood establishments across Europe, although not uniform, have procedures in place to deal with these blood requirements, to recruit and maintain a pool of relevant blood donors.

No standard strategy for donor management

It is noted that no standard strategy for donor management in Europe exists. More than 52% of the countries involved in the survey have a special strategy for donor management specifically directed to provide blood products for these groups of patients. However, the nature of the strategy implemented and the type of 'special donors' registry established in each country, largely reflects the type of chronic patients a blood establishment deals with in its region and country, as is the case in countries with large ethnic minorities, large numbers of thalassaemia patients, or many patients undergoing cancer or organ transplantation treatment.

Within the general population, awareness of the need to recruit prospective donors for these groups of patients is largely absent. Steps needed to enlarge the donor base with special blood types are dealt with in more detail in Chapter 5.

Strategies used throughout Europe

The patients described above, form a miscellaneous group which are often immuno suppressed and in need of multiple transfusions or lifelong transfusions. Most of the blood establishments involved in the DOMAINE survey provide blood products for the needs of these groups of patients. Most blood establishments also regularly inform their (regular) donors about special blood requirements, using various means of communication tools such as telephone, email or text messaging (SMS). Regular donors may be recalled for donation when the need arises, including when recruiting for neonatal patients. Special collections may be organised for ethnic minorities to cater for their needs.

Donor panels

Furthermore, in order to meet the demand for 'special or rare blood phenotypes', a special donor panel policy is advocated for registering donors with these special phenotypes. These donors may be excluded from making regular donations to keep them available for the donor panel.

SECTION 9.2

MULTIPLE-TRANSFUSED PATIENTS AND DONOR MOBILITY

9.2.1 Introduction

A decade ago, neither patient nor blood donor mobility at European level was given much thought. The *Treaty of Amsterdam* [4, 5] made it clear that health systems, which include the blood establishments, were a matter for national governments. This section gives a brief overview on the new situation that is created with the increased migration of populations across Europe, and the opportunities for improvement that may arise with regard to donor management for chronic patients. Finally, a brief description is provided of the costs that may be implicated in implementing these proposed improvements for better donor management.

9.2.2 Migration and demography

Population migration in an expanded Europe is slowly increasing: not just migration of patients, but also of prospective donors. Collaboration between health systems across borders could now become of major benefit.

In fact, patient mobility is considered a positive step towards opening new opportunities not only for the patient, giving greater choice for quality health care in another country that in his/her country is lacking, but also in that it helps to clarify European standards of quality of care. This allows improved cross border collaboration and access to high quality of information. For example, some minor disorders can be managed in a single episode of care. However, many patients may present an aggravation of a pre-existing condition, where either visiting or migrating to another country requires communication with the patient's usual health care provider. This means that medical records preferably are accessible and understandable by different health providers; for example, between various blood establishments where procedures for follow-up assessments and rehabilitation should be available and shared.

Opportunities for improvement

Most of the blood requirement problems arising from chronic patients' mobility stem from the restricted collaboration and the limited sharing of patient and donor data between European blood establishments. Patient and donor mobility now present unique opportunities for improvement that may help to avoid duplication of procedures and unwarranted draining of resources, both human and financial, within blood establishments. Concurrently, a solid blood donor base for chronic patients could be sustained including the following possibilities.

- **E-Health:** EU wide blood establishment donor information systems, within the framework of their countries systems, may lead to better coordination of

information technology through regional and European networks. Collaboration between blood establishments may help to avoid duplication, for example, of screening or confirmatory procedures. This means more efficient use of existing capacities across borders, which, in turn, will increase mutual learning through exchange of knowledge and experience on 'best practices'.

- **Sharing patient and donor records** between blood establishments for improved and faster provision of services to chronic patients.

9.2.3 Implicated costs

Each of these opportunities requires one or more of the following cost items. The projected expenses for the above-stated recommendations can be shared not only between collaborating blood establishments, but also with other stakeholders and institutions.

- **Administrative Personnel** Personnel directly involved in administration and processing of information, including information. It does not include personnel costs of IT, transport and overheads.
- **Services** Purchase of services between collaborating blood establishments for specialised laboratory testing or blood processing.
- **IT-system**
  - **IT-personnel** for support and maintaining the information network between blood establishments, and between blood establishments and hospitals
  - **Hardware:** Computer and printing equipment
  - **Software:** IT-software systems that will alert blood establishments and hospitals for any increased demand for 'special blood group' phenotypes
  - **ID-card** for chronic patient, enabling the patient to notifying the nearest hospital and blood establishments in his/her vicinity of new residence
  - **ID-card** for 'special donors' for automatic recall
- **Transport/logistics:**
  - **Drivers:** personnel costs
  - **Transport vehicles:** purchasing costs, maintenance and fuel costs
- **Overheads** Donor costs that are not specified elsewhere

Conclusions

Multiple-transfused patient mobility presents a challenge to blood establishments and other involved stakeholders such as hospitals. Even though the introduction of a European information network for sharing donor and transfusion-dependent patient information may present a financial obstacle at the beginning, nonetheless, in the long-term, it will save both human and financial resources for blood establishments and will assist them to anticipate the potential fluctuations in terms of their client and donor base. More importantly, it will present a unique opportunity for chronic multiple-transfused patients to receive a good quality and timely service.

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SPECIAL SITUATIONS

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CHAPTER 10

SECTION 10.1

DONOR MANAGEMENT IN DISASTER SITUATIONS[1]

[1] *This section is largely a re-edited version of the American Association of Blood Banks' issue on disaster management (Disaster operations handbook [1])*

10.1.1 Introduction

Blood transfusion is a significant factor in reducing the number of deaths in disasters. Strong community response to disaster is triggered by socially embedded, disaster related altruism and sympathy in the general population. For instance, the publicity given to blood donation and transfusion during World War Two helped create a strong link in the public mind between the individual act of donating blood and the care of victims of war and disaster [2]. Blood donations are thereby increased in both the disaster-affected and unaffected regions.

However, blood is rarely needed in excessive quantities at the moment a disaster occurs, and the outpouring of blood donations, especially at the site of a disaster, often proves counterproductive [3]. To avoid such events, and in order to be prepared to respond to a disaster effectively, many of the activities that normally are involved in the blood supply chain should be planned and adjusted to take account of the precise nature of the disaster and the resulting needs.

This section reviews topics covering blood supply and blood donor management in disaster situations that will help blood establishments, hospital blood banks and blood transfusion services to prepare for and respond to disasters affecting the blood supply.

10.1.2 Definition

The word disaster stems from the Old Italian word *disastro*, which means in the astrological sense a calamity blamed on an unfavourable position of a planet [4]. There are various definitions and classifications of disaster in the literature derived from the complexity of such events. However, a disaster is a natural or man-made event that negatively affects life, property, livelihood or industry often resulting in permanent changes to human societies, ecosystems and environment [5]. In the context of blood supply, the word 'disaster' refers to the following characteristic events giving rise to these needs.

- Suddenly requiring a much larger amount of blood than usual
- Temporarily restricting or eliminating a blood collector's ability to collect, test, process, and distribute blood
- Temporarily restricting or preventing the local population from donating blood, or restricting or preventing the use of the available inventory of blood products: this situation requires immediate replacement or resupply of the region's blood inventory from another region
- A sudden influx of donors, requiring accelerated drawing of blood to meet an emergent need elsewhere [1]

10.1.3 Experience from previous disaster situations

All disasters are unique; however, lessons from the past can be very helpful for improving one's knowledge about disasters and providing better response programmes. Analyses of former disaster situations have shown that there has not yet been any situation where the immediate need for blood or blood components has been beyond the capabilities of the blood community [6]. The requirements for blood in large disaster situations has mainly been determined by the number of injured who survived long enough to be presented for care and the rate of blood used in providing that care [2]. The single greatest risk of disasters is not lack of supply but disruption of the blood distribution system [1]. More lessons learned are stated in Box 1.

Box 1. Lessons of the past: recommendations

- Ensure that facilities maintain inventories to be prepared for disasters at all times in all locations. Keep a seven-day supply of the combined inventory of both blood collectors and hospitals
- Control collections made in response to a disaster that are in excess of actual need
- Send a clear and consistent message to the community, donors, and the public regarding the status of the blood supply (both locally and nationally) during a disaster
- Organise continuous disaster planning, including participation in disaster drills and close coordination with local, state, and federal response agencies
- Entail overall inventory management within the country, including a unified approach to communication among blood facilities and transportation of blood and blood components during a disaster [1]

10.1.4 Disaster management

Each blood establishment should plan, prepare and remain prepared for a disaster situation. The process of emergency management involves four phases: mitigation, preparedness, response, and recovery [7]. In all four phases, key issues (see Box 2) must be dealt with adequately. At the end of this section some special aspects of disaster management (managing people and working with the media) are addressed.

I. Mitigation is the most cost-efficient method for reducing the impact of hazards; however it is not always suitable. Mitigation efforts attempt to prevent hazards from developing into disasters altogether, or to reduce the effects of disasters when they occur. They focus on long-term measures for reducing or eliminating risk. In the context of blood supply the mitigation strategy can be the building of frozen RBC stock especially 0 RhD negative.

Box 2. Key issues in disaster blood management

- Leadership (including command, control and management structure)
- Prioritisation of activities
- Communication
- Maximising and managing the available supply (including shortage management)
- Recipient safety and donor deferral
- Donor safety and availability
- Staff safety and availability
- Consumables and supply chain resilience
- Equipment and infrastructure
- Finance

II. Preparedness encompasses a response plan that is constructed and adapted in accordance with national and local public health guidance and, where possible, should also be devised to be generic and flexible enough to respond to almost every disaster outbreak.

III. Planning and response require contact, collaboration and consultation with major stakeholders, such as the blood establishment management board, regulatory bodies, donor organisations, hospitals and users of blood services, staff and contractors, health and public health departments, neighbouring blood organisations, and neighbouring countries. Disaster plan preparation strategies should be centred on the major response action areas for blood establishments. All this is needed to set up a tailor made Disaster Blood Collection Plan that should address the items mentioned in Box 3. Planning and response to disaster are exhaustively elaborated in the American Association on Blood Bank's Disaster operations handbook [1].

Box 3. Essential elements of a Disaster Blood Collection Plan

- Assess the medical need for blood
- Assess the maximum collection limits (consider staffing, collection, testing, storage, etc.)
- Prioritise the type of blood products to collect
- Decide what to do with extra donors (e.g., draw samples from new donors, schedule future appointments)
- Decide what to do with eventual donor shortages
- Decide what to do with scheduled blood drives and mobile operations that are under way
- Tell donors how they can help immediately and in the future
- Update contact information for donors displaced by the event

Continuous education and training of the blood establishment staff on the disaster plan, as well as active drills are necessary to ensure that planned response will run smoothly and will be managed properly. Upon hiring, and, at least, annually thereafter, each employee should be made aware of, and trained in factors required to implement key elements of the national and internal disaster plan. The exercises should be followed by a written knowledge assessment to ensure competency and to evaluate the course. The organisation should schedule annual refresher training for all staff, along with quarterly or semi-annual disaster drills that include resource-sharing groups.

The response plan should be centred at the blood establishment in the affected area that acts as a main conduit for information and communication [1]. The activation of the response plan is a step-by-step process. The affected blood establishment's role is to assess the local medical need for blood and to communicate this need to the blood supply coordination authority. This authority will then consider the magnitude of needed response and recommend an action strategy including, but not limited to, the shipment of blood to the affected blood collector, and the coordination and dissemination of a message to the national blood community and donors.

The blood supply coordination authority facilitates coordination among national blood organisations, blood competent authority, regional, state, and local government bodies. This is necessary to determine the medical need for blood, facilitate transportation of blood from one facility to another, and to communicate a common message to the national blood community and the public about the status of the blood supply in the disaster-affected area and the nation. General assumptions are that all disasters are inherently local. Immediate shipment of required blood products will be from blood establishments with access to the most rapid means of transportation to the affected blood establishment. The blood supply coordination authority will reassess the needs 24 hours after the event (and daily as necessary) and may alter the strategy for meeting blood needs, depending on the circumstances [1].

The following blood products are the most likely to be needed in each of the following phase of a disaster.

- **First 24 hours:** type O red blood cells (RBCs), Rh negative
- **One to ten days:** RBCs (all ABO/Rh types) and platelets (PLTs)
- **Eleven to thirty days:** RBCs, PLTs, and (for radiologic incidents) stem cells and bone marrow [1].

IV. Recovery phase. After the disaster event, the response plan should be deactivated and the recovery phase should begin. The aim of the recovery phase is to restore the affected area to its previous state. Recovery efforts are primarily concerned with actions that involve rebuilding destroyed property; re-employment; the repair of other essential infrastructure; re-scheduling blood donation sessions.

Managing donors, volunteers, and crowds

Once a disaster has occurred, blood establishments should activate strategies to manage donors and volunteers. The messages to the blood donors and local community through local media should be coordinated and assessed by the blood supply coordination authority.

Box 4. Crowd control

- During a mobile blood collection session, blood establishments should be prepared to control a donor crowd by the following means
- Maintaining frequent communication with waiting donors
- Enforcing limits on the number of donors staff can handle
- Shutting down, where appropriate, mobile collection sites to focus on certain large or fixed sites
- Relocating the primary collection site if it is not sufficient or operational (locate facilities for mass collections)
- Setting up triage tables where donors can be screened for ABO group, medical questions can be answered, and pledges can be obtained
- Allowing plenty of parking
- Setting and communicating clear working time (especially a time to shut down because the lines may be endless)

Blood establishments, with appropriate and carefully prepared messages, should discourage donors from appearing *en masse* until the medical need has been assessed. However, they should be prepared to control significant crowds of blood donors as well as to react if blood donor shortage appears (see Box 4). Special concerns with staff and volunteers are shown in Box 5.

Box 5. Staff and volunteers: Special concerns

- Take steps to prevent staff and volunteer burnout
- Ensure that sufficient water, food, HVAC (heating, ventilation, air conditioning), and restroom facilities are available
- Issue temporary security identification to volunteers
- Assign predetermined, non-regulated tasks to volunteers
- Identify the assigned contact person for volunteers
- Train volunteers on their exact responsibilities
- Track volunteers by getting their names, phone numbers, and training status
- Maintain records of each volunteer's responsibilities.

Working with the media

When a disaster has occurred, it is imperative to inform the general public about blood supply needs. To communicate these needs to its current donor base and potential new donors, blood establishments should contact print and broadcast reporters (if reporters are not already calling the blood establishment) to provide them with an accurate, concise message. However, before talking to the media, blood establishments should speak to and cooperate with the blood supply coordination authority to ensure that a consistent message is being delivered. Blood establishments should have updated local media lists (TV, newspapers, radio stations, wire services), delegate the spokesperson(s) and prepare drafts of press releases. (See also Section 10.2 Media).

10.1.5 Specific disaster events

Specific disaster events can have various potential impacts on the blood supply. It is necessary, therefore, to create specific disaster operation plans for every particular hazard present in the relevant area. The Canadian Disaster Database (CDD) [8] categorised disasters in five different types as follows.

- Biological disasters
- Geological disasters
- Meteorological disasters
- Human conflict disasters
- Technological disasters

10.1.6 Biological disasters

The following paragraph on pandemic influenza was based on the document *Pandemic influenza, planning for blood establishments* by the European Blood Alliance [9].

Pandemic influenza

The impact of a severe human influenza pandemic on the blood supply is likely to be very significant and specific for blood organisations. The risk of transmission of influenza through transfusion of blood components itself or associated activities is low since major symptoms and viremia tend to closely coincide.

However, measures should be taken to minimize any risk of additional transmissions via blood transfusion. Donors should be screened for absence of influenza symptoms and asked about recent close contact with ill persons. They should also be asked to report any personal illness emerging soon after donation.

Reduced demand: Due to an expected (probably temporary) reduction in elective healthcare only a modest (10-25%) reduction in demand for red cells and no reduction in demand for other blood components is assumed. The demand for specialised diagnostic services provided by blood services is likely to be reduced too. The demand for fractionated blood products is assumed not to be significantly changed by a pandemic influenza.

Affected donors: Blood donors will be affected by pandemic influenza to the same extent as the general public. Therefore, they will generally be much less likely to donate blood and will not be eligible to donate until several weeks after making a full recovery from influenza, or for some time after they have been in close contact with an infected person.

Staff shortages: Staff of blood establishments and the suppliers and contractors on whom it depends will be severely impacted by the pandemic. Staff absence rates could peak between 25% and 40% with small teams potentially being hit even harder (up to 100% absence) for short periods of 2-3 weeks. There is a small but real risk that entire departments or sites could be forced to close for short periods due to lack of key staff. Where possible, put in place backup arrangements for such staff.

Key consumables: The supply of key consumables to blood organisations as well as their own infrastructure, IT systems, vehicles and equipment could be impacted due to insufficient staff or as a result of equipment breakdown and abnormal difficulty in sourcing timely repairs. As a result of the pandemic, there will be a significant impact on the economy as a whole with lost capacity and income.

Advance planning: The response to pandemic influenza should be planned and the disaster plan activated in accordance with the current situation in a particular affected country. The overall response objective for the blood organisation is that of maintaining the supply of critical blood products and services at the level demanded by the healthcare community throughout the pandemic, the recovery period and, if applicable, subsequent pandemic wave(s). The importance of ensuring that widely accepted shortage management plans are prepared and published in advance of a pandemic cannot be over-emphasised.

Response management: Managing the response should be a top priority. To maximise the chances of maintaining services for the entire duration of the pandemic, the response should be carefully paced. The major objective will be to make every effort to ensure a continued supply of safe, high quality, life-saving products and services. Standards, operating procedures and related duties and requirements should only be varied to the minimum extent necessary to respond to the disaster. Every effort should be made to maintain normal high standards of service to, and care for, donors and to create an environment in which donors are encouraged to donate and will feel safe to do so without being at increased risk of influenza infection.

Staff and contractors: The blood establishments will need to support staff and contractors so as to optimise their ability to help provide critical, life-saving blood components and services. Additionally, it will need to address the physical, emotional and psychological safety and well-being of staff and others to whom it has health and safety obligations before, during and after the pandemic.

Internal communications policy: It will be important to provide regular, up-to-date and accurate information to employees, their staff side organisations and other key stakeholders regarding the pandemic and the blood service's operational response. This is essential for ensuring understanding of, and agreement and mutual commitment to overcoming the pandemic and to maintaining the supply of essential products and services.

Proportionality: The response should be flexible so as to remain as proportionate as possible to the evolution of the actual pandemic in real time, consistent with government and public health advice. Actions that would facilitate the spread of the pandemic should be avoided.

Cooperation, national and international: Blood establishments should exchange information with, seek help from, and provide help to other international blood services where this is feasible and necessary. They should work especially with other blood services with whom there are operational or national inter-dependencies.

10.1.7 Geographical disasters

Geological disasters generally do not create an immediate need for blood. Floods and earthquakes immobilize a community's transportation and medical care infrastructure, including the blood supply with subsequent failure to fulfil the demand.

Earthquake

The blood supply could be directly affected by the severity of the earthquake. Blood usage may not be initially significant, but the event could significantly hamper collection activities if a large area is deemed uninhabitable. Hospitals may temporarily suspend elective surgeries, followed by a spike in such surgeries once operations are back to normal. Blood establishments should make special preparations to ensure that operations can be quickly resumed following an earthquake (facilities, power supply, staff, transportation).

Post-earthquake communication: Communication channels damaged through earthquake should be reactivated with hospital customers (i.e., to contact each other as soon as the event is over). The blood establishment should also notify staff, donors, and vendors of the facility's status. In addition, a process should be established to routinely update these groups until full operational status is restored. Hospital customers should also be contacted after the earthquake to assess their operational status and blood product needs [10].

Alternative suppliers and premises: The use of alternative suppliers may be needed. If the blood centre's main facility is to be evacuated, activate emergency relocation procedures.

Floods

In an area where flooding has happened, the impact may be small, but can also be devastating. The blood supply may suffer little or no impact unless the blood establishment or its hospitals themselves are flooded. Hospitals may suspend elective surgeries until the event has passed, followed by a spike in such surgeries when operations are back to normal. Citizens may decide to donate blood to help the victims, which may result in a donor surge. If the blood establishment is flooded, emergency evacuation should be executed to ensure the safety of staff. Blood donors, hospital customers and other staff should be notified.

10.1.8 Meteorological disasters

Storms (hurricane, tornado, thunderstorm or winter storm) may have a negative effect on blood collections in the days before (local efforts to prepare for the storm) and right after the storm (reparation activities). In addition to the potential loss of blood collections, there may be a slight decrease in elective surgeries shortly before and after the storm, followed by a spike in such surgeries once hospitals in the region resume full operations.
Occasionally the storms can cause significant, even catastrophic damage. Tornadoes and severe windstorms pose a direct risk to blood facilities and to other medical structures in their path. Blood may be needed to treat casualties, which may number from a few to scores. Blood collection schedules may be disrupted, depending on the severity of the tornado and the size of the destruction path.

Blood establishments should make special preparations to ensure that operations can be quickly resumed following a storm and that disrupted communication channels are repaired so that they can contact hospital customers as soon as the storm has passed.

Wildfires: A wildfire with devastating effects displaces people from their homes and businesses. Blood usage has historically not been significant during wildfires. If the facility is affected by a wildfire, the blood supply will be quarantined until its safety, purity, and potency can be determined. A common response of the public after a disaster is to donate blood, so it is important to prepare for a donor surge.

Heat waves: A heat wave hinders blood donations and causes blood shortages. In high temperatures, blood donor turnout and response to appeals are low and deferrals for low haemoglobin are more frequent [11]. Blood drives in the non air-conditioned facilities and mobile units are often cancelled because the heat makes the mobile centre uncomfortable. However, the need for blood and blood usage is not correspondingly changed; therefore, such heat waves could lead to blood shortages.

In the summer season, more frequent blood drives should be planned. Blood establishments should communicate their concerns about blood shortages to the general community, to existing blood donors, as well as to the hospitals. Additionally, they should assure air-conditioned blood donation areas, and adequate refreshment with drinking water for the donors before and after donation.

10.1.9 Human conflict

Human conflicts, such as wars, biological events, nuclear explosions and explosive events can have major consequences for the blood supply.

War

The supply and use of blood during war are specific for every particular country and require efficient cooperation between national and regional civilian authorities and blood banks, as well as the military chain of command and medical units. Response plans of both sides should be harmonised at national level.

Whole blood consumption markedly increases during the war while the use of components drops. Deviations from standards and prescribed procedures are common and should be carefully approved and monitored.

Wars cause infrastructure damage, staff shortages, and transportation problems, thus increasing the inefficiencies in a blood supply system at the same time as the need for blood supply increases. War creates additional injury victims in need of blood and removes individuals from the donor population: these combined factors can produce shortages in blood supply.

New medical technologies: The recent development of haemorrhage control bandages based on fibrinogen plus thrombin and chitosan, as well as drugs such as recombinant FVIIa, provides more rapid haemorrhage control and reduces the need for blood replacement.

Walking donor transfusion is the collection and transfusion of previously typed and screened whole blood from a healthy donor (soldier) to a patient in need of a lifesaving transfusion. As a rule, military personnel are typed and screened during initial processing to the military.

Biological event

The deliberate release of viruses, bacteria, or other germs (agents) poses the greatest threat to the collection of blood products. Depending on the type of agent involved in the event, staff, volunteers, and donors may be infected; facilities and vehicles may be contaminated; donors may have to be deferred.

Depending on the biological agent, local authorities may direct the blood establishment to implement its shelter-in-place plan or evacuate. Because of the various incubation periods of different agents, the blood establishment may be required to conduct an aggressive call-back of donors who develop symptoms after a blood donation.

Quarantine: Mandated quarantine measures or self-initiated actions by the population could result in loss of blood donations. Such measures or travel restrictions may also prevent or hinder blood establishment employees' ability to travel to work and collection sites, and may affect access to the supply chain for critical supplies, equipment, and fuel.

Nuclear explosion

A nuclear explosion combines large-scale blast damage with dispersal of radioactive material. Unlike conventional mass-casualty events, large numbers of trauma patients over a wide area could consume available blood components to the maximum capacity of functioning hospitals. In the aftermath, patients with severe radiation toxicity would have compromised hematopoiesis and would need bone marrow transplantation (see paragraph 10.1.10, radiological incidents).

National coordination of supply and demand for blood components and hematopoietic progenitor cell units would be required as part of the overall emergency response. If the event occurs elsewhere in the world, demand for matched stem cell donations would be generated.

Explosive event

A large blast from an accidental industrial, military, or flammable-material source, or from an intentional terrorist or criminal bomb, can cause high immediate mortality. Survivors would require resuscitation and surgery with associated transfusion support. Local inventories of blood components would need assessment for adequacy and augmentation. Surges of blood donors have occurred after such events, and coordinated public announcements about the blood supply are helpful to strike the appropriate balance between supply and demand.

10.1.10 Technological disasters

Technological disasters are subdivided into industrial accidents, chemical incidents, radiological incidents and wide-area power outage.

Industrial accidents

Industrial accidents such as fire, collapse of buildings, roads, or bridges, or explosions, can result in large-scale destruction and anywhere from a few to numerous human injuries. If the industrial accident involves the blood establishment (such as a fire), the blood supply should be quarantined until its safety, purity, and potency can be determined. Accidents that do not directly involve the blood establishment may or may not require blood support, depending on the nature and number of injuries. The public often responds by donating blood out of a desire to help.

Chemical incidents

Most chemical events (industrial, terrorist or household) do not increase the immediate demand for blood products, although 'blood agents' or nitrogen mustard compounds may have complications requiring later blood product support. Depending on the type of chemical, the projected path, and the wind speed, the blood centre may have little time to react. Blood establishment occupants may be directed by local authorities to shelter in place until the chemical cloud/plume dissipates. Blood collections may be lost, and transport of blood collected at local blood drives may be adversely affected. Some militarised and industrial chemicals may require specific decontamination of buildings and vehicles and the administration of antidotes to people in the affected areas.

Blood collectors should be prepared to minimise the negative impact of a chemical incident, ensure the reestablishment of operations, and protect staff, donors, and volunteers.

Radiological incidents

An accidental or terrorist dispersal of radioactive material can have a different spectrum of biological effects, depending on its type, amount, half-life (environmental and internal persistence), and particles emitted (penetrating distance). In blood banks, cesium-137 (Cs-137) in blood irradiators could become problematic in the event of a catastrophic barrier breach or acquisition by terrorists. Radiation toxicity includes suppression of hematopoiesis, and victims may need RBC (red blood cell), platelet, and granulocyte transfusions: hematopoietic stem cell transplantation may be considered.

Where radiation is widely dispersed, blood collections would be curtailed if the public (staff and donors) were advised to shelter in place for a period of time during assessment and early radioisotope decay. Blood donors may need extra screening or laboratory testing (blood lymphocyte count) for whether they have taken antiradiation medication or have evidence of radiation exposure by symptoms (e.g., vomiting).

Wide-area power outage

Wide-area power outages jeopardise the storage of blood. Backup generators operate only until available fuel supplies are exhausted. Fuel resupply may be jeopardised because power is needed to pump fuel and a wide-area outage will create higher demand for fuel. Blood collection will also be interrupted, which can have an impact five to seven days later when existing supplies of platelets are exhausted and replacements have not been collected.

10.1.11 Conclusion

Adequate and sufficient supply of blood components is an important part of emergency preparedness for disaster situations. It requires a robust and well developed blood supply system, trained workers and well-equipped staging facilities, combined with thoughtful, flexible, evidence-based, emergency planning and efficient cooperation between blood establishments and civilian/military authorities. Managing donors, volunteers and crowds as well as working with the media are vital parts of the blood supply chain that should be especially carefully planned and enacted during disaster situations.

SECTION 10.2

MEDIA

10.2.1 Introduction

Dealing with the media is a topic that deserves special attention. This section describes the media landscape that is applicable to blood establishments. It stresses the importance of choosing the right medium and identifying important media for different target groups. For communication purposes, it provides rules of thumb for dealing with the media.

10.2.2 Media, definitions

The term *media* is not easy to define. It is all around us, in its old meaning of 'environment', but nowadays media has evolved.

The *Oxford Dictionary* defines 'media' as 'the means of mass communication, especially television, radio, and newspapers collectively'. The term also relates to the world of information technology, communication and entertainment addressed to a huge audience. Over the past several years the ever developing kinds of communication technology have had a tremendous impact on everyday life and are impossible to avoid. Media gadgets are attractive to everyone who has a message to communicate.

From early oral forms, we now have a vast range of electronic media systems, colouring every form of communication. There have been tremendous developments in writing, printing, telegraphic, journalistic and audiovisual communication styles.

Marshall McLuhan, a famous media theorist said almost fifty years ago: 'The medium is the message' [12]. Therefore, choosing the right tool for communication may be more important than the actual message content. McLuhan's words have been analysed by many media theoreticians over the years. A good interpretation is given by Lance Strate in 2008 [13]:

'The words we think to ourselves seem different when we utter them out loud. The words we write down take on a permanence, distance, and impersonal quality in comparison to speech. Along the same lines, information does not exist in a vacuum. It can be found riding radio waves or the electric current running through wires, or stored in magnetic or optical form. Or information can be found in the sequences of chemicals that make up strands of DNA and RNA. The code and the mode of information that is used will determine who has access to the data and who controls its dissemination, how much information will be distributed, how fast it will be transmitted, how far it will travel, how long the information will be available, and the form in which it will be displayed. As these variables change, so does the message that is being communicated'.

Using media is not as simple as it seems: many aspects must be considered. Whose attention is one trying to get? What are their favourite media channels? Is the intention to build up, provoke, or call up and image? Thankfully, the abundance of choices is used extensively by the people responsible for donor recruitment.

The DOMAINE survey on donor management in Europe (see chapter 2) clearly reflects the wide usage and importance of media. Donor management deals with two clearly distinctive aspects of media use. First, the way blood establishments themselves use and apply media in their donor management strategy and everyday practice. Second, the way media (RTV and newspapers) report on blood establishments in their work and for their purposes.

10.2.3 Use of media by blood establishments in donor management

Importance of media among the other recruitment methods

Every single blood establishment uses many recruitment and retention methods. Chapters 5 and 6 address these two donor management steps in more detail. The DOMAINE survey shows that various media tools are used for both donor recruitment and retention.

- Commercials on national and local television and radio
- Advertising in national and local newspapers and magazines
- Advertising on websites

Altogether 80% of blood establishments use websites, local radio and local newspapers. More than half of the blood establishments use national media channels and 40% use advertisements in magazines. The low priority of magazines in this list is explainable by their lower frequency of appearing in print and relatively long preparation time. These are two relatively new methods.

- Cooperation with mobile phone companies for advertising
- Phoning people who have indicated their interest in donation by filling in a relevant internet survey

Media and their suitability for different groups of donors

In choosing the correct medium, the above mentioned 'medium is the message' principle remains here in full force. The right media tool choice comes first and only thereafter the contents of the message itself. Not surprisingly, therefore, the DOMAINE survey shows that 88% of the European blood establishments differentiate between media tools suitable for younger and older generations.

Many blood establishments apply recruitment targeted towards young people – high school pupils and students. New media technologies, internet, web based materials, SMS text messages and e-mails are likely to be more effective for young people. Conventional media such as TV, radio and newspapers work better for potential donors of

an older age. Younger generations adopt new technologies more often and more easily. It is important, therefore, not to be behind such technological novelties, as the line between conventional and unconventional media is moving all the time.

Effective use of media

In general, blood establishments do not monitor cost-effectiveness of their recruitment policy or strategy. For the most part campaigns' successes are measured simply by the number of newly registered donors. It follows that the number of recruited donors seems to be the only indicator of success, regardless of the costs.

National television: According to the DOMAINE survey results, effectiveness of commercials on national television shares the first place with donor-recruits-donor methods in donor recruitment, but these two methods differ widely in costs since commercials can be very costly.

Local radio and television: Other media tools in the top ten most effective recruitment methods are commercials on local radio and local television, and advertising in local and national newspapers.

Donor-recruits-donor methods are cheap and straightforward, if performed wisely.

Websites: Surprisingly, websites are generally not considered as effective recruitment methods. It brings up the question whether blood establishments underestimate the influence of internet. At the same time most blood establishments are convinced that web media is the choice of younger people. If both conventional and unconventional media are used simultaneously, it is conceivable that applying conventional media is more efficient. Considering that ageing of the population presents a problem in most European countries, recruitment of young and middle aged people will become the key issue very soon. Finding the right approach must have high priority.

Chapter 5 and 6 contain several examples of effective media use.

10.2.4 Dealing with the media. Some practical advices

Media and their goals

Using the media is very important for image building and it is often a good idea to be 'in the picture'. However, while dealing with the media several pitfalls exist. It is crucial to be aware of the way media operates when trying to convey messages through these channels.

Journalistic independence: One should realise that journalists and the media act beyond control of the blood establishment. *Freedom of press* entails that one cannot assume or ensure that media will duplicate your message exactly. They may give their own interpretation to the information given by the blood establishment, which can either be positive or negative.

Commercial considerations: Media outlets pursue their own goals: they sell rather than give information. News value comes first in choosing issues. High value news sells easier than low value news. For example, the news value of one patient dying from an erroneous transfusion can be a multiple of the 'routine' fact that one thousand lives have been saved last year. Subsequently, their goal can be directly opposite to the goal of the blood establishment.

Contacting the media

Attracting attention: Blood establishments may actively seek the help of the media, by attracting attention in order to publish news or novelties relating to blood donation or their organisation. It may be a good and relatively cheap way to attract their attention – via donor related news or novelties. Good examples of issues with news value are celebrities visiting to the blood centre, opening a new facility, implementing some progressive method in blood collecting or introducing an e-donor project.

New scientific developments: Many other news matters exist which deserve the attention of the public and the media; for example, new developments in the world of blood transfusion will attract media attention and possibly generate new interest among potential donors.

Public appeals: Practical information and general invitations to donate are effectively brought to public through the media. Information and public appeals may be dispersed in a number of ways. Most commonly they take the following forms.

- Publications – articles in the newspapers, magazines, or on the internet
- News – TV, newspapers, internet portals
- Advertisements

Apart from publications issued through the blood establishment's editorial office or website, media organisations are the primary way of bringing information to the public.

Press releases or interviews: Important ways of contacting the media are through either press releases or interviews. Press releases are issued actively by the blood establishment. Clear, factful and updated press releases represent a very important tool that helps guaranteeing the quality of the information which will be issued. But, of course, the initiative for interviews rests with the media.

Simple points of interest in dealing with the media are listed in Box 6 and Box 7.

The character of messages to be conveyed to donors or the public all together could be divided into three categories.

Box 6. Rules of thumb in press releases

- The number of messages in a press release must be limited. Preferably just one
- Be consistent
- Be the first to bring out bad news. This is not synonymous with bringing out the bad news fast. Careful phrasing and exact documentation of facts are paramount
- Gather all necessary information
- Be prepared for interviews
- Appoint a spokesperson. This person is to be the only person to address the media

Box 7. Rules of thumb in interview contacts

- Be well prepared
- Answer the interviewer, but address the public in doing so
- Have all answers documented
- Do not give undocumented information. 'I do not know' can be a perfect answer
- Always stress the positive side of the matter, without denying the negative side
- Stick to your message
- Be consistent
- Transparency and sincerity pay. Hiding issues and distorting facts necessitates a thorough book keeping of all the hidden and distorted facts. This is doomed to fail
- Unexpected questions always arise. Use them to bring up your issue
- Do not fill in silent gaps with new messages. Say nothing or, if inappropriate, use them to rephrase your message

1. Straightforward informative messages

- Educational items, popular scientific articles or written interviews in newspapers and magazines, and talk shows on radio or TV
- News about novelties or events
- Use of celebrities or otherwise acknowledged positive media personalities
- Peaceful messages

2. Emotional or sensitive issues

- Provoking messages, such as
  - Patient stories
  - Stories on perceived declining intention or motivation to donate
- Small scale serious events, such as serious adverse reactions in patients or donors

3. Highly media sensitive and political issues

- Urgent or 'red alert' calls for blood
- Serious events, such as death in donors or patients, pandemics, large scale accidents and disasters

Dealing with communication technology and the media is an important aspect of modern donor management. Handled prudently, it can greatly facilitate donor management. To conclude, some remarks on the role of the media are important.

- Regularly update your repertoire of media tools, as your imagination of possibilities is limited. Remember that besides conventional media, unconventional media exist. Gossip is inevitable.
- Bad media attention is not better than no media attention. On the contrary, donors and especially potential donors are very sensitive to emotionally charged appeals. Very often negative attention has a strong negative effect and could bring about great losses of donors.
- It is dangerous to overdo desperate appeals to the public. They gradually become ineffective.

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HUMAN RESOURCES MANAGEMENT

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CHAPTER 11

SECTION 11.1

REQUIRED QUALIFICATIONS

11.1.1 Introduction

Among the various factors that impact blood supply efficiency and safety, having good staff for blood establishments is of key importance to the whole system. New staff must learn relevant aspects of blood donor management, which are not taught at school. Clear job descriptions, transparent hierarchical lines and strong commitment are the mainstay of well functioning human resources management. The diversity of jobs and ways in which blood establishments are organised among European countries precludes describing the jobs and hierarchical lines in the context of this manual. Here, focus is on competences, skills, attitudes and training.

This section aims to specify the personnel categories and qualifications, describe and discuss the role of volunteers, and to discuss performance indicators.

11.1.2 The importance of good personnel

Maintaining a safe and sufficient blood supply is the primary goal of blood establishments: employees, both individually and collectively, contribute to achieving this objective. Applying the principles of good human resources management to employees serves several purposes [1]. It allows for optimal use and development of employee knowledge and skills and it encourages efficient methods of working, high productivity, employee commitment and satisfaction. All of these result in low levels of sick leave and low staff turnover.

11.1.3 Positions and required qualifications in donor management

Several positions are involved in the donor management process. Although exact job titles may vary from country to country, in general, the following positions exist.

- Medical doctors responsible for donors
- Medical doctors responsible for clinical or patient consultation
- Nurses
- Donor attendants, qualified for venepuncture
- Donor attendants, not qualified for venepuncture
- Communication, marketing and public relations staff
- Donor administration staff, including call centre staff
- Support staff, such as finance and control, and facility management
- Quality assurance
- Transport
- Volunteers on several jobs, such as donor catering and administrative positions
- Other, country-specific positions

Data from the DOMAINE survey on donor management in Europe show that the largest part of the total number of full time equivalents (*fte*) in donor management is reserved for nurses, followed by donor attendants not qualified for venepuncture.

EU Commission Directives do not provide detailed guidance on required qualifications for personnel: only general regulations are given. All staff involved in blood transfusion activities should be competent and qualified to perform their tasks and should be provided with timely, relevant and regularly updated training [2, 3]. No details are given for required education, preparatory training and skills. More detailed qualification requirements may be included in national legislation or in blood establishments' own guidelines, such as medical degrees, nursing qualifications or other education and training in health care.

In order to have the right person in the right position, both adequate employee recruitment and staff training are important. When hiring new employees with no specific background or education for their new position, specific job training can be offered, e.g. for donor attendants (Section 11.2 contains more information on training).

11.1.4 General competences: knowledge, skills and attitudes

Blood donor management requires general and professional competences that encompass a combination of knowledge, skills and attitudes. Areas of professional competences include those listed in Box 1.

Box 1. Professional competences in donor management

Basic
- Knowledge of blood and blood banking practice
- Understanding the country, its people and its culture, including that of minorities

Medical
- Basic nursing competences
- Venepuncture techniques
- Blood donation procedures
- Donor health and safety management
- Management of adverse events and reactions, including first aid

Behavioural
- Motivation, ability to understand the psychology of (non-)donors
- Liaising with donors, donor organisation and blood banks
- Planning information, education and communication (IEC) materials
- Evaluating launched programmes
- Counselling

Management
- Organising blood donation sessions
- Assisting in relieving emergencies and blood shortages
- Administration, including record keeping
- Working with computers

Knowledge and background training

Blood donor management requires information and knowledge from different disciplines, such as medical science, sociology, psychology, biomedical sciences, communication sciences and organisation sciences. People with background training in bioscience, social science, management science, transfusion medicine, blood banking, haematology, pathology, medicine, surgery, education, psychology, communication, public relations, ethics or literature may be prepared for work in donor management through special training programmes prepared by experts in the field. Their basic specialist knowledge generally requires upgrading and additional training on specific knowledge in the donor management field.

Skills

Box 2 shows skills for which all staff in blood donor management will be held accountable – both in their daily performance and in their performance reviews. These competencies are equally important to all professional skill requirements of blood donor management.

Box 2. General skills

- Task-related skills, such as venepuncture
- Ability to work in a team and to solve problems
- Skills in oral and written communication
- Change control
- Incident reporting
- Quality management
- Safety and security

Additional specific skills

Besides these general skills, specific skills are required for management staff, stated in Box 3.

Box 3. Additional skills for management staff

- Planning skills: ability to conduct planning in blood donor management for geographic areas. Understanding of transportation and infrastructure planning
- Computer skills: skilled in word processing, able to use descriptive statistical packages, knowledgeable about blood donor management information systems
- Organisational skills: ability to organise blood donation sessions
- Communications skills: effective in public relations, presentations of the blood donation data, technical report writing
- Language skills: fluent in one or more languages in addition to the native language
- Analytical skills: understanding of demographic analysis; knowledgeable about basic statistical analysis

Crucial attitudes

The attitudes described in Box 4 are considered as general qualities of staff involved in blood donor management.

Box 4. General attitudes

- Compassion and empathy
- Understanding
- Patience
- Politeness
- Imagination and innovation
- Enthusiasm and stamina
- Strong motivation, conviction and dedication

Desirable attitudes

Additional attitudes desirable for management staff are shown in Box 5.

Box 5. Additional attitudes for management staff

- Loyalty
- Recognition that blood is a valuable product that should be treated with great care
- Commitment to providing excellent blood donor service by treating others with a positive and proactive attitude that demonstrates interest in helping the blood donors, and going the extra mile when necessary
- Following through on commitments in a timely and efficient manner and keeping blood donors appropriately appraised when delays occur
- Actively and patiently listening to donors to ensure that their needs and expectations are well understood before providing service
- Recognizing that each blood donor is a unique individual and important to the blood supply chain

11.1.5 Tasks and responsibilities

The donor management process comprises a variety of tasks. These tasks are divided among several staff positions. For every position and for every employee an up-to-date job description should be available, clearly describing their tasks and responsibilities [3]. Furthermore, an organisational chart showing the hierarchical structure of the organisation and the delineation of lines of responsibilities is recommended [4].

11.1.6 Multiskilling

Particularly in blood collection, tasks are traditionally done by teams composed of employees who have well-delineated, separate tasks. Over the years, more teams have changed to a 'multi-skilling' approach. Multi-skilled staff can perform a range of different tasks within the team; for example, employees who register attending

donors may select donors during a blood session and also perform the venepuncture. Evidently, combining tasks can only be done within the specifications of the prevailing quality system. Multi-skilling within teams demands a clear description of tasks and responsibilities.

Multi-skilling within teams also entails several advantages, as described in Box 6 [5].

Box 6. Advantages of multi-skilling

- Teams are flexible
- Employees are more aware of the workflow
- Employees are better prepared to anticipate problems or requirements of other tasks
- Employees can assume other tasks when there is absenteeism
- Employees can be moved to other positions at peak times of the operation
- Jobs remain interesting and challenging

11.1.7 Performance indicators for human resources management

Section 3.3 describes several performance indicators (PIs) that allow for benchmarking within and between blood establishments. In order to evaluate human resources, the following PIs can be used, in accordance with generally accepted HRM performance indices.

- Number of employees (full timers, part timers, free lance workers)
- Turnover
- Absenteeism

In addition, the following PIs are relevant.

- Training level of all workers
- Number of volunteers in donor management
- Number of volunteer hours spent in donor management
- Ratio of productive workings hours of the donor team to the total of paid hours of the donor teams. Productive, direct hours are those hours within which donors can visit the donor session, i.e. opening hours. Non-productive, but paid hours, may include the travelling time of the donor team, and the time needed for setting up and breaking down the mobile collection site

11.1.8 Volunteers

In several European countries, volunteers are involved in the donor management process. Blood establishments receive help from either individual volunteers or from volunteer organisations, such as the Red Cross. Typically, volunteers are involved in recruiting and retaining blood donors and in activities during blood sessions, such as catering activities, administrative tasks and providing post-donation care. The DOMAINE survey shows that the majority of the responding blood establishments (76%) work with volunteers. Fifty-seven percent of these use the help of volunteers to promote blood sessions, while 52% are assisted by volunteers in donor recruitment activities, such as reminding donors of a scheduled blood session (under the guidance of a qualified blood establishment blood donation coordinator). In addition, 38% use volunteers during the donation process, such as providing post-donation care.

Volunteer skills: The EU Directive 2002/98/EC [2] does not mention or specify whether any volunteers facilitating the efforts of blood establishments need to have any special qualifications. In fact, no special skills are required. For example, volunteers working for the Red Cross have different social and economic backgrounds, talents and skill levels. It seems that all blood establishments welcome such invaluable contributions in facilitating their work, especially in terms of auxiliary assistance.

Blood establishments often have no policy with regard to which individual constitutes a suitable volunteer. There is always room for more volunteers, whose contribution to the chain of securing a continuous blood supply is invaluable. Training programmes specifically aimed at volunteers are recommended, in order to gear staff and volunteer activities.

Volunteers and donors: Donors seem to relate well to volunteers, and are often encouraged by them to donate blood, especially when the volunteers are donors themselves. In addition, involving volunteers from ethnic minorities may be advantageous especially when efforts are made to recruit blood donors within these groups in order to cater for patients of ethnic minorities. Potential donors from ethnic minorities do not feel alienated through language barriers, and seem to relate well to their compatriots.

The use of a volunteer contract, which describes tasks and mutual expectations, and special insurance provided by the blood establishment is highly recommended.

SECTION 11.2

TRAINING

11.2.1 Introduction

Ensuring the competence of blood establishment staff is a crucial element in sustaining a safe blood supply. Good donor management requires specific skills, competences and attitudes, and training of all staff is a legal requirement and responsibility of the blood establishment. Such training should be carefully planned and its quality assessed on a regular basis.

The purpose of this section is to assist blood establishments in EU countries to meet the training needs of blood donor management, in order to improve their capacity to collect sufficient quantities of safe blood and blood components, and cover patient transfusion needs.

This section aims to discuss staff continuous training, and evaluate the criteria for training effectiveness.

11.2.2 The importance of training

Training helps to increase knowledge and to optimise employee skills, which benefits the blood establishment's strategic goals. Skills and knowledge can be increased at each level, which contributes both to the individual development of employees and to team goals. Training can increase understanding for organisational goals and, at the same time, increase performance and productivity.

The EU Commission Directives require that all staff involved in blood transfusion activities should be competent to perform their tasks and receive timely and relevant training[2]. Blood establishments are obliged to have initial and continued training available for all staff, appropriate to their specific tasks. Training records should be maintained[3]. Additionally, the Council of Europe requires that this initial and continued training should cover the relevant principles and practices of transfusion medicine [4].

11.2.3 The education and training cycle

There are five fundamental, cyclical steps to consider when implementing a continuous education and training programme in blood establishments.

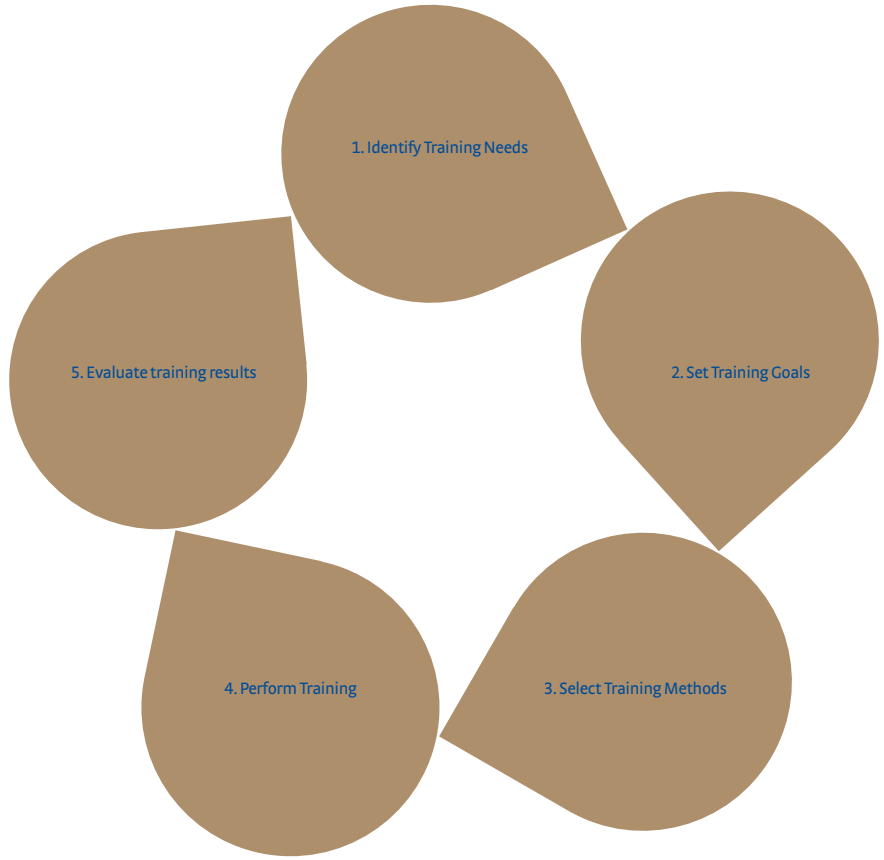

Figure 1. Training cycle. See text for further explanation.

1. Identify training needs

Training needs should be assessed by determining the knowledge and skill requirements for each specific task, and the person responsible for training. The number of staff requiring training should be established together with the training currently available. A baseline assessment of knowledge and practice should take place to identify areas which need improvement and to target training and education. This assessment will also ensure better use of resources and increased efficiency that can improve working relationships, communication, and liaison between staff and management. Two methods often used to gather information about the existing knowledge and practice are questionnaires and observation in practice.

2. Set training goals

Training goals should be determined by and communicated with staff and management.

3. Select training methods

Teaching methods, based on the training needs of the identified staff groups and available resources, should be selected. An effective training programme requires leadership and full commitment from the senior management of the blood establishment. Several forms of training are available: classroom learning, teaching on-the-job, self-teaching e-learning, and train-the trainer methods.

In-company training allows programmes to be tailored to a blood establishment's specific needs and provides concise guidance on all the key practical aspects of developing a training programme. In this way, in-company training is easily adaptable to comply with the legal requirements for staff to have demonstrable evidence of training, and knowledge and competence in the tasks that they perform. Curricula for the training programmes have to be designed to meet all these needs.

4. Perform training

Choosing the right training facilities and training schedule are important organisational steps. Trainers should be acceptable to the trainees to achieve the right outcome. One should not hesitate to switch the trainer, if the 'click' between trainer and trainees is lacking or insufficient.

5. Evaluate training results

Training needs should be evaluated regularly, as knowledge and skills can get out of date. The required knowledge and competence for each position should be evaluated periodically, as emerging new techniques and knowledge can change training needs.

Training programme content

In line with the competences mentioned in Subsection 11.1.4, the contents of training programmes could include the following topics. Choice of topics and level of training depend on the tasks and jobs involved.

- Initial training covering the general blood banking process
- Initial training covering specific position-related knowledge and skills
- Position-specific training, such as venepuncture and donor care
- Haematology or transfusion medicine
- Quality Management, with special reference to Good Manufacturing Practice (GMP) and Standard Operating Procedures (SOPs)
- First aid training
- Management programmes for managerial positions
- Communication skills
- Customer service
- ICT training
- Complaint handling
- Training for volunteers

DOMAINE training programme on donor management

The quality of donor management relies on the competence and appropriate and timely training of staff. Up until now, no public training programs with set syllabi have been in place for blood donor management. However, in 2011 the DOMAINE project will provide a donor management programme for blood establishments. The training programme will be based on this DOMAINE Donor Management Manual.

11.2.4 Evaluating training effectiveness

Training staff is a continuous process. New staff receive initial training and employees already employed at the blood establishment receive continual training in order to keep up with current knowledge and required skills.

Staff assessment: EU Commission Directive 2005/62/EC [2] states that the competence of personnel should be evaluated regularly. The Council of Europe adds that all personnel should have a competency evaluation appropriate to their specific tasks and that this should at least include good practice and relevant knowledge in microbiology and hygiene.

The assessment of theoretical knowledge and practical competency is necessary to evaluate or measure learning achievements and competence as well as to provide information for more effective teaching. A record management system should be developed for the training. The evaluation of a teaching programme against predetermined goals can help determine the overall effectiveness of several components including participant learning, trainer effectiveness, learning environment, use of resources and organisational impact. Commitment and maintaining momentum will assure higher levels of awareness and motivation of the staff for training that will bring the continuity in training.

Training Evaluation: EU Commission Directive 2005/62/EC [2] also requires periodic assessment of training programmes. Such training programmes must be periodically reviewed and the effectiveness of training courses periodically assessed [3]. Training and competency should be documented and a training record maintained for each employee.

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INFORMATION TECHNOLOGY

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CHAPTER 12

SECTION 12.1

BASIC ISSUES

12.1.1 Introduction

Most blood establishments use information technology (IT) and computerised systems, not only for blood donor and collection management, but also for the whole transfusion chain process from donors to patients. The first objective of using such technology and equipment is to ensure complete and reliable traceability of actions and (intermediary) products in the entire process. Beyond this primary objective, there are some additional ones.

First, IT-systems improve the safety of donors and recipients. Second, they simplify the donation process and help the staff involved to systematically comply with the regulatory/mandatory requirements. Last but not least, they greatly facilitate managing the entire donation process by facilitating information retrieval.

This chapter is not meant for IT managers. It is written for donor managers, including employees involved in donor related activities to highlight the most relevant IT-principles and to mark points of interest when acquiring (new) ICT systems.

- **Functions:** What could be expected from computerised systems for blood donor and collection management?
- **Processes:** Which donor management steps benefit from ICT?

12.1.2 Donor information management

The DOMAINE survey on donor management in Europe showed that a large majority of blood establishments in Europe use computerised systems to register data. However, a few blood establishments still use handwritten registries. All blood establishments register the donor's name, date of birth, gender, home address and telephone number. A majority also record a donor's email address. Less often, they record the country of birth, profession and level of education.

The majority of blood establishments keep a registry of the number of donations; the number of deferrals and their reasons; the length of the deferral period; and reasons for stopping. Finally, many blood establishments register the donor's preference in invitation method, and even keep track of which direct marketing materials are sent to their donors (see Figure 1).

The foremost requirement for an effective computerised system for blood collection organisations is a robust (personal) data record system which meets current confidentiality demands. All parts of the system should comply with data confidentiality legislation and preferably should facilitate on-line access for direct data update or change of contact details or donation status. Boxes 1, 2, and 3 display recommended items to be stored in a (computerised) registry. Storing that many items is not feasible without the use of a computer.

Registration by blood establishments (%)

Figure 1. Percentage of blood establishments that register the data mentioned

Box 1. Basic donor entry information

- Name
- Gender
- Birth date, birthplace and, when authorised, ethnicity
- Contact details
  - home address
  - working address
  - (mobile) telephone number
  - e-mail address
- Preferred contact medium
- Preferred address of donating opportunity when appropriate
- Response(s) to invitation(s)
- Special donor category or 'club' status
- Donor relationship communications record
- Donor call up status
- Donor awards/recognition record, marketing materials sent

All of the above should be available for direct on line update, accessed after submission of agreed personal password.

Box 2. Health screening history data

- Health questionnaire results
- Health screening data and comments
- Medication
- Biometry
- (pre-donation) Hemoglobin and or hematocrit level
- Any other health check results
- Deferrals
  - reasons
  - length of the deferral period, in case of definite deferral: infinite
- Laboratory results
  - blood group: ABO, Rhesus type, any other
  - infectious disease markers
- Post-donation donor information baring consequences for collected products

Box 3.

a. Donation History
- Dates and types of donations
- Volumes collected
- Total number of each type of donation
- Adverse events

b. Donor Status
From the donation history the donor status can be derived (see Section 4.1 for further explanation and definitions)

- Newly registered donor
- First time donor
- Regular donor
- Returning donor
- Lapsing donor, including reason if available
- Inactive donor, including reason if available
- Stopped donor, including reason if available

12.1.3 Donor invitation

The computerised system can be used to develop and facilitate invitations to donors to donate at a given collection venue, date and time. It allows developing different modalities of invitations: post letter, SMS, e-mail. A website connected to the blood establishment's computerised system may also allow donors to make reservations for a next donation and, in some cases, to register their interest in becoming a donor. A range of dedicated software for this purpose is commercially available.

12.1.4 Pre-donation interviews

As was recently reported, a computer-assisted touch screen for donor self-interviewing could replace the classical face to face interviews [1]. The authors' experience has shown that the automated donor interviewing system was enthusiastically accepted by the blood donors and collections staff. This system proved to be more effective than face to face interviews in eliciting a higher frequency of truthful answers to sexual and socially sensitive questions, and in reducing the frequency of staff errors and omissions during the interviewing process. It was also shown to be more efficient, with an average staff time reduction of five minutes per interview. It is highly probable that such a computer-assisted interviewing system will be developed in blood establishments in the near future.

12.1.5 Donation process information management

Concerning the donation process itself, it is currently recommended that bar codes and handheld scanners be used (see also Section 12.2 Technical Aspects). In doing so, one can actually register in 'real-time' the different equipment and disposables successively used in each collection process, and identify the employees involved at each step of the process. Thus, at the end of the collection line, the up-to-the-minute story of each collected whole blood unit or blood component will be available.

12.1.6 Archiving historic data

Storage time of data contained in the donor/donation database regularly exceeds the time limit fixed in the regulatory requirements (minimum of 15 years in the Directive 2002/98/EC) or in the blood establishment's country regulations (which could indicate longer time limits). It also happens that the current computerised system is replaced by a new one, with consequences for data storage. The data not required for immediate access, may or may not be archived, depending on national rules and regulations (among other considerations). Archiving must be done in such a way that data can be retrieved and read (unless the data is migrated to a validated replacement system). An archive report should be generated describing the appropriate archive approach and listing the electronic records archived, again fully in compliance with current rules and regulations.

SECTION 12.2

TECHNICAL ASPECTS

12.2.1 Introduction

Working with ICT is not feasible without proper hardware, software and specially trained personnel. Moreover, if a blood establishment works with ICT-systems, all members of the staff will be confronted with different parts of the system. Donor management is not an exception. This section describes some practical aspects.

The first and most important practical requirement is that the systems used in the different parts of the blood transfusion chain are compatible with the training level of the employees and compatible with each other. New and renewed technologies are continuously made available and some of them are very promising for the management of the complex processes present in the blood establishment. However, incompatibility may turn a good purchase into a 'nightmare'.

Validation and safety issues are discussed also in this section. Easiness of managing the donor data base and extracting management information are also important requirements when selecting (new) ICT systems.

- **Precautions:** What general precautions have to be taken regarding IT system infrastructure, programs and software, interfaces with identification means and interfaces with other software: technical aspects?
- **Validation:** What are the main principles of computerised system validation?
- **Confidentiality:** What are the main confidentiality and safety aspects to take into account?
- **Performance indicators:** How can the computerised system be used to produce performance indicators and help managing both donors and collections?

12.2.2 IT-system hardware and infrastructure

IT-system infrastructure can be divided into several parts as follows.

- **Servers and hosts** including operating systems and database hardware
- **Internal network infrastructure**, which can be defined as the transportation and communications systems, including switches, routers, cabling and network monitoring tools within the blood establishment organisation
- **User interfaces:** workstations, laptops, web access tools
- **External interfaces**, networks and security components

For each component of the IT infrastructure, great attention should be paid to writing the *User Requirement Specification* (URS). This key document should describe what the process owner (the blood establishment or, more precisely, the donor managers) want or expect from the system. It is required for any new automated system or significant change to an existing system.

12.2.3 Programmes, software, donor relationship software

The DOMAINE survey showed that in 2007 a large majority of participating blood establishments used data processing software. They either used commercial software only, in-house software only, or a combination of both. Only three blood establishments (7%) indicated no use of an electronic data processing system and two of them reported that their data registration was handwritten.

Internal and Europe wide IT compatibility: Countries differ with respect to requiring uniformity within a country for those data processing systems used by different blood establishments. Somewhat less than half of the blood establishments indicated with-in country uniformity, i.e. that their system is used in their country by all other blood establishments. Most blood establishments reported non-uniformity or compatibility, i.e. that the data processing systems in their country, used by other blood establishments, were different. Given the growing effect of increased migration, it is recommended that, at least on a national scale, but preferably Europe wide, some exchange of data could be facilitated. Therefore, uniformity and compatibility, at least within countries, should be considered.

Donor management software: Besides their regular data processing system, some blood establishments use special donor relationship management software (or Client Relation Management, CRM, software), defined as software used specifically to manage communications with donors, co-ordinate campaigns and assist with donor recruitment.

User Requirement Specifications: In all cases, writing the *User Requirement Specification* (URS) for these functional requirements of the computerised system is essential. The approval of the URS should be documented in accordance with the prevailing Quality Management System and should integrate compliance with the current regulatory requirements as stated by the blood establishment or the national government.

12.2.4 Interfaces with means of personal identification

An increasing number of automated technologies exist for identifying persons, and identifying and labelling products. Apart from the old passport (or other form of personal identification, such as driver's licence), the applicability of systems such as finger print readers or iris scans to identify persons is expanding. At present, bar code identification (labels and readers) is applied by most blood establishments in some way. Labelling and subsequent identification using newer technologies is also on the rise. The technology of Radio Frequency Identification Device, RFID, which is more or less in a developmental stage in the blood transfusion world, seems very promising.

Barcode

For many years, a bar-code donor (and patient) identification system has been found to simplify and make safer the transfusion process [2]. A great deal of important information is carried by the bar-coded blood product labels. Since blood collected and processed in one blood establishment may be used in another blood establishment or

even in another country, it is important to use globally unique blood product coding and labelling systems.

The international system for coding and labelling blood products, called ISBT 128, has been implemented in many blood establishments in Europe and all over the world. These implementations have always been successful [3]. It is highly recommended that the ISBT 128 coding and labelling system be implemented in every blood establishment.

Whilst most existing bar coding systems in blood transfusion are based on the linear bar code (Code 128), two dimensional (2D) barcodes are also available. 2D codes are able to store much more information in a small amount of space making them a suitable alternative for labelling small items. ISBT 128 recommends use of the Data Matrix 2D symbology and provides a means of placing several ISBT 128 data structures into a single Datamatrix code.

RFID

Radio Frequency Identification Devices (RFID) are currently being actively evaluated as information carriers for use in the transfusion chain. The recently published ISBT Guidelines on RFID [(4)] recognise the importance on ensuring consistency between information held in bar codes and RFID and recommend the use of ISBT 128 data structures in RFID. Such an approach will minimise the impact of this new technology on data processing software.

RFIDs enables more information to be stored on the RFID tag, it allows for automated identification and data capture, it can include sensors for condition monitoring such as time and temperature, and in certain conditions it permits simultaneous read of multiple tags. The potential advantages of passive RFID technology (where the tag is activated by the energy from the reader's RF field) and its potential benefits for improving safety, quality and efficiency have been explored by several teams [5-7].

Among others, RFID technology offers the following possibilities.

- Inserting much if not all relevant donor data in the donor card
- Inserting all relevant data in the tag of any collected product
- Inserting any additional information in the tag of any (intermediary) blood product all along the transfusion chain process
- Helping to manage blood products in (secondary) blood processing and issuing units at a distance from the central blood establishment facility
- Ultimately, improving recipient safety in allowing an electronic cross-match at the bedside of the patient, also tagged and identified through RFID technology

For all these reasons, it is expected that this technology will be developed for application to the transfusion chain in the near future. Nevertheless, an important statement from the conclusion of the RFID guideline is that 'RFID adds another layer of safety to the safeguards of current labelling systems. The tag will not substitute, replace, or interfere with any required barcode or labelling information, and RFID software will augment existing blood bank and transfusion systems and not replace them' [4].

Identification of the donor by means of a chip card

Chip cards (or smart cards) can be used for donor identification. These are pocket-sized cards that contain embedded integrated computer circuits. Donor data can be stored on these chip cards. Every time a donor presents himself at a donor session, his identity should be checked. Chip cards can facilitate this process.

There are two types of card readers for chip cards. The most common is the contact 'contact chip card reader', which is a communications medium between the smart card and the donor database. A second type is the 'contactless chip card reader', in which the chip communicates with the card reader through RFID-technology.

Chip cards can be used for authentication of identity. The most secure way is to use PKI (Public key Infrastructure) and digital certificates. The owner has to use a PIN-code that will be validated by a central organisation. The need for specific infrastructure makes that this identification technique is mostly used in applications supported by the internet. The central and local infrastructure is costly and not easy to implement in a mobile environment. The easiest way of identification is when the card has a photograph of the owner. In that case there is a visual check that the card belongs to the right person.

In some countries such as Belgium, the entire population has a chip card, eID, issued by the Belgian government. Every citizen is obliged to have the card with him. The eID is used to identify the donor and to manage the donor registration process for each donation. If the data on the card deviates from the data in the donor database, e.g. when the donor's address has changed, the donor database can be updated in an easy, electronical way.

Figure 2. Bar code, 2d bar code, RFID and chip

12.2.5 Interfaces with other software

Two important, but different software linkage or interface issues arise: the first is directly linked to the blood collection process; the second concerns the blood chain and related processes. A way to overcome compatibility difficulties between software systems is to construct a data warehouse.

Directly linked to the collection process

It is possible to use different software for different parts of the donor or collection management process. For example, some blood establishments are using both com-

mercial software for blood banking activities and specific, different software for donor relationship management (see above). Also, it is conceivable that specific software could be developed for managing donor marketing activities. In all these cases, ensuring compatibility between different software simultaneously used for different parts of the process is essential to prevent frustration and the loss of time.

Not directly linked to the collection process

The same applies to the human resources software, as they are used at least for work time planning, working time managing for collections staff, and also for calculating indicators as collection efficiency ratios (see Chapter 7 Collection). Current experiences reported by many blood establishments show that ensuring compatibility between commercial blood banking software and commercial human resources software seems to be difficult everywhere.

Other examples of similar compatibility difficulties can be given in relation to temperature monitoring software (monitoring the temperature of collected products), maintenance recording software and finance software (particularly for cost accounting). In all these cases, special effort should be made to ensure compatibility between the different software systems to optimise the benefit that could be drawn from the simultaneous use of different software for donor/collection management.

Data warehousing

The reason compatibility difficulties arise between software systems relates to the differences between programming languages, data and file architecture. The principles to construct a data warehouse, to help overcoming these problems, are briefly described thereafter.

Data from incompatible software systems is extracted and transformed into a common format as it is loaded into the warehouse. This allows reports using data from different computer software to be analysed and reports written in a common format. This can provide the basis for the establishment of an overarching management information system (M.I.S.)
Such data warehouses allow the integration of electronic information from many sources and the provision of useful management reports. Data can be taken from systems such as the following.

- Blood Banking Software
- Customer Relationship Management Software including donor appointments
- Human Resources software
- Resource Planning and Scheduling software
- Accounting System software
- Automated collection equipment such as that used for the collection of double red cell donations, aphaeresis platelets and plasma donations
- External data sources – census information, geographical/mapping data, post code databases

12.2.6 Validation

The guidelines published in early 2010 by the *Working Party on Information Technology Validation Task Force of the International Society of Blood Transfusion* updated the *ISBT* guidelines for validation of automated systems in blood establishments [8]. They provide guidance on the validation of automated systems in blood establishments and this covers the organisations involved in donor management and blood collections.

In all cases, the validation process consists of evaluating the automated system against established *User Requirement Specifications* and against regulation and standards as applicable in the concerned blood establishment or country. The validation process also includes evaluating the needs of system and environment configuration, evaluating the requirements for installation, and evaluating the training requirements. In all cases, installation qualification, operational qualification and performance qualification will be performed for each component of the computerised system infrastructure and for the functional aspects.

12.2.7 Confidentiality and safety issues

Security policies should be developed to define the rules and provide guidance regarding the use of and access to critical information. This could be performed through the *Guidelines on Information Security* from *ISBT* [9]. User access policies should be developed requiring unique identification codes for each user, periodic password change, and prohibition of password sharing. Appropriate measures should be taken against unauthorised input, deletion, or modification of critical data. System access policies should be developed in order to protect the system from unauthorised access (see also Chapter 13 on ethical considerations for a discussion on related issues).

Risk assessment: Risk assessment is required when a new automated system is to be implemented, changed or upgraded. It is also required when it has never been performed previously for an existing automated system. It must be performed to identify critical control points and to define risk mitigation or elimination plans. This requires consideration of the impact, probability and detectability of a potential hazard or harm to the computerised system.

Business plan: A business continuity plan is required and consists of a number of elements designed to minimise disruption to the business in case of system failure/unavailability. An approach based on such risk assessments is recommended.

12.2.8 Donor database management

Maintaining a data base and validly extracting data from it is a specialty of its own. Although the (donor) managers should be in the lead when defining data extractions, often called 'data base queries', this is doomed to fail without the specialised help of IT-personnel, such as programmers.

Database maintenance

One important function of any IT system is to record data and to establish relevant and useful indicators from the recorded data. For donor and collection managers, this relates to donor database management and it is of paramount importance to regularly improve the donor database quality. As an example, this concerns the donor classification into segments for donor marketing activities and updating donor data.

This work should allow for the clear delineation or elimination of *stopped donors* from the active donor data base, as far as possible. The ratios of the different population segments are important to consider regularly in order to deduce the appropriate corrective measures. (See also Chapter 4 Donor Base for a more thorough discussion).

Donor identification: Another example concerns the quality of donor identification. Some blood establishments developed daily alerts enabling recognition of evident abnormalities of donor identification, according to predefined rules. This kind of tool could significantly contribute to improving the safety of the whole transfusion process in regularly correcting donor identification errors, thus improving donor identification quality.

Performance Indicators

Structuring and maintaining the Donor Data Base and related data bases are, amongst others, processes set up to produce relevant and useful performance indicators, and to help donor managers to manage these processes. This potentially concerns all the performance indicators shown in this manual.

Making performance indicators easily available could give managers additional time to analyse the results and to find and implement appropriate solutions to continuously improve the donor and collection management process. The kind and definitions of these Performance Indicators, PIs, are discussed throughout this manual. General or Key Performance Indicators, KPIs, are discussed in Section 3.3 Performance Indicators.

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ETHICAL CONSIDERATIONS

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CHAPTER 13

SECTION 13.1

ETHICAL ISSUES IN BLOOD DONATION

13.1.1 Introduction

For good reasons, participating in the blood product chain, from donation to transfusion, entails a series of ethical [1] issues. Blood is of human origin and this precious resource has a limited shelf life. Donor management carries a two-sided moral responsibility towards both donors and blood product recipients. This often entails negotiating between different interests and ethical decision making.

Policy and donor management decisions are founded on four principles of ethics.

- Respect for individuals and their autonomy
- Protecting individuals' rights and well being
- Avoiding exploitation, part of the more general principle of distributive justice [2]
- The Hippocratic principle of *primum non nocere* or 'first, do no harm'

In donor management, some special ethical issues arise and can be divided into two groups.

Commercial considerations: There is a lengthy and heated debate on the permissibility of trading one's own blood. Given that blood products derive from non-remunerated donations, how can one avoid exploitation and ensure distributive justice if such products then enter a commercial chain?

Mistreatment of donors and prospective donors: Blood is a sensitive matter, and perceived or true mistreatment of donors can have a strong impact on public and political discussions.

This section touches upon some of the ethical issues. For additional information and discussion, further references are mentioned below.

13.1.2 Remuneration or not?

All over the world, donating blood, tissues or even organs represents for many, their giving the priceless, special 'gift of life'. Preferably, this is done out of true altruism and is simply meant to help others in need of blood products, without which they soon would die or lose quality of life.

Dangers of exploitation: Selling one's bodily parts, such as blood, traditionally is 'not done'. Even though hardly any risk is involved in the act of blood donation, exploitation may easily emerge when bodily parts become subject to the market system. Importantly, the blood products donated become 'joint property', meaning that everybody is entitled to receive them, if appropriate for improving health. From that point of view, this unique human act precludes any trade or commercialisation [3 - 6]

Blood as commodity? In contrast, some people argue that blood is a commodity or good like many other health care products, albeit that it has special and partially unique properties.
Every individual produces blood in the same way: only 'production conditions' vary and so do some of the product specifications, such as blood type. Commercialisation from that point of view is a logical result.

Selling blood? Some argue that 'People sell their talent, experience, skills, services, creations, et cetera, and their value is determined by the laws of the market. So, why should persons not be able to sell their blood? There is hardly any risk involved in donating blood, is there?'

Economics

Notably, among all the actors in the blood transfusion chain, recipients, volunteers and donors are the ones who do not make money.

Recipients: Recipients of blood products (patients, or 'clients') can, in fact, be expected to pay for blood products, either themselves or through their insurance, or in whatever way, depending on a country's health care financing system. The patient's gain for this payment is extra life expectancy and quality of life.

Volunteers: By definition, volunteers deny payment. We all accept their choice, and take proper advantage of it.

Donors: This leaves the blood donor as the only person breaking the common rules of economics in the entire transfusion chain. This works out well, as long as no shortages arise [7]. All the others in the blood transfusion chain do make money, not uncommonly, even for a living. They include the following groups of persons.

- **Management and employees** of a blood establishment
- **Suppliers** of equipment, disposables, housing and all other materials necessary to run a blood establishment
- **Health care workers**, such as prescribing doctors, those involved in administering blood products and supporting activities such as laboratory testing and distribution

There is probably nothing wrong with that, as long as market principles are considered a socially acceptable elaboration in accordance with distributive justice. Subsequently, these 'paid actors' in the transfusion chain must guarantee individual rights and well being. Paid staff must show respect for a different set of opinions. They should, for example, not refuse transfusing blood products to people merely on the grounds that they are not (or have not been) blood donors themselves.

Blood as tradable good? All of this may imply that blood is some kind of tradable commodity or good. However, from a legal point of view, the question arises as to whether blood or blood products can actually be considered a good.

In the European Union goods have been defined as: 'products which can be valued in money and which are capable, as such, of forming the subject of commercial transactions' [8]. In their reasoning the European Commission did not exclude the possibility that blood may be considered a 'good', for the following reasons.

1. Although international treaties prohibit financial gain of blood, these treaties are not binding.
2. In the European Community, blood is subject to normal customs tariff.

The question as to whether or not blood is a 'good' has not yet been decided and could become a matter before the European Court of Justice. The door to commercialisation has not been closed.

Recipient safety: Another important reason remains for not wanting blood to be commercialised: the safety of the recipient. It is a proven fact that donors paid in cash show a much higher risk of having a transfusion transmittable infectious disease [9]. But also other types of payment, including vouchers or free tickets and time off work, could imply an increased risk [10]. A plausible reason behind that increased risk is that the prospective donor involved might be inclined to 'forget' recent risky behaviour or health impairment that could interfere with their being eligible for blood donations.

13.1.3 Voluntary donation

Possible coercion? As is laid down, for example, in the *ISBT Code of Ethics*, 'blood donation including haematopoietic tissues for transplantation shall, in all circumstances, be voluntary and non-remunerated; no coercion should be brought to bear upon the donor' (see Box 1). Although many people and organisations, including the WHO, agree with the above principles, in many places some kind of coercion is present, as is the case when so-called replacement donations occur.

Donor motivation: When donors are asked why they donate, five primary motives emerge.

- **Altruism:** out of unselfish concern for others, or, for the benefit of someone else, not impossibly at one's own expense
- **Solidarity:** for the unity resulting from common interests, feelings, or sympathies
- **Social Capital:** some people donate blood, others donate money or goods and so, everybody takes their share of duties
- **Reciprocity**: exchanging blood donations with others for mutual benefit. 'I donate blood now, because I want to get it when I need it'
- **Incentives** ('quid pro quo'): better self-esteem, items of small or limited value, payment, compensation, health check, or anything else that represents value to the donor

Box 1a. ISBT code of ethics for blood donation and transfusion [11]

A CODE OF ETHICS FOR BLOOD DONATION AND TRANSFUSION
The objective of this code is to define the ethical principles and rules to be observed in the field of Transfusion Medicine.

Blood Centers: donors and donation

1. Blood donation including haematopoietic tissues for transplantation shall, in all circumstances, be voluntary and non-remunerated; no coercion should be brought to bear upon the donor. A donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonable needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation. The donor should provide informed consent to the donation of blood or blood components and to the subsequent (legitimate) use of the blood by the transfusion service.
2. A profit motive should not be the basis for the establishment and running of a blood service.
3. The donor should be advised of the risks connected with the procedure; the donor's health and safety must be protected. Any procedures relating to the administration to a donor of any substance for increasing the concentration of specific blood components should be in compliance with internationally accepted standards.
4. Anonymity between donor and recipient must be ensured except in special situations and the confidentiality of donor information assured.
5. The donor should understand the risks to others of donating infected blood and his or her ethical responsibility to the recipient.
6. Blood donation must be based on regularly reviewed medical selection criteria and not entail discrimination of any kind, including gender, race, nationality or religion. Neither donor nor potential recipient has the right to require that any such discrimination be practiced.
7. Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.
8. All matters related to whole blood donation and haemaphaeresis should be in compliance with appropriately defined and internationally accepted standards.
9. Donors and recipients should be informed if they have been harmed.
10. Blood is a public resource and access should not be restricted.
11. Wastage should be avoided in order to safeguard the interests of all potential recipients and the donor.

Box 1b. Hospitals: patients

12. Patients should be informed of the known risks and benefits of blood transfusion and/or alternative therapies and have the right to accept or refuse the procedure. Any valid advance directive should be respected.

13. In the event that the patient is unable to give prior informed consent, the basis for treatment by transfusion must be in the best interests of the patient.

14. Transfusion therapy must be given under the overall responsibility of a registered medical practitioner.

15. Genuine clinical need should be the only basis for transfusion therapy.

16. There should be no financial incentive to prescribe a blood transfusion.

17. As far as possible the patient should receive only those particular components (cells, plasma, or plasma derivatives) that are clinically appropriate and afford optimal safety.

18. Blood transfusion practices established by national or international health bodies and other agencies competent and authorised to do so should be in compliance with this code of ethics.

The Code has been elaborated with the technical support and adopted by the WHO
Adopted by General Assembly of ISBT, July 12, 2000
Amended by the General Assembly of ISBT, September 5, 2006

13.1.4 Right to donate?

From the outset, the question regularly arises: are all people eligible to donate blood? This is definitely not the case. Of course, all free persons have the right to present themselves for blood donation. But this does not mean that they have the right to donate blood. What is the justification for refusing some people, or even groups of people from donation?

Safety: The safety of both donor and recipient is the main reason for deferring prospective donors, thus ensuring the second principle: protection of the individual. A person is only entitled to donate blood, when he or she fulfils the eligibility criteria. Eligibility criteria must not be in conflict with other, fundamental rights. Eligibility criteria must not entail discrimination – i.e. unjustified distinction, meaning that eligibility criteria must be built on solid ground. The burden of proof for criteria to be acceptable rests with the person or organisation formulating them.

Precautionary principle: On several occasions the precautionary principle [12] is applied. In health care and transfusion contexts this principle is applied by letting the safety of the recipient prevail. This becomes tricky when sensitive issues arise, such as the exclusion of men having had sex with other men (MSM)[13]. Clearly, discrimination must be avoided.

Criteria for exclusion: On the other hand, justified distinctions may still be made for deferring certain groups of prospective donors, when clear health risks for the recipient exist [14]. The primary reason for excluding candidate male donors on the ground of MSM is not that being homosexual made them non-eligible, but that their sexual behaviour carries a greater risk of transmitting HIV-infected blood. The deferral criteria are not a judgement on behaviour or (sexual) preference or (ethnic) descent, but a judgement on the (general, anticipated) risk related to behaviour. Having travelled in the jungle does not make someone a bad person, but does entail that person carrying a greater risk of transmitting malaria.

Age concerns: Inclusion of certain groups may also cause concern and debate, as the example of minors show. Most countries do not allow persons under 18 to donate. But the threat of blood shortages forces many countries to lower, or consider lowering the age standard down to 17 or 16. Here, not the safety of the recipient, but the safety of the donor is at issue. Younger donors show a higher risk of adverse reactions to donating blood [15, 16].

Other potential limitations: There seems to be a general consensus that being handicapped or disabled should not prevent people from donating blood. On the contrary, it is generally felt that all should be done to increase accessibility of collection centres, so as to facilitate donating blood by people who may experience some kind of limitation. Many limitations can be neutralised by personal help, environmental accommodations, or special equipment.

13.1.5 DOMAINE survey findings

Remuneration of donors: The principle of voluntary and unpaid donations does not exclude compensation for donors, if it is limited to reimbursing the expenses and inconveniences related to the donation. These expense allowances can be given in different ways. In some blood establishments such compensation is limited to travelling costs reimbursement, or a food voucher. In six of the 35 countries involved in the DOMAINE survey, donors might be given an expense allowance in cash, based on the incurred expenditure and the particular type of donation. Not all six countries are EU member states. Expense allowance mainly relates to plasma or platelet aphaeresis donations, and in only one country all donors are offered an amount of money. The sum, given to donors, ranges from €12 to €25 per donation.

Other incentives: Other establishments may offer a free physical check-up, or a free vaccination for influenza in winter. To some extent, these two means may be considered as useful for the blood establishment to maintain a safe donor population.

Free time off work: The DOMAINE survey (see Chapter 2) shows that donors are allowed free time off work in 14 countries. In most of these countries, this time is capped to the time needed for the entire donation process or to a limited amount of time (e.g. two or four hours). However, some blood establishments continue to allow donors to get a full day off work and this obviously is closer to real remuneration. Most

countries have discontinued such practices. It is important to underline that this discontinuation never resulted in a shortage of donors.

Commercial establishments: Blood establishments in seven countries reported the existence of commercial establishments. In four countries the commercial establishments only collect plasma for fractionation, but in three countries they also collect whole blood. This introduces competition for both donor recruitment and blood product selling, which, in recent experience, strongly impacts on donor retention, donor safety and patient safety (see also Section 3.5 on competition).

In conclusion, voluntary, non-remunerated blood donation forms the ethical cornerstone for donor management worldwide and is reflected in written literature and ethical deliberations. However, discussions are ongoing and the DOMAINE survey indicated that the margin between compensation and remuneration in practice is not always clear.

SECTION 13.2

ETHICO-LEGAL ISSUES IN TREATING DONORS

13.2.1 Introduction

The following subsections deal with issues that historically relate to legal rather than to ethical aspects of treating donors. In particular, some fundamental rights of the individual are discussed: the integrity of the body and protection of donor privacy. In general, these items have become accepted as ethical issues.

13.2.2 Informed consent

No donation can be collected without the informed consent of the (prospective) donor and several rules and regulations have been set up to that end [17, 18]. But not all blood establishments seem always to adhere to them [19]. To obtain informed consent, the information given to the donor must include the following items (see also Section 5.4.5).

- The purpose of donating blood
- The risks and potential consequences of donating blood
- A description of any benefits of donating
- Information on insurance coverage for donors
- A statement describing the extent of confidentiality of records
- Explanation of whom to contact for answers to pertinent questions
- Statement that participation is voluntary
- Statement that refusal to participate will involve no penalty or loss of benefits/ statement that the subject may discontinue participation at any time without penalty
- The ability to withdraw and not continue with the donation process

Information should be available in writing, but that does not preclude the necessity of personal communication.

13.2.3 Treating the donor respectfully

Staff must observe general etiquette. There is no difference of opinion on that, although cultural diversity may lead to differences on what is considered appropriate. The special situation in the collection centre, however, puts some extra demands on how donors should be treated.

- Donating blood is voluntary at all time. Care must be taken to prevent any kind of real or perceived coercion or pressure. Some blood supply systems still rely on the phenomenon of replacement donors. Whenever possible, this should be avoided
- A donor has the right to stop a donation procedure or being a donor at any time

for any reason whatsoever
- The donor has the right to ask questions. Staff must therefore be receptive and amenable to any question that may arise
- The privacy of the donor must be guaranteed at every stage of the donation process
- Premises must be accessible for people with physical restraints

13.2.4 Privacy, confidentiality

Blood establishments gather much personal data on the donor that is usually put into computerised systems. These systems are governed by current laws.

- Confidentiality of the data must be secured
- Access to personal data must be limited to authorized staff
- The donor has the right to inspect his records
- The donor has the right of correction and removal of his personal data within the boundaries of the current laws

13.2.5 Specific issues regarding the donation

In keeping with the principle of distributive justice, implying universal access to blood products, the donor has no say in determining the destination of the blood products derived from the donation. It is up to the doctor in attendance to decide how to administer the blood products. There are two exceptions to this rule.

- **Personal use:** Donors can make an autologous donation, i.e. a donation for therapeutical use in themselves. Then, the blood products can only be used for that purpose
- **Research:** With direct informed consent, a donation can be used for non-therapeutic purposes, e.g. research. The donor has the right to grant permission for this purpose, not to change or modify its use

13.2.6 Notification of important (adverse) information

The blood establishment must notify a donor of any important result or findings that arise during or after the visit to the blood establishment.

- Positive screening tests for infectious diseases
- Abnormal results from the biometrics or medical examination
- Hereditary predispositions-/diseases [20]
- Any other accidental finding that can be considered to be important to the donor or his/her family or acquaintances

Bringing important information to donors requires special skills, also known as counselling skills. In Section 8.3 counselling is treated in more detail.
The reverse also holds. A donor must notify the blood establishment of any information that can reasonably be considered of importance to the safety of the donor or the recipient of the blood products.

References

1 Ethics (Oxford English Dictionary): the moral principles governing or influencing conduct

2 Distributive Justice. Principles of distributive justice are normative principles designed to guide the allocation of the benefits and burdens of economic activity. The first relatively simple principle of distributive justice examined *[for further explanation, see the website page, Eds]* is strict egalitarianism, which advocates the allocation of equal material goods to all members of society. John Rawls' alternative distributive principle, which he calls the Difference Principle, is then examined. The Difference Principle allows allocation that does not conform to strict equality so long as the inequality has the effect that the least advantaged in society are materially better off than they would be under strict equality. However, some have thought that Rawls' Difference Principle is not sensitive to the responsibility people have for their economic choices. Resource-based distributive principles, and principles based on what people deserve because of their work, endeavor to incorporate this idea of economic responsibility. Advocates of Welfare-based principles do not believe that the primary distributive concern should be material goods and services. They argue that material goods and services have no intrinsic value and are valuable only in so far as they increase welfare. Hence, they argue, the distributive principles should be designed and assessed according to how they affect welfare. Advocates of Libertarian principles, on the other hand, generally criticize any patterned distributive ideal, whether it is welfare or material goods that are the subjects of the pattern. They generally argue that such distributive principles conflict with more important moral demands such as those of liberty or respecting self-ownership. Finally, feminist critiques of existing distributive principles note that they tend to ignore the particular circumstances of women, especially the fact that women often have primary responsibility for child-rearing. Some feminists therefore are developing and/or modifying distributive principles to make them sensitive to the circumstances of women and to the fact that, on average, women spend less of their lifetimes in the market economy than men. *Stanford Encyclopedia of Phylosophy*. Retrieved March 19 2010 from http:// plato.stanford.edu/entries/justice-distributive

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11 International Society of Blood Transfusion. *A code of ethics for blood donation and transfusion*. Retrieved 19 March 2010 from http://www.isbt-web.org/files /documentation/code_of_ethics.pdf

12 The definition of the precautionary principle most widely used relates to environmental issues and stems from the Rio Declaration of the UN, 1992: 'In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.' There is no law or European Directive on the precautionary principle. However, the EU Commission stated that the principle might be invoked where 'preliminary objective scientific evaluation, indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen for the Community'. Commission of the European Communities (2000) *Communication from the Commission on the Precautionary Principle*. Brussels: Commission of the European Communities

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APPENDIX I

Websites of relevant organisations

Council of Europe
www.coe.int

European Union
http://europa.eu

European Blood Alliance
www.europeanbloodalliance.eu

World Health Organization
www.who.int

Executive Agency for Health and Consumers
http://ec.europa.eu/eahc

International Federation of Blood Donor Organizations
www.fiods.org

Websites of related EU-projects

EU Optimal Blood Use Project
www.optimalblooduse.eu

EU-Q-Blood-SOP Project
ww.eu-q-blood-sop.de

European Blood Inspection Project (EuBIS)
www.eubis-europe.eu

APPENDIX II

Websites of DOMAINE partners

Blutspendedienst Sweizerisches Rotes Kreuz
(Blood Transfusion Service of the Swiss Red Cross)
Switzerland
www.transfusion.ch

Deutsches Rotes Kreuz Blutspendedienst Baden-Württemberg - Hessen gGmbH
(German Red Cross Blood Donation Service)
Germany
www.blutspende.de

Établissement Français du Sang
(French Blood Establishment)
France
www.dondusang.net

Κέντρο Αίματος Κύπρου
(Cyprus Blood Establishment)
Cyprus
Website is not available yet

Het Belgische Rode Kruis Dienst voor het Bloed (Belgian Red Cross Blood Service)
Belgium
www.bloedgevendoetleven.be

Instituto Português do Sangue, IP
(Portugese Blood Institute)
Portugal
www.ipsangue.org

Irish Blood Transfusion Service
Ireland
www.giveblood.ie

National Blood Transfusion Service Malta
Malta
www.health.gov.mt/nbts

NHS Blood and Transplant
England
www.nhsbt.nhs.uk

Northern Ireland Blood Transfusion Service
Northern Ireland
www.nibts.org

Põhja-Eesti Regionaalhaigla
(North Estonian Regional Hospital)
Estonia
www.regionaalhaigla.ee

Országos Vérellátó Szolgálat
(Hungarian National Blood Transfusion Service)
Hungary
www.ovsz.hu

Österreichisches Rotes Kreuz
(Austrian Red Cross) Austria
www.roteskreuz.at / www.blut.at

Rdeči križ Slovenije
(Slovenian Red Cross) Slovenia
www.rks.si

Regionale Blutspendedienst
Schweizerisches Rotes Kreuz Bern AG
(Regional Blood Transfusion Service of the Swiss Red Cross Bern)
Switzerland
www.bsd-be.ch

Scottish National Blood Transfusion Service
Scotland
www.scotblood.co.uk

South-eastern Europe Health Network
Blood Safety Programme
www.euro.who.int/stabilitypact/network/20040611_1

Stichting Sanquin Bloedvoorziening
(Sanquin Blood Supply Foundation)
The Netherlands
www.sanquin.nl

Suomen Punainen Risti Veripalvelu
(Finnish Red Cross Blood Service)
Finland
www.veripalvelu.fi

Thalassaemia International Federation
www.thalassaemia.org.cy

The Welsh Blood Service
Wales
www.welsh-blood.org.uk

Zavod Republike Slovenije za transfuzijsko medicino (Blood Transfusion Centre of Slovenia)
Slovenia
www.ztm.si

APPENDIX III

Directive 2002/98/EC

DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 January 2003

setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(a) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the Economic and Social Committee [2],

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [4], in the light of the joint text approved by the Conciliation Committee on 4 November 2002,

Whereas:

(1) The extent to which human blood is used therapeutically demands that the quality and safety of whole blood and blood components be ensured in order to prevent in particular the transmission of diseases.

(2) The availability of blood and blood components used for therapeutic purposes is dependent largely on Community citizens who are prepared to donate. In order to safeguard public health and to prevent the transmission of infectious diseases, all precautionary measures during their collection, processing, distribution and use need to be taken making appropriate use of scientific progress in the detection and inactivation and elimination of transfusion transmissible pathogenic agents.

(3) The quality, safety, and efficacy requirements of proprietary industrially-prepared medicinal products derived from human blood or plasma were ensured through Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [5]. The specific exclusion of whole blood, plasma and blood cells of human origin from that Directive, however, has led to a situation whereby their quality and safety, in so far as they are intended for transfusion and not processed as such, are not subject to any binding Community legislation. It is essential, therefore, that whatever the intended purpose, Community provisions should ensure that blood and its components are of comparable quality and safety throughout the blood transfusion chain in all Member States, bearing in mind the freedom of movement of citizens within Community territory. The establishment of high standards of quality and safety, therefore, will help to reassure the public that human blood and blood components which are derived from donations in another Member State nonetheless meet the same requirements as those in their own country.

(4) In respect of blood or blood components as a starting material for the manufacture of proprietary medicinal products, Directive 2001/83/EC refers to measures to be taken by Member States to prevent the transmission of infectious diseases, comprising the application of the monographs of the European Pharmacopoeia and the recommendations of the Council of Europe and the World Health Organisation (WHO) as regards in particular the selection and testing of blood and plasma donors. Furthermore, Member States should take measures to promote Community self-sufficiency in human blood or blood components and to encourage voluntary unpaid donations of blood and blood components.

(5) In order to ensure that there is an equivalent level of safety and quality of blood components, whatever their intended purpose, technical requirements for the collection and testing of all blood and blood components including starting materials for medicinal products should be established by this Directive. Directive 2001/83/EC should be amended accordingly.

(6) The Commission's Communication of 21 December 1994 on Blood Safety and Self-sufficiency in the European Community identified the need for a blood strategy in order to reinforce confidence in the safety of the blood transfusion chain and promote Community self-sufficiency.

(7) In its Resolution of 2 June 1995, on blood safety and self-sufficiency in the Community [6], the Council invited the Commission to submit appropriate proposals in the framework of the development of a blood strategy.

(8) In its Resolution of 12 November 1996 on a strategy towards blood safety and self-sufficiency in the European Community [1], the Council invited the Commission to submit proposals as a matter of urgency with a view to encouraging the development of a coordinated approach to the safety of blood and blood products.

(9) In its Resolutions of 14 September 1993 [2], 18 November 1993 [3], 14 July 1995 [4], and 17 April 1996 [5] on blood safety and self-sufficiency through voluntary unpaid donations in the European Community, the European Parliament stressed the importance of ensuring the highest level of blood safety and has reiterated its continued support for the objective of Community self-sufficiency.

(10) In elaborating the provisions of this Directive account has been taken of the opinion of the Scientific Committee for Medicinal Products and Medical Devices as well as international experience in this field.

(11) The nature of autologous transfusion necessitates a specific consideration in respect of how and when to apply the different provisions of this Directive.

(12) Hospital blood banks are hospital units which perform a limited number of activities, storage, distribution, and compatibility tests. In order to ensure that the quality and safety of blood and blood components are preserved during the whole transfusion chain, while taking account of the specific nature and functions of hospital blood banks, only provisions relevant to these activities should apply to hospital blood banks.

(13) Member States should ensure that an appropriate mechanism for designating, authorising, accrediting or licensing exists to ensure that the activities of blood establishments are performed in accordance with the requirements of this Directive.

(14) Member States should organise inspection and control measures, to be carried out by officials representing the competent authority, to ensure the compliance of the blood establishment with the provisions of this Directive.

(15) Personnel directly involved in the collection, testing, processing, storage and distribution of blood and blood components need to be appropriately qualified and provided with timely and relevant training, without prejudice to existing Community legislation on the recognition of professional qualifications and on the protection of workers.

(16) Blood establishments should establish and maintain quality systems involving all activities that determine the quality policy objectives and responsibilities and implement them by such means as quality planning, quality control, quality assurance, and quality improvement within the quality system, taking into account the principles of good manufacturing practice as well as the EC conformity assessment system.

(17) An adequate system to ensure traceability of whole blood and blood components should be established. Traceability should be enforced through accurate donor, patient, and laboratory identification procedures, through record maintenance, and through an appropriate identification and labelling system. It is desirable that a system is developed in order to enable the unique and unmistakable identification of donations of blood and blood components in the Community. In the case of blood and blood components imported from third countries, it is important that an equivalent level of traceability be ensured by the blood establishments in the stages preceding importation into the Community. The same requirements of traceability which apply to blood and blood components collected in the Community should be ensured in the stages following importation.

(18) It is important to introduce a set of organised surveillance procedures to collect and evaluate information on the adverse or unexpected events or reactions resulting from the collection of blood or blood components in order to prevent similar or equivalent events or reactions from occurring thereby improving the security of transfusion by adequate measures. To this end a common system of notification of serious adverse events and reactions linked to the collection, processing, testing, storage, and distribution of blood and blood components should be established in Member States.

(19) It is important that when abnormal findings are reported to the donor, relevant counselling is also provided.

(20) Modern blood-transfusion practice has been founded on the principles of voluntary donor services, anonymity of both donor and recipient, benevolence of the donor, and absence of profit on the part of the establishments involved in blood transfusion services.

(21) All necessary measures need to be taken in order to provide prospective donors of blood or blood components with assurances regarding the confidentiality of any health-related information provided to the authorised personnel, the results of the tests on their donations as well as any future traceability of their donation.

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[1] OJ C 154 E, 29.5.2001, p. 141 and OJ C 75 E, 26.3.2002, p. 104.
[2] OJ C 221, 7.8.2001, p. 106.
[3] OJ C 19, 22.1.2002, p. 6.
[4] Opinion of the European Parliament of 6 September 2001 (OJ C 72 E, 21.3.2002, p. 289), Council Common Position of 14 February 2002 (OJ C 113 E, 14.5.2002, p. 93) and Decision of the European Parliament of 12 June 2002 (not yet published in the Official Journal). Decision of the European Parliament of 18 December 2002 and Decision of the Council of 16 December 2002.
[5] OJ L 311, 28.11.2001, p. 67.
[6] OJ C 164, 30.6.1995, p. 1.
[1] OJ C 374, 11.12.1996, p. 1.
[2] OJ C 268, 4.10.1993, p. 29.
[3] OJ C 329, 6.12.1993, p. 268.
[4] OJ C 249, 25.9.1995, p. 231.
[5] OJ C 141, 13.5.1996, p. 131.

(22) According to Article 152(5) of the Treaty, the provisions of this Directive cannot affect national provisions on the donations of blood. Article 152(4)(a) of the Treaty states that Member States cannot be prevented from maintaining or introducing more stringent protective measures as regards standards of quality and safety of blood and blood components.

(23) Voluntary and unpaid blood donations are a factor which can contribute to high safety standards for blood and blood components and therefore to the protection of human health. The efforts of the Council of Europe in this area should be supported and all necessary measures should be taken to encourage voluntary and unpaid donations through appropriate measures and initiatives and through ensuring that donors gain greater public recognition, thereby also increasing self-sufficiency. The definition of voluntary and unpaid donation of the Council of Europe should be taken into account.

(24) Blood and blood components used for therapeutic purposes or for use in medical devices should be obtained from individuals whose health status is such that no detrimental effects will ensue as a result of the donation and that any risk of transmission of infectious diseases is minimised; each and every blood donation should be tested in accordance with rules which provide assurances that all necessary measures have been taken to safeguard the health of individuals who are the recipients of blood and blood components.

(25) Directive 95/46/EC of the European Parliament and the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data [1] requires that data related to the health of an individual be subject to reinforced protection. However, it covers only personal data and not that rendered anonymous. This Directive should therefore introduce additional safeguards to prevent any unauthorised changes to donation registries, or processing records, or the unauthorised disclosure of information.

(26) The Commission should be empowered to establish technical requirements and adopt any necessary changes thereto and to the Annexes in order to take into account scientific and technical progress.

(27) Setting of technical requirements and adaptation to progress should take into account the Council recommendation of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the EC [2], relevant recommendations of the Council of Europe and the WHO as well as indications of relevant European institutions and organisations such as the monographs of the European Pharmacopoeia.

(28) It is necessary that the best possible scientific advice is available to the Community in relation to the safety of blood and blood components, in particular as regards adapting the provisions of this Directive to scientific and technical progress.

(29) Tests should be carried out in conformity with the latest scientific and technical procedures that reflect current best practice as defined by, and regularly reviewed and updated through, an appropriate expert consultation process. This review process should also take due account of scientific advances in the detection, inactivation and elimination of pathogens which can be transmitted via transfusion.

(30) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3].

(31) In order to increase the effective implementation of the provisions adopted under this Directive it is appropriate to provide for penalties to be applied by Member States.

(32) Since the objectives of this Directive, namely to contribute to general confidence both in the quality of donated blood and blood components and in the health protection of donors, to attain self-sufficiency at a Community level and to enhance confidence in the safety of the transfusion chain among the Member States, cannot be sufficiently achieved by the Member States and can therefore by reason of its scale and effects be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.

(33) Responsibility for the organisation of health services and the provision of medical care should remain the responsibility of each Member State,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

GENERAL PROVISIONS

Article 1

Objectives

This Directive lays down standards of quality and safety of human blood and of blood components, in order to ensure a high level of human health protection.

[1] OJ L 281, 23.11.1995, p. 31.
[2] OJ L 203, 21.7.1998, p. 14.
[3] OJ L 184, 17.7.1999, p. 23.

Article 2

Scope

1. This Directive shall apply to the collection and testing of human blood and blood components, whatever their intended purpose, and to their processing, storage, and distribution when intended for transfusion.

2. Where blood and blood components are collected and tested for the sole purpose and exclusive use in autologous transfusion and are clearly identified as such, the requirements to be complied with in respect thereof shall be in accordance with those referred to in Article 29(g).

3. This Directive shall apply without prejudice to Directives 93/42/EEC [1], 95/46/EC or 98/79/EC [2].

4. This Directive does not apply to blood stem cells.

Article 3

Definitions

For the purposes of this Directive:

(a) 'blood' shall mean whole blood collected from a donor and processed either for transfusion or for further manufacturing;

(b) 'blood component' shall mean a therapeutic constituent of blood (red cells, white cells, platelets, plasma) that can be prepared by various methods;

(c) 'blood product' shall mean any therapeutic product derived from human blood or plasma;

(d) 'autologous transfusion' shall mean transfusion in which the donor and the recipient are the same person and in which pre-deposited blood and blood components are used;

(e) 'blood establishment' shall mean any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion. This does not include hospital blood banks;

(f) 'hospital blood bank' shall mean a hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities;

(g) 'serious adverse event' shall mean any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity;

(h) 'serious adverse reaction' shall mean an unintended response in donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;

(i) 'blood component release' shall mean a process which enables a blood component to be released from a quarantine status by the use of systems and procedures to ensure that the finished product meets its release specification;

(j) 'deferral' shall mean suspension of the eligibility of an individual to donate blood or blood components such suspension being either permanent or temporary;

(k) 'distribution' shall mean the act of delivery of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood and plasma derived products. It does not include the issuing of blood or blood components for transfusion.

(l) 'haemovigilance' shall mean a set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors;

(m) 'inspection' shall mean formal and objective control according to adopted standards to assess compliance with this Directive and other relevant legislation and to identify problems.

Article 4

Implementation

1. Member States shall designate the competent authority or authorities responsible for implementing the requirements of this Directive.

2. This Directive shall not prevent a Member State from maintaining or introducing in its territory more stringent protective measures which comply with the provisions of the Treaty.

In particular, a Member State may introduce requirements for voluntary and unpaid donations, which include the prohibition or restriction of imports of blood and blood components, to ensure a high level of health protection and to achieve the objective set out in Article 20(1), provided that the conditions of the Treaty are met.

3. In carrying out the activities covered by this Directive the Commission may have recourse to technical and/or administrative assistance to the mutual benefit of the Commission and of the beneficiaries, relating to identification, preparation, management, monitoring, audit and control, as well as to support expenditure.

[1] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1). Directive as last amended by Directive 2001/104/EC of the European Parliament and of the Council (OJ L 6, 10.1.2002, p. 50).
[2] Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

CHAPTER II

OBLIGATIONS ON MEMBER STATES AUTHORITIES

Article 5

Designation, authorisation, accreditation or licensing of blood establishments

1. Member States shall ensure that activities relating to the collection and testing of human blood and blood components, whatever their intended purpose, and to their preparation, storage, and distribution when intended for transfusion, are undertaken only by the blood establishments which have been designated, authorised, accredited or licensed by the competent authority for that purpose.

2. For the purpose of paragraph 1, the blood establishment shall submit the information listed in Annex I to the competent authority.

3. The competent authority, having verified whether the blood establishment complies with the requirements set out in this Directive, shall indicate to the blood establishment which activities it may undertake and which conditions apply.

4. No substantial change in activities shall be undertaken by the blood establishment without prior written approval by the competent authority.

5. The competent authority may suspend or revoke the designation, authorisation, accreditation or licence of a blood establishment if inspection or control measures demonstrate that the blood establishment does not comply with the requirements of this Directive.

Article 6

Hospital blood banks

Articles 7, 10, 11(1), 12(1), 14, 15, 22 and 24 shall apply to hospital blood banks.

Article 7

Provisions for existing establishments

Member States may decide to maintain national provisions for nine months after the date laid down in Article 32 so as to enable blood establishments operating under their legislation to comply with the requirements of this Directive.

Article 8

Inspection and control measures

1. Member States shall ensure that the competent authority organise inspections and appropriate control measures in blood establishments to ensure that the requirements of this Directive are complied with.

2. Inspection and control measures shall be organised by the competent authority on a regular basis. The interval between two inspections and control measures shall not exceed two years.

3. Such inspection and control measures shall be carried out by officials representing the competent authority who must be empowered to:

(a) inspect blood establishments as well as facilities of any third parties on its own territory entrusted by the holder of the designation, authorisation, accreditation or licence referred to in Article 5 with the task of carrying out evaluation and testing procedures pursuant to Article 18;

(b) take samples for examination and analysis;

(c) examine any documents relating to the object of the inspection, subject to the provisions in force in the Member States at the time of the entry into force of this Directive and which place restrictions on these powers with regard to the descriptions of the method of preparation.

4. The competent authority shall organise inspection and other control measures as appropriate in the event of any serious adverse event or reaction or suspicion thereof in accordance with Article 15.

CHAPTER III

PROVISIONS FOR BLOOD ESTABLISHMENTS

Article 9

Responsible person

1. Blood establishments shall designate a person (responsible person), responsible for:

— ensuring that every unit of blood or blood components has been collected and tested, whatever its intended purpose, and processed, stored, and distributed, when intended for transfusion, in compliance with the laws in force in the Member State,

— providing information to the competent authority in the designation, authorisation, accreditation or licensing procedures as required in Article 5,

— the implementation of the requirements of Articles 10, 11, 12, 13, 14 and 15 in the blood establishment.

2. The responsible person shall fulfil the following minimum conditions of qualification:

(a) he/she shall possess a diploma, certificate or other evidence of formal qualifications in the field of medical or biological sciences awarded on completion of a university course of study or a course recognised as equivalent by the Member State concerned;

(b) he/she shall have practical post-graduate experience in relevant areas for at least two years, in one or more establishments which are authorised to undertake activities related to collection and/or testing of human blood and blood components, or to their preparation, storage, and distribution.

3. The tasks specified in paragraph 1 may be delegated to other persons who shall be qualified by training and experience to perform such tasks.

4. Blood establishments shall notify the competent authority of the name of the responsible person referred to in paragraph 1 and other persons referred to in paragraph 3 together with information on the specific tasks for which they are responsible.

5. Where the responsible person or such other persons referred to in paragraph 3 are permanently or temporarily replaced, the blood establishment shall provide immediately the name of the new responsible person and his or her date of commencement to the competent authority.

Article 10

Personnel

Personnel directly involved in collection, testing, processing, storage, and distribution of human blood and blood components shall be qualified to perform those tasks and be provided with timely, relevant and regularly updated training.

CHAPTER IV

QUALITY MANAGEMENT

Article 11

Quality system for blood establishments

1. Member States shall take all necessary measures to ensure that each blood establishment establishes and maintains a quality system for blood establishments based on the principles of good practice.

2. The Commission shall establish the Community standards and specifications referred to in Article 29(h) for the activities relating to a quality system to be carried out by a blood establishment.

Article 12

Documentation

1. Member States shall take all necessary measures in order to ensure that blood establishments maintain documentation on operational procedures, guidelines, training and reference manuals, and reporting forms.

2. Member States shall take all necessary measures in order to ensure that access is provided to these documents for officials entrusted with inspection and control measures referred to in Article 8.

Article 13

Record keeping

1. Member States shall take all necessary measures to ensure that blood establishments maintain records of the information required in Annexes II and IV and under Article 29(b), (c) and (d). The records shall be kept for a minimum of 15 years.

2. The competent authority shall keep records of the data received from the blood establishments according to Articles 5, 7, 8, 9 and 15.

CHAPTER V

HAEMOVIGILANCE

Article 14

Traceability

1. Member States shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored, released and/or distributed on their territory can be traced from donor to recipient and vice versa.

To this end, Member States shall ensure that blood establishments implement a system for identification of each single blood donation and each single blood unit and components thereof enabling full traceability to the donor as well as to the transfusion and the recipient thereof. The system must unmistakably identify each unique donation and type of blood component. This system shall be established in accordance with the requirements referred to in Article 29(a).

With regard to blood and blood components imported from third countries, Member States shall ensure that the donor identification system to be implemented by blood establishments permits an equivalent level of traceability.

2. Member States shall take all necessary measures in order to ensure that the system used for the labelling of blood and blood components collected, tested, processed, stored, released and/or distributed on their territory complies with the identification system referred to in paragraph 1 and the labelling requirements listed in Annex III.

3. Data needed for full traceability in accordance with this Article shall be kept for at least 30 years.

Article 15

Notification of serious adverse events and reactions

1. Member States shall ensure that:

— any serious adverse events (accidents and errors) related to the collection, testing, processing, storage and distribution of blood and blood components which may have an influence on their quality and safety, as well as any serious adverse reactions observed during or after transfusion which may be attributed to the quality and the safety of blood and blood components are notified to the competent authority,

— blood establishments have in place a procedure accurately, efficiently and verifiably to withdraw from distribution blood or blood components associated with the notification referred to above.

2. These serious adverse events and reactions shall be notified in accordance with the procedure and notification format referred to in Article 29(i).

CHAPTER VI

PROVISIONS FOR THE QUALITY AND SAFETY OF BLOOD AND BLOOD COMPONENTS

Article 16

Provision of information to prospective donors

Member States shall ensure that all prospective donors of blood or blood components in the Community are provided with information referred to in Article 29(b).

Article 17

Information required from donors

Member States shall take all necessary measures to ensure that, upon agreement of a willingness to commence the donation of blood or blood components, all donors in the Community provide the information referred to in Article 29(c) to the blood establishment.

Article 18

Eligibility of donors

1. Blood establishments shall ensure that there are evaluation procedures in place for all donors of blood and blood components and that the criteria for donation referred to in Article 29(d) are met.

2. The results of the donor evaluation and testing procedures shall be documented and any relevant abnormal findings shall be reported to the donor.

Article 19

Examination of donors

An examination of the donor, including an interview, shall be carried out before any donation of blood or blood components. A qualified health professional shall be responsible, in particular, for giving to and gathering from donors the information which is necessary to assess their eligibility to donate and shall, on the basis thereof, assess the eligibility of donors.

Article 20

Voluntary and unpaid blood donation

1. Member States shall take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations.

2. Member States shall submit reports to the Commission on these measures two years after the entry into force of this Directive, and thereafter every three years. On the basis of these reports the Commission shall inform the European Parliament and the Council of any necessary further measure it intends to take at Community level.

Article 21

Testing of donations

Blood establishments shall ensure that each donation of blood and blood components is tested in conformity with requirements listed in Annex IV.

Member States shall ensure that blood and blood components imported into the Community are tested in conformity with requirements listed in Annex IV.

Article 22

Storage, transport and distribution conditions

Blood establishments shall ensure that the storage, transport and distribution conditions of blood and blood components comply with the requirements referred to in Article 29(e).

Article 23

Quality and safety requirements for blood and blood components

Blood establishments shall ensure that quality and safety requirements for blood and blood components meet the high standards in compliance with the requirements referred to in Article 29(f).

CHAPTER VII

DATA PROTECTION

Article 24

Data protection and confidentiality

Member States shall take all necessary measures to ensure that all data, including genetic information, collated within the scope of this Directive to which third parties have access have been rendered anonymous so that the donor is no longer identifiable.

For that purpose, they shall ensure:

(a) that data security measures are in place as well as safeguards against unauthorised data additions, deletions or modifications to donor files or deferral records, and transfer of information;

(b) that procedures are in place to resolve data discrepancies;

(c) that no unauthorised disclosure of such information occurs, whilst guaranteeing the traceability of donations.

CHAPTER VIII

EXCHANGE OF INFORMATION, REPORTS AND PENALTIES

Article 25

Information exchange

The Commission shall hold regular meetings with the competent authorities designated by the Member States, delegations of experts from blood establishments and other relevant parties to exchange information on the experience acquired with regard to the implementation of this Directive.

Article 26

Reports

1. Member States shall send to the Commission, commencing on 31 December 2003 and every three years thereafter, a report on the activities undertaken in relation to the provisions of this Directive, including an account of the measures taken in relation to inspection and control.

2. The Commission shall transmit to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, the reports submitted by the Member States on the experience gained in implementing this Directive.

3. The Commission shall transmit to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, commencing on 1 July 2004 and every three years thereafter, a report on the implementation of the requirements in this Directive, and in particular those relating to inspection and control.

Article 27

Penalties

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. Member States shall notify those provisions to the Commission by the date specified in Article 32 at the latest and shall notify it without delay of any subsequent amendments affecting them.

CHAPTER IX

COMMITTEES

Article 28

Regulatory procedure

1. The Commission shall be assisted by a Committee.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 29

Technical requirements and their adaptation to technical and scientific progress

The adaptation of the technical requirements set out in Annexes I to IV to technical and scientific progress shall be decided in accordance with the procedure referred to in Article 28(2).

The following technical requirements and their adaptation to technical and scientific progress shall be decided in accordance with the procedure referred to in Article 28(2):

(a) traceability requirements;

(b) information to be provided to donors;

(c) information to be obtained from donors including the identification, health history, and the signature of the donor;

(d) requirements concerning the suitability of blood and plasma donors and the screening of donated blood including

— permanent deferral criteria and possible exemption thereto

— temporary deferral criteria;

(e) storage, transport and distribution requirements;

(f) quality and safety requirements for blood and blood components;

(g) requirements applicable to autologous transfusions;

(h) Community standards and specifications relating to a quality system for blood establishments;

(i) Community procedure for notifying serious adverse reactions and events and notification format.

Article 30

Consultation of scientific committee(s)

The Commission may consult the relevant scientific committee(s) when establishing the technical requirements referred to in Article 29 and when adapting the technical requirements set out in Annexes I to IV to scientific and technical progress, in particular with a view to ensuring an equivalent level of quality and safety of blood and blood components used for transfusion and blood and blood components used as a starting material for the manufacture of medicinal products.

CHAPTER X

FINAL PROVISIONS

Article 31

Amendment of Directive 2001/83/EC

Article 109 of Directive 2001/83/EC shall be replaced by the following:

'*Article 109*

For the collection and testing of human blood and human plasma, Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (*) shall apply.

(*) OJ L 33, 8.2.2003, p. 30.'

Article 32

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 8 February 2005. They shall forthwith inform the Commission thereof.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the texts of the provisions of national law that they have already adopted or which they adopt in the field governed by this Directive.

Article 33

Entry into force

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 34

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 27 January 2003.

For the European Parliament	*For the Council*
The President	*The President*
P. COX	G. DRYS

ANNEX I

INFORMATION TO BE PROVIDED BY BLOOD ESTABLISHMENT TO THE COMPETENT AUTHORITY FOR THE PURPOSES OF DESIGNATION, AUTHORISATION, ACCREDITATION OR LICENSING IN ACCORDANCE WITH ARTICLE 5(2)

Part A: General information:

— identification of the blood establishment
— name, qualification and contact details of responsible persons
— a list of hospital blood banks which it supplies.

Part B: A description of the quality system, to include:

— documentation, such as an organisation chart, including responsibilities of responsible persons and reporting relationships
— documentation such as site master file or quality manual describing the quality system in accordance with Article 11(1)
— number and qualifications of personnel
— hygiene provisions
— premises and equipment
— list of standard operating procedures for recruitment, retention and assessment of donors, for processing and testing, distribution and recall of blood and blood components and for the reporting and recording of serious adverse reactions and events.

ANNEX II

REPORT OF THE BLOOD ESTABLISHMENT'S PRECEDING YEAR'S ACTIVITY

This annual report will include:
— total number of donors who give blood and blood components
— total number of donations
— an updated list of the hospital blood banks which it supplies
— total number of whole donations not used
— number of each component produced and distributed
— incidence and prevalence of transfusion transmissible infectious markers in donors of blood and blood components
— number of product recalls
— number of serious adverse events and reactions reported.

ANNEX III

LABELLING REQUIREMENTS

The label on the component must contain the following information:

— the official name of the component
— the volume or weight or number of cells in the component (as appropriate)
— the unique numeric or alphanumeric donation identification
— the name of producing blood establishment
— the ABO Group (not required for plasma intended only for fractionation)
— the Rh D Group, either Rh D positive or Rh D negative (not required for plasma intended only for fractionation)
— the date or time of expiry (as appropriate)
— the temperature of storage
— the name, composition and volume of anticoagulant and/or additive solution (if any).

ANNEX IV

BASIC TESTING REQUIREMENTS FOR WHOLE BLOOD AND PLASMA DONATIONS

The following tests must be performed for whole blood and apheresis donations, including autologous predeposit donations:

— ABO Group (not required for plasma intended only for fractionation)
— Rh D Group (not required for plasma intended only for fractionation)
— testing for the following infections in the donors:
  — Hepatitis B (HBs-Ag)
  — Hepatitis C (Anti-HCV)
  — HIV 1/2 (Anti-HIV 1/2)

Additional tests may be required for specific components or donors or epidemiological situations.

APPENDIX IV

Commission Directive 2004/33/EC

COMMISSION DIRECTIVE 2004/33/EC

of 22 March 2004

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC [1], and in particular points (b) to (g) of the second paragraph of Article 29 thereof,

Whereas:

(1) Directive 2002/98/EC lays down standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and for their processing, storage and distribution when intended for transfusion so as to ensure a high level of human health protection.

(2) In order to prevent the transmission of diseases by blood and blood components and to ensure an equivalent level of quality and safety, Directive 2002/98/EC calls for the establishment of specific technical requirements.

(3) This Directive lays down those technical requirements, which take account of Council Recommendation 98/463/EC of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community [2], certain recommendations of the Council of Europe, the opinion of the Scientific Committee for Medicinal Products and Medical Devices, the monographs of the European Pharmacopoeia, particularly in respect of blood or blood components as a starting material for the manufacture of proprietary medicinal products and recommendations of the World Health Organisation (WHO), as well as international experience in this field.

(4) Blood and blood components imported from third countries, including those used as starting material/raw material for the manufacture of medicinal products derived from human blood and human plasma, should meet the quality and safety requirements set out in this Directive.

(5) With regard to blood and blood components collected for the sole purpose of, and exclusive use in, autologous transfusion (autologous donation), specific technical requirements should be laid down, as required by Article 2(2) of Directive 2002/98/EC. Such donations should be clearly identified and kept separate from other donations to ensure that they are not used for transfusion to other patients.

(6) It is necessary to determine common definitions for technical terminology in order to ensure the consistent implementation of Directive 2002/98/EC.

(7) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2002/98/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Definitions

For the purposes of this Directive, the definitions set out in Annex I shall apply.

Article 2

Provision of information to prospective donors

Member States shall ensure that blood establishments provide prospective donors of blood or blood components with the information set out in Part A of Annex II.

Article 3

Information required from donors

Member States shall ensure that upon agreement of willingness to commence the donation of blood or blood components, donors provide the information set out in Part B of Annex II to the blood establishment.

Article 4

Eligibility of donors

Blood establishments shall ensure that donors of whole blood and blood components comply with the eligibility criteria set out in Annex III.

Article 5

Storage, transport and distribution conditions for blood and blood components

Blood establishments shall ensure that the storage, transport and distribution conditions for blood and blood components comply with the requirements set out in Annex IV.

[1] OJ L 33, 8.2.2003, p. 30.
[2] OJ L 203, 21.7.1998, p. 14.

Article 6

Quality and safety requirements for blood and blood components

Blood establishments shall ensure that the quality and safety requirements for blood and blood components comply with the requirements set out in Annex V.

Article 7

Autologous donations

1. Blood establishments shall ensure that autologous donations comply with the requirements set out in Directive 2002/98/EC and the specific requirements set out in this Directive.

2. Autologous donations shall be clearly identified as such and shall be kept separate from allogeneic donations.

Article 8

Validation

Member States shall ensure that all testing and processes referred to in Annexes II to V are validated.

Article 9

Transposition

1. Without prejudice to Article 7 of Directive 2002/98/EC, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 8 February 2005 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 10

Entry into force

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 11

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 22 March 2004.

For the Commission
David BYRNE
Member of the Commission

ANNEX I

DEFINITIONS

(as referred to in Article 1)

1. 'Autologous donation' means blood and blood components collected from an individual and intended solely for subsequent autologous transfusion or other human application to that same individual.

2. 'Allogeneic donation' means blood and blood components collected from an individual and intended for transfusion to another individual, for use in medical devices or as starting material/raw material for manufacturing into medicinal products.

3. 'Validation' means the establishment of documented and objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

4. 'Whole blood' means a single blood donation.

5. 'Cryopreservation' means prolongation of the storage life of blood components by freezing.

6. 'Plasma' means the liquid portion of the blood in which the cells are suspended. Plasma may be separated from the cellular portion of a whole blood collection for therapeutic use as fresh-frozen plasma or further processed to cryoprecipitate and cryoprecipitate-depleted plasma for transfusion. It may be used for the manufacture of medicinal products derived from human blood and human plasma or used in the preparation of pooled platelets, or pooled, leucocyte-depleted platelets. It may also be used for re-suspension of red cell preparations for exchange transfusion or perinatal transfusion.

7. 'Cryoprecipitate' means a plasma component prepared from plasma, fresh-frozen, by freeze-thaw precipitation of proteins and subsequent concentration and re-suspension of the precipitated proteins in a small volume of the plasma.

8. 'Washed' means a process of removing plasma or storage medium from cellular products by centrifugation, decanting of the supernatant liquid from the cells and addition of an isotonic suspension fluid, which in turn is generally removed and replaced following further centrifugation of the suspension. The centrifugation, decanting, replacing process may be repeated several times.

9. 'Red cells' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed.

10. 'Red cells, buffy coat removed' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. The buffy coat, containing a large proportion of the platelets and leucocytes in the donated unit, is removed.

11. 'Red cells, leucocyte-depleted' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed.

12. 'Red cells in additive solution' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. A nutrient/preservative solution is added.

13. 'Additive solution' means a solution specifically formulated to maintain beneficial properties of cellular components during storage.

14. 'Red cells, buffy coat removed, in additive solution' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. The buffy coat, containing a large proportion of the platelets and leucocytes in the donated unit, is removed. A nutrient/preservative solution is added.

15. 'Buffy coat' means a blood component prepared by centrifugation of a unit of whole blood, and which contains a considerable proportion of the leucocytes and platelets.

16. 'Red cells, leucocyte-depleted, in additive solution' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed. A nutrient/preservative solution is added.

17. 'Red cells, apheresis' means the red cells from an apheresis red cell donation.

18. 'Apheresis' means a method of obtaining one or more blood components by machine processing of whole blood in which the residual components of the blood are returned to the donor during or at the end of the process.

19. 'Platelets, apheresis' means a concentrated suspension of blood platelets obtained by apheresis.

20. 'Platelets, apheresis, leucocyte-depleted' means a concentrated suspension of blood platelets, obtained by apheresis, and from which leucocytes are removed.

21. 'Platelets, recovered, pooled' means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation.

22. 'Platelets, recovered, pooled, leucocyte-depleted' means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation, and from which leucocytes are removed.

23. 'Platelets, recovered, single unit' means a concentrated suspension of blood platelets, obtained by processing of a single unit of whole blood.

24. 'Platelets, recovered, single unit, leucocyte-depleted' means a concentrated suspension of blood platelets, obtained by processing of a single whole blood unit from which leucocytes are removed.

25. 'Plasma, fresh-frozen' means the supernatant plasma separated from a whole blood donation or plasma collected by apheresis, frozen and stored.

26. 'Plasma, cryoprecipitate-depleted for transfusion' means a plasma component prepared from a unit of plasma, fresh-frozen. It comprises the residual portion after the cryoprecipitate has been removed.

27. 'Granulocytes, apheresis' means a concentrated suspension of granulocytes obtained by apheresis.

28. 'Statistical process control' means a method of quality control of a product or a process that relies on a system of analysis of an adequate sample size without the need to measure every product of the process.

ANNEX II

INFORMATION REQUIREMENTS

(as referred to in Articles 2 and 3)

PART A

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

1. Accurate educational materials, which are understandable for members of the general public, about the essential nature of blood, the blood donation procedure, the components derived from whole blood and apheresis donations, and the important benefits to patients.

2. For both allogeneic and autologous donations, the reasons for requiring an examination, health and medical history, and the testing of donations and the significance of 'informed consent'.

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

3. Information on the protection of personal data: no unauthorised disclosure of the identity of the donor, of information concerning the donor's health, and of the results of the tests performed.

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

5. 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.

6. 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 the donation process, without any undue embarrassment or discomfort.

7. 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.

8. 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.

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

10. 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.

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

PART B

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

1. *Identification of the donor*

   Personal data uniquely, and without any risk of mistaken identity, distinguishing the donor, as well as contact details.

2. *Health and medical history of the donor*

   Health and medical history, provided on a questionnaire and through a personal interview performed by a qualified healthcare professional, that includes 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.

3. *Signature of the donor*

   Signature of the donor, on the donor questionnaire, countersigned by the health care staff member responsible for obtaining the health history confirming that the donor has:

   (a) read and understood the educational materials provided;

   (b) had an opportunity to ask questions;

   (c) been provided with satisfactory responses to any questions asked;

   (d) given informed consent to proceed with the donation process;

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

   (f) acknowledged that all the information provided by the donor is true to the best of his/her knowledge.

ANNEX III

ELIGIBILITY CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

(as referred to in Article 4)

1. ACCEPTANCE CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

Under exceptional circumstances, individual donations from donors who do not comply with the following criteria may be authorised by a qualified healthcare professional in the blood establishment. All such cases must be clearly documented and subject to the quality management provisions in Articles 11, 12, and 13 of Directive 2002/98/EC.

The following criteria do not apply to autologous donations.

1.1. **Age and body weight of donors**

Age	18 to 65 years	
	17 to 18 years	— unless classified as a minor by law, or with written consent of parent or legal guardian in accordance with law
	First time donors over 60 years	— at the discretion of the physician in the blood establishment
	Over 65 years	— with permission of the physician in the blood establishment, given annually
Body weight	≥ 50 kg for donors either of whole blood or apheresis blood components	

1.2. **Haemoglobin levels in donor's blood**

Haemoglobin	for females ≥ 125 g/l	for males ≥ 135 g/l	*Applicable to allogeneic donors of whole blood and cellular components*

1.3. **Protein levels in donor's blood**

Protein	≥ 60 g/l	*The protein analysis for apheresis plasma donations must be performed at least annually*

1.4. **Platelet levels in donor's blood**

Platelets	Platelet number greater than or equal to 150×10^9/l	*Level required for apheresis platelet donors*

2. DEFERRAL CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

The tests and deferral periods indicated by an asterisk (*) are not required when the donation is used exclusively for plasma for fractionation.

2.1. **Permanent deferral criteria for donors of allogeneic donations**

Cardiovascular disease	Prospective donors with active or past serious cardiovascular disease, except congenital abnormalities with complete cure
Central nervous system disease	A history of serious CNS disease
Abnormal bleeding tendency	Prospective donors who give a history of a coagulopathy

Repeated episodes of syncope, or a history of convulsions	Other than childhood convulsions or where at least three years have elapsed since the date the donor last took anticonvulsant medication without any recurrence of convulsions
Gastrointestinal, genitourinary, haematological, immunological, metabolic, renal, or respiratory system diseases	Prospective donors with serious active, chronic, or relapsing disease
Diabetes	If being treated with insulin
Infectious diseases	Hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune
	Hepatitis C
	HIV-1/2
	HTLV I/II
	Babesiosis (*)
	Kala Azar (visceral leishmaniasis) (*)
	Trypanosomiasis cruzi (Chagas' disease) (*)
Malignant diseases	Except *in situ* cancer with complete recovery
Transmissible spongiform encephalopathies (TSEs), (e.g. Creutzfeldt Jakob Disease, variant Creutzfeldt Jakob Disease)	Persons who have a family history which places them at risk of developing a TSE, or persons who have received a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands. For variant Creutzfeldt Jacob disease, further precautionary measures may be recommended.
Intravenous (IV) or intramuscular (IM) drug use	Any history of non-prescribed IV or IM drug use, including body-building steroids or hormones
Xenotransplant recipients	
Sexual behaviour	Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood

2.2. **Temporary deferral criteria for donors of allogeneic donations**

2.2.1. *Infections*

Duration of deferral period

After an infectious illness, prospective donors shall be deferred for at least two weeks following the date of full clinical recovery.

However, the following deferral periods shall apply for the infections listed in the table:

Brucellosis (*)	**2** years following the date of full recovery
Osteomyelitis	**2** years after confirmed cured
Q fever (*)	**2** years following the date of confirmed cured
Syphilis (*)	**1** year following the date of confirmed cured
Toxoplasmosis (*)	**6** months following the date of clinical recovery
Tuberculosis	**2** years following the date of confirmed cured

Rheumatic fever	**2** years following the date of cessation of symptoms, unless evidence of chronic heart disease
Fever > °C	**2** weeks following the date of cessation of symptoms
Flu-like illness	**2** weeks after cessation of symptoms
Malaria (*)	
— individuals who have lived in a malarial area within the first five years of life	**3** years following return from last visit to any endemic area, provided person remains symptom free; may be reduced to 4 months if an immunologic or molecular genomic test is negative at each donation
— individuals with a history of malaria	**3** years following cessation of treatment *and* absence of symptoms. Accept thereafter only if an immunologic or molecular genomic test is negative
— asymptomatic visitors to endemic areas	**6** months after leaving the endemic area unless an immunologic or molecular genomic test is negative
— individuals with a history of undiagnosed febrile illness during or within six months of a visit to an endemic area	**3** years following resolution of symptoms; may be reduced to 4 months if an immunologic or molecular test is negative
West Nile Virus (WNV) (*)	**28** days after leaving an area with ongoing transmission of WNV to humans

2.2.2. *Exposure to risk of acquiring a transfusion-transmissible infection*

— Endoscopic examination using flexible instruments, — mucosal splash with blood or needlestick injury, — transfusion of blood components, — tissue or cell transplant of human origin, — major surgery, — tattoo or body piercing, — acupuncture unless performed by a qualified practitioner and with sterile single-use needles, — persons at risk due to close household contact with persons with hepatitis B.	Defer for **6** months, or for **4** months provided a NAT test for hepatitis C is negative
Persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood.	Defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests

2.2.3. *Vaccination*

Attenuated viruses or bacteria	**4** weeks
Inactivated/killed viruses, bacteria or rickettsiae	No deferral if well
Toxoids	No deferral if well
Hepatitis A or hepatitis B vaccines	No deferral if well and if no exposure
Rabies	No deferral if well and if no exposure If vaccination is given following exposure defer for one year
Tick-borne encephalitis vaccines	No deferral if well and if no exposure

2.2.4. *Other temporary deferrals*

Pregnancy	**6** months after delivery or termination, except in exceptional circumstances and at the discretion of a physician
Minor surgery	**1** week
Dental treatment	Minor treatment by dentist or dental hygienist — defer until next day (NB: Tooth extraction, root-filling and similar treatment is considered as minor surgery)
Medication	Based on the nature of the prescribed medicine, its mode of action and the disease being treated

2.3. **Deferral for particular epidemiological situations**

Particular epidemiological situations (e.g. disease outbreaks)	Deferral consistent with the epidemiological situation (These deferrals should be notified by the competent authority to the European Commission with a view to Community action)

2.4. **Deferral criteria for donors of autologous donations**

Serious cardiac disease	Depending on the clinical setting of the blood collection
Persons with or with a history of — hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune — hepatitis C — HIV-1/2 — HTLV I/II	Member States may, however, establish specific provisions for autologous donations by such persons
Active bacterial infection	

ANNEX IV

STORAGE, TRANSPORT AND DISTRIBUTION CONDITIONS FOR BLOOD AND BLOOD COMPONENTS

(as referred to in Article 5)

1. STORAGE

1.1. **Liquid storage**

Component	Temperature of storage	Maximum storage time
Red cell preparations and whole blood (if used for transfusion as whole blood)	+ 2 to + 6 °C	**28** to **49** days according to the processes used for collection, processing and storage
Platelet preparations	+ 20 to + 24 °C	**5** days; may be stored for **7** days in conjunction with detection or reduction of bacterial contamination
Granulocytes	+ 20 to + 24 °C	**24** hours

1.2. **Cryopreservation**

Component	Storage conditions and duration
Red blood cells	Up to **30** years according to processes used for collection, processing and storage
Platelets	Up to **24** months according to processes used for collection, processing and storage
Plasma and cryoprecipitate	Up to **36** months according to processes used for collection, processing and storage

Cryopreserved red blood cells and platelets must be formulated in a suitable medium after thawing. The allowable storage period after thawing to depend on the method used.

2. TRANSPORT AND DISTRIBUTION

Transport and distribution of blood and blood components at all stages of the transfusion chain must be under conditions that maintain the integrity of the product.

3. ADDITIONAL REQUIREMENTS FOR AUTOLOGOUS DONATIONS

3.1. Autologous blood and blood components must be clearly identified as such and stored, transported and distributed separately from allogeneic blood and blood components.

3.2. Autologous blood and blood components must be labelled as required by Directive 2002/98/EC and in addition the label must include the identification of the donor and the warning 'FOR AUTOLOGOUS TRANSFUSION ONLY'.

ANNEX V

QUALITY AND SAFETY REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS

(as referred to in Article 6)

1. THE BLOOD COMPONENTS

1. **Red cell preparations**	The components listed in points 1.1 to 1.8 may be further processed within blood establishments and must be labelled accordingly
1.1	Red cells
1.2	Red cells, buffy coat removed
1.3	Red cells, leucocyte-depleted
1.4	Red cells, in additive solution
1.5	Red cells, buffy coat removed, in additive solution
1.6	Red cells, leucocyte-depleted, in additive solution
1.7	Red cells, apheresis
1.8	Whole blood
2. **Platelet preparations**	The components listed in points 2.1 to 2.6 may be further processed within blood establishments and must be labelled accordingly
2.1	Platelets, apheresis
2.2	Platelets, apheresis, leucocyte-depleted
2.3	Platelets, recovered, pooled
2.4	Platelets, recovered, pooled, leucocyte-depleted
2.5	Platelets, recovered, single unit
2.6	Platelets, recovered, single unit, leucocyte-depleted
3. **Plasma preparations**	The components listed in 3.1 to 3.3 may be further processed within blood establishments and must be labelled accordingly.
3.1	Fresh-frozen plasma
3.2	Fresh-frozen plasma, cryoprecipitate-depleted
3.3	Cryoprecipitate
4.	Granulocytes, apheresis
5. **New components**	Quality and safety requirements for new blood components must be regulated by the competent national authority. Such new components must be notified to the European Commission with a view to Community action

2. QUALITY CONTROL REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS

2.1. Blood and blood components must comply with the following technical quality measurements and meet the acceptable results.

2.2. Appropriate bacteriological control of the collection and manufacturing process must be performed.

2.3. Member States must take all necessary measures to ensure that all imports of blood and blood components from third countries, including those used as starting material/raw material for the manufacture of medicinal products derived from human blood or human plasma, shall meet equivalent standards of quality and safety to the ones laid down in this Directive.

2.4. For autologous donations, the measures marked with an asterisk (*) are recommendations only.

Component	Quality measurements required *The required frequency of sampling for all measurements shall be determined using statistical process control*	Acceptable results for quality measurements
Red cells	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 45 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, buffy coat removed	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 43 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40 g per unit
	Leucocyte content	Less than 1×10^6 per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 45 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, buffy coat removed, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 43 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, leucocyte-depleted, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40 g per unit
	Leucocyte content	Less than 1×10^6 per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life

Component	Quality measurements required *The required frequency of sampling for all measurements shall be determined using statistical process control*	Acceptable results for quality measurements
Red cells, apheresis	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Whole blood	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis 450 ml +/- 50ml For paediatric autologous whole blood collections — not to exceed 10,5 ml per kg body weight
	Haemoglobin (*)	Not less than 45 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Platelets, apheresis	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single donation are permitted within limits that comply with validated preparation and preservation conditions
	pH	6,4 – 7,4 corrected for 22 °C, at the end of the shelf life
Platelets, apheresis, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single donation are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 1×10^6 per unit
	pH	6,4 – 7,4 corrected for 22 °C, at the end of the shelf life
Platelets, recovered, pooled	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per pool are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than $0,2 \times 10^9$ per single unit (platelet-rich plasma method) Less than $0,05 \times 10^9$ per single unit (buffy coat method)
	pH	6,4 – 7,4 corrected for 22 °C, at the end of the shelf life

Component	Quality measurements required *The required frequency of sampling for all measurements shall be determined using statistical process control*	Acceptable results for quality measurements
Platelets, recovered, pooled, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per pool are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 1×10^6 per pool
	pH	6,4 – 7,4 corrected for 22 °C, at the end of the shelf life
Platelets, recovered, single unit	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single unit are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than $0,2 \times 10^9$ per single unit (platelet-rich plasma method) Less than $0,05 \times 10^9$ per single unit (buffy coat method)
	pH	6,4 – 7,4 corrected for 22 °C, at the end of the shelf life
Platelets, recovered, single unit, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single unit are permitted within limits that comply with validated preparation and preservation conditions
	Leukocyte content	Less than 1×10^6 per unit
	pH	6, 4 — 7,4 corrected for 22 °C, at the end of the shelf life
Plasma, fresh-frozen	Volume	Stated volume +/- 10 %
	Factor VIIIc (*)	Average (after freezing and thawing): 70 % or more of the value of the freshly collected plasma unit
	Total protein (*)	Not less than 50 g/l
	Residual cellular content (*)	Red cells: less than $6,0 \times 10^9$/l Leucocytes: less than $0, 1 \times 10^9$/l Platelets: less than 50×10^9/l
Plasma, fresh-frozen, cryoprecipitate-depleted	Volume	Stated volume: +/- 10 %
	Residual cellular content (*)	Red cells: less than $6,0 \times 10^9$/l Leucocytes: less than $0,1 \times 10^9$/l Platelets: less than 50 × 109/l
Cryoprecipitate	Fibrinogen content (*)	Greater than or equal to 140 mg per unit
	Factor VIIIc content (*)	Greater than or equal to 70 international units per unit
Granulocytes, apheresis	Volume	Less than 500 ml
	Granulocyte content	Greater than 1×10^{10} granulocytes per unit

APPENDIX V

Commission Directive 2005/61/EC

COMMISSION DIRECTIVE 2005/61/EC

of 30 September 2005

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC [1], and in particular points (a) and (i) of the second paragraph of Article 29 thereof,

Whereas:

(1) Directive 2002/98/EC lays down standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and for their processing, storage and distribution when intended for transfusion so as to ensure a high level of human health protection.

(2) In order to prevent the transmission of diseases by blood and blood components and to ensure an equivalent level of quality and safety, Directive 2002/98/EC calls for the establishment of specific technical requirements dealing with traceability, a Community procedure for notifying serious adverse reactions and events and the notification format.

(3) Notification of suspected serious adverse reactions or serious adverse events should be submitted to the competent authority as soon as known. This Directive therefore establishes the notification format defining the minimum data needed, without prejudice to the faculty of Member States to maintain or introduce in their territory more stringent protective measures which comply with the provisions of the Treaty as provided under Article 4(2) of Directive 2002/98/EC.

(4) This Directive lays down those technical requirements, which take account of Council Recommendation 98/463/EC of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community [2], Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [3], Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components [4], and certain recommendations of the Council of Europe.

(5) Accordingly, blood and blood components imported from third countries, including those used as starting material or raw material for the manufacture of medicinal products derived from human blood and human plasma, intended for distribution in the Community, should meet equivalent Community standards and specifications relating to traceability and serious adverse reaction and serious adverse event notification requirements as set out in this Directive.

(6) It is necessary to determine common definitions for technical terminology in order to ensure the consistent implementation of Directive 2002/98/EC.

(7) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2002/98/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Definitions

For the purposes of this Directive, the following definitions shall apply:

(a) 'traceability' means the ability to trace each individual unit of blood or blood component derived thereof from the donor to its final destination, whether this is a recipient, a manufacturer of medicinal products or disposal, and vice versa;

(b) 'reporting establishment' means the blood establishment, the hospital blood bank or facilities where the transfusion takes place that reports serious adverse reactions and/or serious adverse events to the competent authority;

(c) 'recipient' means someone who has been transfused with blood or blood components;

[1] OJ L 33, 8.2.2003, p. 30.
[2] OJ L 203, 21.7.1998, p. 14.
[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).
[4] OJ L 91, 30.3.2004, p. 25.

(d) 'issue' means the provision of blood or blood components by a blood establishment or a hospital blood bank for transfusion to a recipient;

(e) 'imputability' means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused or that a serious adverse reaction in a donor can be attributed to the donation process;

(f) 'facilities' means hospitals, clinics, manufacturers, and biomedical research institutions to which blood or blood components may be delivered.

Article 2

Traceability

1. Member States shall ensure the traceability of blood and blood components through accurate identification procedures, record maintenance and an appropriate labelling system.

2. Member States shall ensure that the traceability system in place in the blood establishment enables the tracing of blood components to their location and processing stage.

3. Member States shall ensure that every blood establishment has a system in place to uniquely identify each donor, each blood unit collected and each blood component prepared, whatever its intended purpose, and the facilities to which a given blood component has been delivered.

4. Member States shall ensure that all facilities have a system in place to record each blood unit or blood component received, whether or not locally processed, and the final destination of that received unit, whether transfused, discarded or returned to the distributing blood establishment.

5. Member States shall ensure that every blood establishment has a unique identifier that enables it to be precisely linked to each unit of blood that it has collected and to each blood component that it has prepared.

Article 3

Verification procedure for issuing blood or blood components

Member States shall ensure that the blood establishment, when it issues units of blood or blood components for transfusion, or the hospital blood bank has in place a procedure to verify that each unit issued has been transfused to the intended recipient or if not transfused to verify its subsequent disposition.

Article 4

Record of data on traceability

Member States shall ensure that blood establishments, hospital blood banks, or facilities retain the data set out in Annex I for at least 30 years in an appropriate and readable storage medium in order to ensure traceability.

Article 5

Notification of serious adverse reactions

1. Member States shall ensure that those facilities where transfusion occurs have procedures in place to retain the record of transfusions and to notify blood establishments without delay of any serious adverse reactions observed in recipients during or after transfusion which may be attributable to the quality or safety of blood and blood components.

2. Member States shall ensure that reporting establishments have procedures in place to communicate to the competent authority as soon as known all relevant information about suspected serious adverse reactions. The notification formats set out in Part A and Part C of Annex II shall be used.

3. Member States shall ensure that reporting establishments:

(a) notify to the competent authority all relevant information about serious adverse reactions of imputability level 2 or 3, as referred to in Part B of Annex II, attributable to the quality and safety of blood and blood components;

(b) notify the competent authority of any case of transmission of infectious agents by blood and blood components as soon as known;

(c) describe the actions taken with respect to other implicated blood components that have been distributed for transfusion or for use as plasma for fractionation;

(d) evaluate suspected serious adverse reactions according to the imputability levels set out in Part B of Annex II;

(e) complete the serious adverse reaction notification, upon conclusion of the investigation, using the format set out in Part C of Annex II;

(f) submit a complete report on serious adverse reactions to the competent authority on an annual basis using the format set out in Part D of Annex II.

Article 6

Notification of serious adverse events

1. Member States shall ensure that blood establishments and hospital blood banks have procedures in place to retain the record of any serious adverse events which may affect the quality or safety of blood and blood components.

2. Member States shall ensure that reporting establishments have procedures in place to communicate to the competent authority as soon as known, using the notification format set out in Part A of Annex III, all relevant information about serious adverse events which may put in danger donors or recipients other than those directly involved in the event concerned.

3. Member States shall ensure that reporting establishments:

(a) evaluate serious adverse events to identify preventable causes within the process;

(b) complete the serious adverse event notification, upon conclusion of the investigation, using the format set out in Part B of Annex III;

(c) submit a complete report on serious adverse events to the competent authority on an annual basis using the format set out in Part C of Annex III.

Article 7

Requirements for imported blood and blood components

1. Member States shall ensure that for imports of blood and blood components from third countries blood establishments have a system of traceability in place equivalent to that provided for in Article 2(2) to (5).

2. Member States shall ensure that for imports of blood and blood components from third countries blood establishments have a system of notification in place equivalent to that provided for in Articles 5 and 6.

Article 8

Annual reports

Member States shall submit to the Commission an annual report, by 30 June of the following year, on the notification of serious adverse reactions and events received by the competent authority using the formats in Part D of Annex II and Part C of Annex III.

Article 9

Communication of information between competent authorities

Member States shall ensure that their competent authorities communicate to each other such information as is appropriate with regard to serious adverse reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded.

Article 10

Transposition

1. Without prejudice to Article 7 of Directive 2002/98/EC, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 August 2006 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 11

Entry into force

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 12

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 30 September 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

Record of data on traceability as provided for in Article 4

BY BLOOD ESTABLISHMENTS

1. Blood establishment identification

2. Blood donor identification

3. Blood unit identification

4. Individual blood component identification

5. Date of collection (year/month/day)

6. Facilities to which blood units or blood components are distributed, or subsequent disposition.

BY FACILITIES

1. Blood component supplier identification

2. Issued blood component identification

3. Transfused recipient identification

4. For blood units not transfused, confirmation of subsequent disposition

5. Date of transfusion or disposition (year/month/day)

6. Lot number of the component, if relevant.

ANNEX II

NOTIFICATION OF SERIOUS ADVERSE REACTIONS

PART A

Rapid notification format for suspected serious adverse reactions

Reporting establishment

Report identification

Reporting date (year/month/day)

Date of transfusion (year/month/day)

Age and sex of recipient

Date of serious adverse reaction (year/month/day)

Serious adverse reaction is related to

— **Whole blood**

— **Red blood cells**

— **Platelets**

— **Plasma**

— **Other** ***(specify)***

Type of serious adverse reaction(s)

— **Immunological haemolysis due to ABO incompatibility**

— **Immunological haemolysis due to other allo-antibody**

— **Non-immunological haemolysis**

— **Transfusion-transmitted bacterial infection**

— **Anaphylaxis/hypersensitivity**

— **Transfusion related acute lung injury**

— **Transfusion-transmitted viral infection (HBV)**

— **Transfusion-transmitted viral infection (HCV)**

— **Transfusion-transmitted viral infection (HIV-1/2)**

— **Transfusion-transmitted viral infection, Other** ***(specify)***

— **Transfusion-transmitted parasitical infection (Malaria)**

— **Transfusion-transmitted parasitical infection, Other** ***(specify)***

— **Post-transfusion purpura**

— **Graft versus host disease**

— **Other serious reaction(s)** ***(specify)***

Imputability level (NA, 0-3)

PART B

Serious adverse reactions — imputability levels

Imputability levels to assess serious adverse reactions.

Imputability level		Explanation
NA	Not assessable	When there is insufficient data for imputability assessment.
0	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to alternative causes.
	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes.
2	Likely, Probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.

PART C

Confirmation format for serious adverse reactions

Reporting establishment

Report identification

Confirmation date (year/month/day)

Date of serious adverse reaction (year/month/day)

Confirmation of serious adverse reaction (Yes/No)

Imputability level (NA, 0-3)

Change of type of serious adverse reaction (Yes/No)

If Yes, ***specify***

Clinical outcome (if known)

— **Complete recovery**

— **Minor sequelae**

— **Serious sequelae**

— **Death**

PART D

Annual notification format for serious adverse reactions

Reporting establishment

Reporting period

This Table refers to **[ ] Whole blood** **[ ] Red blood cells** **[ ] Platelets** **[ ] Plasma** **[ ] Other** *(use separate table for each component)*		Number of units issued (total number of units issued with a given number of blood components)					
		Number of recipients transfused (total number of recipients transfused with a given number of blood components) *(if available)*					
		Number of units transfused (the total number of blood components (units) transfused over the reporting period) *(if available)*					
		Total number reported	Number of serious adverse reactions with imputability level 0 to 3 after confirmation (see Annex IIA)				
		Number of deaths					
			not assessable	Level 0	Level 1	Level 2	Level 3
Immunological Haemolysis	Due to ABO incompatibility	Total					
		Deaths					
	Due to other allo-antibody	Total					
		Deaths					
Non-immunological haemolysis		Total					
		Deaths					
Transfusion-transmitted bacterial infection		Total					
		Deaths					
Anaphylaxis/hypersensitivity		Total					
		Deaths					
Transfusion related acute lung injury		Total					
		Deaths					
Transfusion-transmitted viral Infection	HBV	Total					
		Deaths					
	HCV	Total					
		Deaths					
	HIV-1/2	Total					
		Deaths					
	Other *(specify)*	Total					
		Deaths					
Transfusion-transmitted parasitical infection	Malaria	Total					
		Deaths					
	Other *(specify)*	Total					
		Deaths					

Post-transfusion purpura	Total					
	Deaths					
Graft versus host disease	Total					
	Deaths					
Other serious reactions *(specify)*	Total					
	Deaths					

ANNEX III

NOTIFICATION OF SERIOUS ADVERSE EVENTS

PART A

Rapid Notification Format for Serious Adverse Events

Reporting establishment	
Report identification	
Reporting date (year/month/day)	
Date of serious adverse event (year/month/day)	

Serious adverse event, which may affect quality and safety of blood component due to a deviation in:	**Specification**			
	Product defect	Equipment failure	Human error	Other *(specify)*
Whole blood collection				
Apheresis collection				
Testing of donations				
Processing				
Storage				
Distribution				
Materials				
Others *(specify)*				

PART B

Confirmation Format for Serious Adverse Events

Reporting establishment
Report identification
Confirmation date *(year/month/day)*
Date of serious adverse event *(year/month/day)*
Root cause analysis (details)
Corrective measures taken (details)

PART C

Annual Notification Format for Serious Adverse Events

Reporting establishment	
Reporting period	**1 January-31 December *(year)***
Total number of blood and blood components processed:	

Serious adverse event, affecting quality and safety of blood component due to a deviation in:	**Total number**	**Specification**			
		Product defect	Equipment failure	Human error	Other *(specify)*
Whole blood collection					
Apheresis collection					
Testing of donations					
Processing					
Storage					
Distribution					
Materials					
Others *(specify)*					

APPENDIX VI

Commission Directive 2005/62/EC

COMMISSION DIRECTIVE 2005/62/EC

of 30 September 2005

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC [1], and in particular point (h) of the second paragraph of Article 29 thereof,

Whereas:

(1) Directive 2002/98/EC lays down standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and for their processing, storage and distribution when intended for transfusion so as to ensure a high level of human health protection.

(2) In order to prevent the transmission of diseases by blood and blood components and to ensure an equivalent level of quality and safety, Directive 2002/98/EC calls for the establishment of specific technical requirements including Community standards and specifications with regard to a quality system for blood establishments.

(3) A quality system for blood establishments should embrace the principles of quality management, quality assurance, and continuous quality improvement, and should include personnel, premises and equipment, documentation, collection, testing and processing, storage and distribution, contract management, non-conformance and self-inspection, quality control, blood component recall, and external and internal auditing.

(4) This Directive lays down those technical requirements, which take account of Council Recommendation 98/463/EC of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community [2], Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [3], Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use [4], Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components [5], certain recommendations of the Council of Europe, the monographs of the European Pharmacopoeia, particularly in respect of blood or blood components as a starting material for the manufacture of proprietary medicinal products, recommendations of the World Health Organisation, as well as international experience in this field.

(5) In order to ensure the highest quality and safety for blood and blood components, guidance on good practice should be developed to support the quality system requirements for blood establishments taking fully into account the detailed guidelines referred to in Article 47 of Directive 2001/83/EC so as to ensure that the standards required for medicinal products are maintained.

(6) Blood and blood components imported from third countries, including those used as starting material or raw material for the manufacture of medicinal products derived from human blood and human plasma intended for distribution in the Community, should meet equivalent Community standards and specifications relating to a quality system for blood establishments as set out in this Directive.

(7) It is necessary to specify that a quality system is to be applied for any blood and blood components circulating in the Community and that Member States therefore should ensure that for blood and blood components coming from third countries there is a quality system in place for blood establishments in the stages preceding importation equivalent to the quality system provided under this Directive.

[1] OJ L 33, 8.2.2003, p. 30.
[2] OJ L 203, 21.7.1998, p. 14.
[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).
[4] OJ L 262, 14.10.2003, p. 22.
[5] OJ L 91, 30.3.2004, p. 25.

(8) It is necessary to determine common definitions for technical terminology in order to ensure the consistent implementation of Directive 2002/98/EC.

(9) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2002/98/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Definitions

For the purposes of this Directive, the following definitions shall apply:

(a) 'standard' means the requirements that serve as the basis for comparison;

(b) 'specification' means a description of the criteria that must be fulfilled in order to achieve the required quality standard;

(c) 'quality system' means the organisational structure, responsibilities, procedures, processes, and resources for implementing quality management;

(d) 'quality management' means the co-ordinated activities to direct and control an organisation with regard to quality at all levels within the blood establishment;

(e) 'quality control' means part of a quality system focussed on fulfilling quality requirements;

(f) 'quality assurance' means all the activities from blood collection to distribution made with the object of ensuring that blood and blood components are of the quality required for their intended use;

(g) 'trace-back' means the process of investigating a report of a suspected transfusion-associated adverse reaction in a recipient in order to identify a potentially implicated donor;

(h) 'written procedures' means controlled documents that describe how specified operations are to be carried out;

(i) 'mobile site' means a temporary or movable place used for the collection of blood and blood components which is in a location outside of but under the control of the blood establishment;

(j) 'processing' means any step in the preparation of a blood component that is carried out between the collection of blood and the issuing of a blood component;

(k) 'good practice' means all elements in established practice that collectively will lead to final blood or blood components that consistently meet predefined specifications and compliance with defined regulations;

(l) 'quarantine' means the physical isolation of blood components or incoming materials/reagents over a variable period of time while awaiting acceptance, issuance or rejection of the blood components or incoming materials/reagents;

(m) 'validation' means the establishment of documented and objective evidence that the pre-defined requirements for a specific procedure or process can be consistently fulfilled;

(n) 'qualification', as part of validation, means the action of verifying that any personnel, premises, equipment or material works correctly and delivers the expected results;

(o) 'computerised system' means a system including the input of data, electronic processing and the output of information to be used either for reporting, automatic control or documentation.

Article 2

Quality system standards and specifications

1. Member States shall ensure that the quality system in place in all blood establishments complies with the Community standards and specifications set out in the Annex to this Directive.

2. Good practice guidelines shall be developed by the Commission, in accordance with Article 28 of Directive 2002/98/EC, for the interpretation of the Community standards and specifications referred to in paragraph 1. When developing these guidelines, the Commission shall take fully into account the detailed principles and guidelines of good manufacturing practice, as referred to in Article 47 of Directive 2001/83/EC.

3. Member States shall ensure that for blood and blood components imported from third countries and intended for use or distribution in the Community, there is a quality system for blood establishments in the stages preceding importation equivalent to the quality system provided for in Article 2.

Article 3

Transposition

1. Without prejudice to Article 7 of Directive 2002/98/EC, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 August 2006 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 4

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 5

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 30 September 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

Quality system standards and specifications

1. INTRODUCTION AND GENERAL PRINCIPLES

1.1. **Quality system**

1. Quality shall be recognised as being the responsibility of all persons involved in the processes of the blood establishment with management ensuring a systematic approach towards quality and the implementation and maintenance of a quality system.

2. The quality system encompasses quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, blood component recall, and external and internal auditing, contract management, non-conformance and self-inspection.

3. The quality system shall ensure that all critical processes are specified in appropriate instructions and are carried out in accordance with the standards and specifications set out in this Annex. Management shall review the system at regular intervals to verify its effectiveness and introduce corrective measures if deemed necessary.

1.2. **Quality assurance**

1. All blood establishments and hospital blood banks shall be supported by a quality assurance function, whether internal or related, in fulfilling quality assurance. That function shall be involved in all quality-related matters and review and approve all appropriate quality related documents.

2. All procedures, premises, and equipment that have an influence on the quality and safety of blood and blood components shall be validated prior to introduction and be re-validated at regular intervals determined as a result of these activities.

2. PERSONNEL AND ORGANISATION

1. Personnel in blood establishments shall be available in sufficient numbers to carry out the activities related to the collection, testing, processing, storage and distribution of blood and blood components and be trained and assessed to be competent to perform their tasks.

2. All personnel in blood establishments shall have up to date job descriptions which clearly set out their tasks and responsibilities. Blood establishments shall assign the responsibility for processing management and quality assurance to different individuals and who function independently.

3. All personnel in blood establishments shall receive initial and continued training appropriate to their specific tasks. Training records shall be maintained. Training programmes shall be in place and shall include good practice.

4. The contents of training programmes shall be periodically assessed and the competence of personnel evaluated regularly.

5. There shall be written safety and hygiene instructions in place adapted to the activities to be carried out and are in compliance with Council Directive 89/391/EEC [1] and Directive 2000/54/EC of the European Parliament and of the Council [2].

3. PREMISES

3.1. **General**

Premises including mobile sites shall be adapted and maintained to suit the activities to be carried out. They shall enable the work to proceed in a logical sequence so as to minimise the risk of errors, and shall allow for effective cleaning and maintenance in order to minimise the risk of contamination.

[1] OJ L 183, 29.6.1989, p. 1.
[2] OJ L 262, 17.10.2000, p. 21.

3.2. **Blood donor area**

There shall be an area for confidential personal interviews with and assessment of individuals to assess their eligibility to donate. This area shall be separated from all processing areas.

3.3. **Blood collection area**

Blood collection shall be carried out in an area intended for the safe withdrawal of blood from donors, appropriately equipped for the initial treatment of donors experiencing adverse reactions or injuries from events associated with blood donation, and organised in such a way as to ensure the safety of both donors and personnel as well as to avoid errors in the collection procedure.

3.4. **Blood testing and processing areas**

There shall be a dedicated laboratory area for testing that is separate from the blood donor and blood component processing area with access restricted to authorised personnel.

3.5. **Storage area**

1. Storage areas shall provide for properly secure and segregated storage of different categories of blood and blood components and materials including quarantine and released materials and units of blood or blood components collected under special criteria (e.g. autologous donation).

2. Provisions shall be in place in the event of equipment or power failure in the main storage facility.

3.6. **Waste disposal area**

An area shall be designated for the safe disposal of waste, disposable items used during the collection, testing, and processing and for rejected blood or blood components.

4. EQUIPMENT AND MATERIALS

1. All equipment shall be validated, calibrated and maintained to suit its intended purpose. Operating instructions shall be available and appropriate records kept.

2. Equipment shall be selected to minimise any hazard to donors, personnel, or blood components.

3. Only reagents and materials from approved suppliers that meet the documented requirements and specifications shall be used. Critical materials shall be released by a person qualified to perform this task. Where relevant, materials, reagents and equipment shall meet the requirements of Council Directive 93/42/EEC ([1]) for medical devices and Directive 98/79/EC of the European Parliament and of the Council ([2]) for in vitro diagnostic medical devices or comply with equivalent standards in the case of collection in third countries.

4. Inventory records shall be retained for a period acceptable to and agreed with the competent authority.

5. When computerised systems are used, software, hardware and back-up procedures must be checked regularly to ensure reliability, be validated before use, and be maintained in a validated state. Hardware and software shall be protected against unauthorised use or unauthorised changes. The back-up procedure shall prevent loss of or damage to data at expected and unexpected down times or function failures.

5. DOCUMENTATION

1. Documents setting out specifications, procedures and records covering each activity performed by the blood establishment shall be in place and kept up to date.

2. Records shall be legible and may be handwritten, transferred to another medium such as microfilm or documented in a computerised system.

([1]) OJ L 169, 12.7.1993, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).
([2]) OJ L 331, 7.12.1998, p. 1. Directive as amended by Regulation (EC) No 1882/2003.

3. All significant changes to documents shall be acted upon promptly and shall be reviewed, dated and signed by a person authorised to perform this task.

6. BLOOD COLLECTION, TESTING AND PROCESSING

6.1. **Donor eligibility**

1. Procedures for safe donor identification, suitability interview and eligibility assessment shall be implemented and maintained. They shall take place before each donation and comply with the requirements set out in Annex II and Annex III to Directive 2004/33/EC.

2. The donor interview shall be conducted in such a way as to ensure confidentiality.

3. The donor suitability records and final assessment shall be signed by a qualified health professional.

6.2. **Collection of blood and blood components**

1. The blood collection procedure shall be designed to ensure that the identity of the donor is verified and securely recorded and that the link between the donor and the blood, blood components and blood samples is clearly established.

2. The sterile blood bag systems used for the collection of blood and blood components and their processing shall be CE-marked or comply with equivalent standards if the blood and blood components are collected in third countries. The batch number of the blood bag shall be traceable for each blood component.

3. Blood collection procedures shall minimise the risk of microbial contamination.

4. Laboratory samples shall be taken at the time of donation and appropriately stored prior to testing.

5. The procedure used for the labelling of records, blood bags and laboratory samples with donation numbers shall be designed to avoid any risk of identification error and mix-up.

6. After blood collection, the blood bags shall be handled in a way that maintains the quality of the blood and at a storage and transport temperature appropriate to further processing requirements.

7. There shall be a system in place to ensure that each donation can be linked to the collection and processing system into which it was collected and/or processed.

6.3. **Laboratory testing**

1. All laboratory testing procedures shall be validated before use.

2. Each donation shall be tested in conformity with the requirements laid down in Annex IV to Directive 2002/98/EC.

3. There shall be clearly defined procedures to resolve discrepant results and ensure that blood and blood components that have a repeatedly reactive result in a serological screening test for infection with the viruses mentioned in Annex IV to Directive 2002/98/EC shall be excluded from therapeutic use and be stored separately in a dedicated environment. Appropriate confirmatory testing shall take place. In case of confirmed positive results, appropriate donor management shall take place including the provision of information to the donor and follow-up procedures.

4. There shall be data confirming the suitability of any laboratory reagents used in the testing of donor samples and blood component samples.

5. The quality of the laboratory testing shall be regularly assessed by the participation in a formal system of proficiency testing, such as an external quality assurance programme.

6. Blood group serology testing shall include procedures for testing specific groups of donors (e.g. first time donors, donors with a history of transfusion).

6.4. **Processing and validation**

1. All equipment and technical devices shall be used in accordance with validated procedures.

2. The processing of blood components shall be carried out using appropriate and validated procedures including measures to avoid the risk of contamination and microbial growth in the prepared blood components.

6.5. **Labelling**

1. At all stages, all containers shall be labelled with relevant information of their identity. In the absence of a validated computerised system for status control, the labelling shall clearly distinguish released from non-released units of blood and blood components.

2. The labelling system for the collected blood, intermediate and finished blood components and samples must unmistakably identify the type of content, and comply with the labelling and traceability requirements referred to in Article 14 of Directive 2002/98/EC and Commission Directive 2005/61/EC [1]. The label for a final blood component shall comply with the requirements of Annex III to Directive 2002/98/EC.

3. For autologous blood and blood components, the label also shall comply with Article 7 of Directive 2004/33/EC and the additional requirements for autologous donations specified in Annex IV to that Directive.

6.6. **Release of blood and blood components**

1. There shall be a safe and secure system to prevent each single blood and blood component from being released until all mandatory requirements set out in this Directive have been fulfilled. Each blood establishment shall be able to demonstrate that each blood or blood component has been formally released by an authorised person. Records shall demonstrate that before a blood component is released, all current declaration forms, relevant medical records and test results meet all acceptance criteria.

2. Before release, blood and blood components shall be kept administratively and physically segregated from released blood and blood components. In the absence of a validated computerised system for status control the label of a unit of blood or blood component shall identify the release status in accordance with 6.5.1.

3. In the event that the final component fails release due to a confirmed positive infection test result, in conformity with the requirements set out in Section 6.3.2 and 6.3.3, a check shall be made to ensure that other components from the same donation and components prepared from previous donations given by the donor are identified. There shall be an immediate update of the donor record.

7. STORAGE AND DISTRIBUTION

1. The quality system of the blood establishment shall ensure that, for blood and blood components intended for the manufacture of medicinal products, the storage and distribution requirements shall comply with Directive 2003/94/EC.

2. Procedures for storage and distribution shall be validated to ensure blood and blood component quality during the entire storage period and to exclude mix-ups of blood components. All transportation and storage actions, including receipt and distribution, shall be defined by written procedures and specifications.

3. Autologous blood and blood components as well as blood components collected and prepared for specific purposes shall be stored separately.

4. Appropriate records of inventory and distribution shall be kept.

5. Packaging shall maintain the integrity and storage temperature of blood or blood components during distribution and transportation.

6. Return of blood and blood components into inventory for subsequent reissue shall only be accepted when all quality requirements and procedures laid down by the blood establishment to ensure blood component integrity are fulfilled.

[1] See page 32 of this Official Journal.

8. CONTRACT MANAGEMENT

Tasks that are performed externally shall be defined in a specific written contract.

9. NON-CONFORMANCE

9.1. **Deviations**

Blood components deviating from required standards set out in Annex V to Directive 2004/33/EC shall be released for transfusion only in exceptional circumstances and with the recorded agreement of the prescribing physician and the blood establishment physician.

9.2. **Complaints**

All complaints and other information, including serious adverse reactions and serious adverse events, which may suggest that defective blood components have been issued, shall be documented, carefully investigated for causative factors of the defect and, where necessary, followed by recall and the implementation of corrective actions to prevent recurrence. Procedures shall be in place to ensure that the competent authorities are notified as appropriate of serious adverse reactions or serious adverse events in accordance with regulatory requirements.

9.3. **Recall**

1. There shall be personnel authorised within the blood establishment to assess the need for blood and blood component recall and to initiate and coordinate the necessary actions.

2. An effective recall procedure shall be in place, including a description of the responsibilities and actions to be taken. This shall include notification to the competent authority.

3. Actions shall be taken within pre-defined periods of time and shall include tracing all relevant blood components and, where applicable, shall include trace-back. The purpose of the investigation is to identify any donor who might have contributed to causing the transfusion reaction and to retrieve available blood components from that donor, as well as to notify consignees and recipients of components collected from the same donor in the event that they might have been put at risk.

9.4. **Corrective and preventive actions**

1. A system to ensure corrective and preventive actions on blood component non-conformity and quality problems shall be in place.

2. Data shall be routinely analysed to identify quality problems that may require corrective action or to identify unfavourable trends that may require preventive action.

3. All errors and accidents shall be documented and investigated in order to identify system problems for correction.

10. SELF-INSPECTION, AUDITS AND IMPROVEMENTS

1. Self-inspection or audit systems shall be in place for all parts of the operations to verify compliance with the standards set out in this Annex. They shall be carried out regularly by trained and competent persons in an independent way according to approved procedures.

2. All results shall be documented and appropriate corrective and preventive actions shall be taken in a timely and effective manner.

APPENDIX VII

Council Recommendation 98/463/EC

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL RECOMMENDATION

of 29 June 1998

on the suitability of blood and plasma donors and the screening of donated blood in the European Community

(98/463/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 129(4), second indent,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament [1],

(1) Whereas in accordance with Article 3(o) of the Treaty, Community activity is to include a contribution towards the attainment of a high level of health protection;

(2) Whereas the Commission's Communication of 21 December 1994 on Blood Safety and Self-sufficiency in the European Community identified the need for a blood strategy in order to reinforce confidence in the safety of the blood transfusion chain and promote Community self-sufficiency;

(3) Whereas, in response to the Commission's Communication, the Council adopted, on 2 June 1995, a Resolution on blood safety and self-sufficiency in the Community [2];

(4) Whereas the Council adopted, on 12 November 1996, a Resolution on a strategy towards blood safety and self-sufficiency in the European Community [3];

(5) Whereas the European Parliament in its Resolutions on blood safety and self-sufficiency in the European Community [4] [5] [6] [7] has stressed the importance of ensuring the highest level of safety in the selection of donors and the testing of donations and the principle of voluntary unpaid donations and has reiterated its continued support for the objective of Community self-sufficiency;

(6) Whereas Directive 89/381/EEC [8] extended the scope of pharmaceutical legislation to guarantee the quality, safety, and efficacy of proprietary industrially prepared medicinal products derived from human blood or human plasma; whereas that Directive as such does not apply to whole blood, to plasma, or to blood cells of human origin;

(7) Whereas therapeutic use of blood and medicinal products derived from human blood and plasma contributes significantly to saving lives and yields considerable benefits for those suffering from long term blood disorders; whereas, however, in spite of their significant therapeutic value, blood, blood components, and blood and plasma derivatives have the potential to transmit infectious diseases;

(8) Whereas the availability of blood and plasma used for therapeutic purposes and as starting material for the manufacture of medicinal products is dependent on the willingness and generosity of Community citizens who are prepared to donate;

(9) Whereas donations should be voluntary and unpaid;

(10) Whereas in respect of blood or plasma as a starting material for the manufacture of medicinal products, Article 3 of Directive 89/381/EEC refers to measures covered by the amendments to testing requirements, referred to in Article 6 of that Directive, to be taken by Member States to prevent the transmission of infectious diseases, including the application of the monographs of the European Pharmacopoeia and the measures recommended by the Council of Europe and the World Health Organisation (WHO) particularly with reference to the selection and testing of blood and plasma donors; to promote Community self-sufficiency in human blood or human plasma; and to encourage voluntary unpaid donations of blood and plasma;

(11) Whereas it is not always possible to know at the time of whole blood or plasma collection which donation may be used for further manufacture rather than used in transfusion;

(12) Whereas all blood and plasma used for therapeutic purposes, whether for transfusion or for further manufacture into industrially-prepared medicinal products, should be obtained from individuals whose health status is such that no detrimental effects to their state of health will ensue as a result of the donation and any risk of transmission of infectious diseases is minimised; whereas each and every blood donation should be tested in accordance with rules which provide assurances that all necessary measures have been taken to safeguard the health of Community citizens who are the recipients of blood and blood products;

(13) Whereas given that the blood transfusion systems in the Member States exist to serve their citizens, it is necessary to secure their confidence in the safety of these systems;

(14) Whereas there are disparities in policies and practices among the Member States regarding the selection of donors and the screening of donations within the Community for epidemiological, historical and cultural reasons;

(15) Whereas to ensure sufficient supply for clinical purposes, cooperation among the Member States is essential in order to overcome such disparities and build mutual confidence in all aspects of safety of the blood transfusion chain;

(16) Whereas the suitability of an individual to donate blood and plasma is an essential component in contributing to the safety of blood and blood products;

(17) Whereas information should be sought from potential donors on the basis of a written questionnaire, which may vary from Member State to Member State, whose aim should be to identify common risk behaviour and diseases;

(18) Whereas it is essential that all measures be taken to safeguard the health of those who give blood or plasma and to minimise the hazard of transmission of infectious diseases by blood or blood products;

(19) Whereas convergence of practice throughout the Community in the acceptance of donors, the screening of donations and the recording of relevant data will help to contribute to increasing confidence in the safety of blood and plasma donations and the transfusion process; whereas in order to bring about such convergence of practice, measures are required at Community level;

(20) Whereas measures at Community level should take into account existing guidelines, recommendations and standards in the area of blood at national level and international level, in particular those of the WHO and of the Council of Europe;

(21) Whereas in accordance with the principle of subsidiarity, any new measure taken in an area which does not fall within the exclusive competence of the Community, such as donor suitability and testing of donations, may be taken up by the Community only if, by reason of the scale or effects of the proposed action, the objectives of the proposed action can be better achieved by the Community than by Member States; whereas commonly agreed recommendations on donor suitability and testing of donations need, therefore, to be introduced in order to contribute to the safety of donated blood and plasma and the health protection of donors and to permit confidence in the safety of the transfusion chain among citizens, especially as they move about within the Community, and to contribute to the attainment of Community self-sufficiency as provided for in Community legislation;

[1] OJ C 138, 4. 5. 1998, p. 139.
[2] OJ C 164, 30. 6. 1995, p. 1.
[3] OJ C 374, 11. 12. 1996, p. 1.
[4] OJ C 268, 4. 10. 1993, p. 29.
[5] OJ C 329, 6. 12. 1993, p. 268.
[6] OJ C 141, 13. 5. 1996, p. 131.
[7] OJ C 249, 25. 9. 1995, p. 231.
[8] Council Directive 89/381/EEC of 14 June 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relation to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma (OJ L 181, 28. 6. 1989, p. 44).

(22) Whereas however, Member States remain free, while respecting the provisions of the Treaty or measures adopted thereunder, to maintain or introduce requirements over and above the core criteria recommended in this Recommendation, and remain responsible for decisions about the import and export of donated blood and plasma;

(23) Whereas in accordance with the principle of proportionality, the means to be deployed at Community level for promoting sound practices and consistency throughout the Community in the suitability of blood and plasma donors and the screening of donated blood must be in proportion to the objective pursued; whereas recommendations by the Council, pursuant to Article 129 of the Treaty, are the appropriate means for doing so at Communhity level; whereas such recommendations must be congruent with Directive 89/381/EEC;

(24) Whereas recommendations on donor suitability and testing requirements form part of a strategy to enhance the safety of the blood transfusion chain, the other elements of which include the inspection and accreditation of blood collection establishments, requirements related to quality assurance of the processes involved, the optimal use of blood and blood products, haemovigilance and public awareness;

(25) Whereas it is necessary that the best possible scientific advice is available to the Community in relation to the safety of blood and blood products and that the precautionary principle prevails when scientific evidence is not available;

(26) Whereas Directive 95/46/EC of the European Parliament of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and the free movement of such data [1] lays down special requirements for the processing of data concerning health,

HEREBY RECOMMENDS THAT:

1. **Definitions**

For the purpose of this Recommendation, Member States should assign to the terms listed in Annex I the meaning given to them therein.

[1] OJ L 281, 23. 11. 1995, p. 31.

2. **Provision of information to prospective donors**

Member States should ensure that all prospective donors of blood or plasma are provided with:

2.1. *For donor awareness*

(a) accurate but generally understandable educational materials about the essential nature of blood, the products derived from it, and the important benefits to patients of blood and plasma donations;

(b) the reasons for requiring a medical history, physical examination, and the testing of donations; information on the risk of infectious diseases that may be transmitted by blood and blood products; the signs and symptoms of HIV/AIDS and hepatitis, and the significance of 'informed consent', self-deferral, and temporary and permanent deferral;

(c) the reasons why they should not donate which may be detrimental to their own health;

(d) the reasons why they should not donate which put recipients at risk, such as unsafe sexual behaviour, HIV/AIDS, hepatitis, drug addiction and the use and abuse of drugs;

(e) the option of changing their mind about donating prior to proceeding further without any undue enbarrassment or discomfort;

(f) information on the possibility of withdrawing or self-deferring at any time during the donation process;

(g) the opportunity to ask questions at any time;

(h) the assurance that if test results show evidence of any pathology, they will be informed and deferred from donation, as recommended in Annex II B and C, for their own safety as well as that of potential recipients; prospective donors who object to being so informed should be excluded from the donation process;

(i) specific information on the nature of the procedures involved in the donation process and associated risks for those willing to participate in whole blood donation or in apheresis programmes.

2.2. *For confidentiality*

(a) information on the measures taken to ensure the confidentiality of: any health-related information provided to the health personnel, the results of the tests on their donations, as well as any future traceability of their donation;

(b) the assurance that all interviews with prospective donors are carried out in confidence;

(c) the option of requesting through a confidential self-deferral procedure the blood and plasma collection establishment not to use their donation.

3. **Information required from prospective donors**

Member States should ensure that, upon agreement of a willingness to proceed to donate blood or plasma, all prospective donors provide to the blood and plasma collection establishment:

3.1. *Identification*

Appropriate means of identification, providing name (first and surname), addresss, and date of birth, or alternative means allowing each donor to be uniquely identified.

3.2. *Health history*

(a) Information on their health and medical history, including any relevant behavioural characteristics, that may assist in identifying and screening out persons whose donation could present a health risk to themselves or a risk of transmitting diseases to others, by way of a written questionnaire addressing the criteria recommended in Annex II and a personal interview with a trained health care staff member.

(b) Their signature alongside that of the health care staff member conducting the interviews on the donor questionnaire or their signature on a separate attestation to acknowledge that the educational materials provided have been read and understood, that the opportunity to ask questions has been presented, and that satisfactory responses have been received; to give their agreement that their blood or plasma donation could be used for patients needing transfusion or blood products in the country where the donation is made or in another country, to which it would be transferred in accordance with the provisions of the legislation of the country where the donation is made, particularly with regard to the destination of the donation; and to indicate their informed consent that they wish to proceed with the donation process.

4. **Registration of donor**

Member States should ensure the establishment of a donor identification/registration system to:

4.1. *Donor centre identification*

Permit every donation establishment in each Member State to be uniquely identified;

4.2. *Donor identification and records*

(a) Record information regarding the identification of prospective donors in an automated or manual system which allows verification each time a donation is made;

(b) Provide for the keeping of records on donors and prospective donors in such a way as to ensure unique identification, protect the identity of the donor from unauthorised access to confidential information, but facilitate future traceabiity of any donation;

(c) Allow for the inclusion of information related to adverse donor reaction to the donation, reasons for preventing an individual from donating, whether on a temporary or permanent basis while ensuring confidentiality.

5. **Donor eligibility**

Member States, in order to ensure the eligibility of individuals to be accepted as donors of blood and plasma, should ensure that:

5.1. *Eligibility criteria for the acceptance of donors of whole blood and donors of components by apheresis*

(a) the general criteria for the acceptance of blood and plasma donors are publicised in every donation establishment and that clear messages are presented to donors as to the importance of their willingness to donate but also the importance of the acceptance criteria;

(b) the responses given to the issues raised in the written questionnaire and/or the personal interview provide the necessary confidence that the donation will not adversely affect the health of a future recipient of the products derived from that donation;

(c) the prospective donor meets the physical requirements criteria recommended in Annex II A in order that there are no detrimental effects to his/her own health as a result of the donation;

(d) the prospective donor's eligibility is determined at each donation session;

(e) the practice of using 'replacement donors' is phased out;

(f) a responsible physician gives his/her written authorisation of the acceptance of prospective donors, when their eligibility may be questionable;

5.2. *Deferral criteria for donors of whole blood and donors of components by apheresis*

Those who may show evidence of any of the conditions and characteristics listed in Annex II B and C should be declared either permanently or temporarily ineligible to donate blood and plasma;

5.3. *Deferral records*

Donation establishments should maintain a record of any prospective donor deferral, whether permanent or temporary, including the reasons why.

6. **Data protection**

Member States should, in accordance with Directive 95/46/EC, ensure the confidentiality of sensitive medical information about prospective donors, and in particular:

(a) ensure that data security measures are in place as well as safeguards against unauthorised data additions, deletions or modifications to donor files or deferral registers, and transfer of information;

(b) ensure that procedures are in place to resolve data discrepancies;

(c) prevent the unauthorised disclosure of such information, while ensuring the traceability of donations.

7. **Volumes and time intervals**

To protect the health of the donor, Member States should ensure that:

(a) volumes of blood and plasma collected are no greater than those recommended in Annex III;

(b) time intervals between donations are no less than those recommended in Annex III;

(c) medical attention is available to the donor in the event of an adverse event related to the donation.

8. **Testing samples of donated blood**

Member States, in order to ensure the safety of all blood and plasma donations, should:

(a) ensure that a sample of all donations of blood or plasma whether intended for transfusion purposes or for further manufacturing into industrially prepared medicinal products is tested for diseases transmissible by blood or plasma using approved screening tests to eliminate units that are repeat reactive;

(b) ensure that all blood and plasma donations be found non-reactive for the transmissible disease markers listed in Annex IV prior to use;

(c) require re-testing of the blood samples found to be reactive in an initial screening test taking account of the indicative algorithm set out in Annex V.

9. **Additional measures**

Member States should:

(a) ensure that appropriate provisions are in place in the donation establishment for counselling, as appropriate, to prospective donors who are deferred;

(b) encourage the collection, analysis and evaluation of epidemiological data concerning donors and donations, with a view to improving the safety of blood transfusion;

(c) take the necessary steps for the dissemination of this recommendation to all parties concerned, and in particular to blood collecting establishments in their territory;

(d) take all necessary measures to encourage the voluntary and unpaid donation of blood and plasma, and entirely support the efforts of the Council of Europe in this area; take account of the Council of Europe definition of voluntary and non-remunerated donation as follows:

'A donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donations.'

INVITES THE COMMISSION

— to report on the application of these recommendations and keep the matters covered therein under review in order to make the necessary proposals for revision and updating; to involve national experts from all the Member States in the preparation of such proposals;

— to promote as a priority, in the light of scientific studies, work on the potential health effects of departing from the maximum volume limits and minimum time intervals between donations set out in Annex III, in order in particular to determine whether or not adverse health effects may result from collecting, by apheresis, annual plasma volumes higher than those recommended in existing international guidelines; and to undertake work on common volume and frequency limits for other types of apheresis;

— to propose where appropriate common terminology for the purpose of further developing the Community strategy on blood safety and self-sufficiency;

— to examine as soon as possible, in close cooperation with the Member States, all the aspects related to the use of genome amplification technology (GAT), including polymerase chain reaction (PCR)-screening, in order to prevent the transmission of communicable diseases by blood transfusion.

Done at Luxembourg, 29 June 1998.

For the Council

The President

R. COOK

ANNEX I

COMMON TERMINOLOGY

Blood	Whole blood collected from a single donor and processed either for transfusion or further manufacturing
Blood product	Any therapeutic product derived from human blood or plasma
Blood component	Therapeutic components of blood (red cells, white cells, platelets, plasma) that can be prepared by centrifugation, filtration, and freezing using conventional blood bank methodology
Medicinal product derived from blood or plasma	Same meaning as that given in Directive 89/381/EEC
Donor	A person in normal health with a good medical history who voluntarily gives blood or plasma for therapeutic use
Prospective donor	Someone who presents himself/herself at a blood or plasma collection establishment and states his/her wish to give blood or plasma
First time donor	Someone who has never donated either blood or plasma
Repeat donor	Someone who has donated before but not within the last two years in the same donation centre
Regular donor	Someone who routinely donates their blood or plasma (i.e. within the last two years), in accordance with minimum time intervals, in the same donation centre
Replacement donor	Donors recruited by patients to enable them to undergo therapy which requires blood transfusion

ANNEX II

CORE CRITERIA FOR ACCEPTANCE OR DEFERRAL OF BLOOD AND PLASMA DONORS

A: **Physical requirements criteria for acceptance of blood and plasma donors for their own protection**

Age

Blood and plasma donors should be 18-65 years of age. Acceptance of first time donors age 60-65 is at the discretion of the responsible physician. Repeat donors may continue to donate after the age of 65 with the permission of the responsible physician given annually.

For whole blood, donors aged 17, and not legally classified as minors, may be accepted; otherwise written consent should be required according to applicable law.

Body weight

Donors weighing no less than 50 kg may donate whole blood or plasma.

Blood pressure

The systolic blood pressure should not exceed 180 mm of mercury and the diastolic pressure should not exceed 100 mm of mercury.

Pulse

The pulse should be regular and between 50 to 110 beats per minute. Those prospective donors who undergo intensive sport training and have a pulse rate lower than 50 beats per minute may be accepted.

Either:

Haemoglobin

The haemoglobin concentration should be determined at the time of the donation and should be no less than 12,5 g/100 ml for females and 13,5 g/100 ml for males (or equivalent values expressed in mmol/I).

or

Haematocrit

The packed cell volume (haematocrit) should be determined at the time of the donation and should be no less than 38 % for females and 40 % for males. For apheresis plasma donors, the minimum should be 38 %.

For plasmapheresis only

Protein should measure a minimum of 60 g per litre.

B: **Deferral criteria blood and plasma donors for their own protection**

If prospective donors have, or have a history of, any of the following, a qualified physician in the blood collection establishment should consider declaring them permanently or temporarily ineligible to donate blood or plasma for the protection of their own health:

1. *Permanent deferral*

— Auto-immune diseases
— Cardiovascular diseases
— Central nervous system diseases
— Malignant diseases
— Abnormal bleeding tendency
— Fainting spells (syncope) or convulsions
— Severe or chronic gastrointestinal, haematological, metabolic, respiratory or renal disease, not included in the preceding categories

2. *Temporary deferral*

Ineligible for nine months

— Pregnancy (after delivery)
— Abortion

Ineligible (time frame variable)

— Participation in hazardous sports
— Employment which might cause problems shortly after blood donation
— Other reasons.

C: **Deferral criteria for blood and plasma donors for the protection of recipients**

If prospective donors have, or have a history of, any of the following, a qualified physician in the blood collection establishment should consider declaring them permanently or temporarily ineligible to donate blood or plasma for the protection of potential recipients:

1. *Permanent deferral*

— Auto-immune diseases
— Infectious diseases — persons suffering or having suffered from:
  — Babesiosis
  — Hepatitis B (HBsAg confirmed positive)
  — Hepatitis C
  — Hepatitis, infectious (of unexplained aetiology)
  — HIV/AIDS
  — HTLV I/II
  — Leprosy
  — Kala Azar (leishmaniasis)
  — Q fever
  — Syphilis
  — Trypanosoma cruzi (Chagas' disease)
— Malignant diseases
— TSEs (or history thereof in the genetic family)
— Alcoholism, chronic
— Cornea/dura mater transplantation recipient
— Diabetes, if treated with insulin
— Intravenous (IV) drug use
— Pituitary hormone of human origin (e.g. human growth hormone) recipient
— Sexual behaviour which places them at a high risk of transmitting infectious diseases, including persons who have had sex in return for money or drugs

2. *Temporary deferral*

2.1 Ineligible for two years

— Tuberculosis (after declared cured)
— Toxoplasmosis (after recovery and absence of IgM antibodies)
— Brucellosis (after full recovery)

2.2 Ineligible for one year

— Accidental exposure to blood or blood contaminated instruments
— Acupuncture (if not performed by a qualified practitioner)
— Endoscopic examination
— Treatment involving use of catheters
— Blood transfusion or major surgery
— Tissue or cell transplant
— Body piercing
— Drug allergy, in particular allergy to penicillin (after last exposure)
— Tattoo
— Close contact with a case of hepatitis B or C
— Rabies vaccine (if post exposure)

2.3 Ineligible for six months

— Infectious mononucleosis (after recovery)

2.4 Ineligible for four weeks

— Following administration of live attenuated viral vaccines

2.5 Ineligible for two weeks

— Minor infectious diseases

2.6 Ineligible for one week

— Minor surgery

2.7 Ineligible for 72 hours

— Following administration of vaccines (desensitising)

2.8 Ineligible for 48 hours

— Treatment by dentist or dental hygienist
— Following administration of killed/inactivated viral/bacterial and rickettsial vaccines
— Rabies vaccine (prophylactic administration)

2.9 Ineligible (time frame variable)

— Hepatitis A
— Medicines
— Malaria (does not apply to plasmapheresis donors)
— Tropical diseases (other)

Additional reasons may exist for the temporary deferral of a donor for the protection of the recipient. A decision as to length of time is as the discretion of a qualified physician in the blood collection establishment.

ANNEX III

WHOLE BLOOD AND PLASMA DONATIONS

recommended maximum volumes and minimum time intervals between donations

Whole blood		
Maximum volume	per donation	500 ml
	per consecutive 12 month period	three litres
Minimum time interval between donations		eight weeks
Automated plasmapheresis		
Maximum volume (excluding anticoagulant)	per donation	650 ml
Minimum time interval between donations		At least two days should elapse between donations. No more than two donations should be permitted within a seven-day period

Existing guidelines at international level in the area of blood recommend 15 litres as the maximum annual volume of plasma to be collected via automated plasmapheresis; there is no scientific evidence of whether or not adverse health effects may result from higher volume collection; this area should be a priority area for scientific study.

In assessing individually appropriate donation volumes, account should also be taken of physical characteristics such as gender and body weight.

ANNEX IV

CORE SCREENING TESTS FOR ALL BLOOD SAMPLES WHETHER FROM A WHOLE BLOOD OR PLASMA DONATION

Antibodies to the hepatitis C virus	Anti-HCV
Antibodies to the human immunodeficiency virus 1	Anti-HIV 1
Antibodies to the human immunodeficiency virus 2	Anti-HIV 2
Surface antigen of hepatitis B	HBsAg

ABO-group [A] [B]
Rh-type [A] [B]

Malaria [B] for travellers to endemic areas (unless risk of malaria transmission is otherwise dealt with by a deferral period of three years for such travellers)

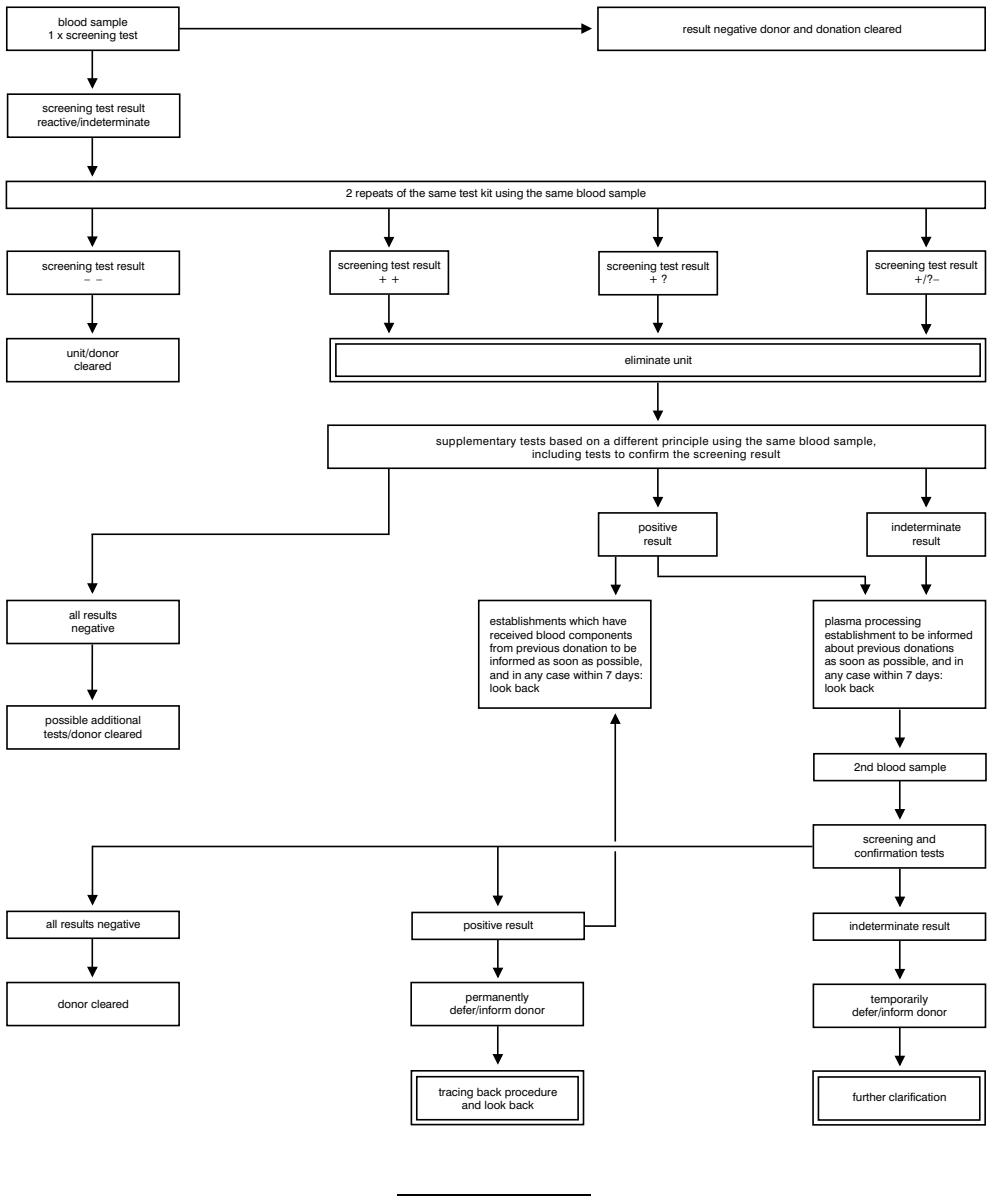
Treponema pallidum (syphilis) [B]

[A] If it can be proven that the blood group of an already known blood donor, whose blood group has been previously determined and verified from two separate donations, can be reliably transferred into the label of the blood component by using a validated automated information technology system, it is not necessary to repeat the determination of ABO- and Rh-groups at the time of every blood donation. In such a case the blood group of the blood donor should be periodically verified.

[B] Not required for apheresis plasma intended only for fractionation.

ANNEX V

Indicative Algorithm for Interpretation of reactive results in screening tests in relation to clinical use of donation and Reactive results in supplementary/confirmation tests in relation to donor deferral



GLOSSARY

Apheresis Method of obtaining one or more blood components by machine processing of whole blood in which the residual components of the blood are returned to the donor during or at the end of the process.

Autologous donation The donation of a donor, collected for therapeutic use in the same donor

Blood Whole blood collected from a single donor and processed either for transfusion or further manufacturing.

Blood component Therapeutic components of blood (red cells, white cells, platelets, plasma) that can be prepared by centrifugation, filtration and freezing using conventional blood bank methodology.

Blood establishment Any structure or body that is responsible for any aspect of the collection and testing of human blood or blood components, whatever their intended purpose, and their processing, storage and distribution when intended for transfusion. This does not include hospital blood banks.

Blood session Session during which blood is collected, which can take place in a fixed site, a mobile site or a mobile vehicle site.

Deferral Suspension of the eligibility of an individual to donate blood or blood components, such suspension being either permanent or temporary.

Deferral rate Total number of temporary and permanent deferrals in the reporting period, excluding self-deferral, divided by the total number of donors attending a blood session.

Donation The result of collecting whole blood or blood components from an individual in a single procedure; a donation is counted from the point of skin puncture onwards

Donation not-for-transfusion The donation of a donor collected for other purposes than transfusion to patients

Donor Someone who voluntarily gives blood or blood components.

Donor association Association established by donors in order to unite donor interests. Some donor associations are involved in donor recruitment.

Donor attendant An employee without nursing qualification, who has received some medical and/or procedural training relating to blood donation.

Donor attrition of those donors that did give blood in the year before, the percentage of donors who did not give blood in the year of concern.

Donor panel A group of donors whose blood is only used for a specific patient group.

Donor recruitment All activities directed at recruiting new donors.

Donor relationship management software Software used specifically to manage communications with donors, co-ordinate campaigns and assist with donor recruitment.

First time donor Someone who has made his first and to date only donation within the last 12 months.

First time donation The lifetime first non-autologous donation of a donor

Fixed site A location where blood session materials are permanently present.

Hospital blood bank A hospital unit which stores and distributes and may perform compatibility tests on blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities. Please compare 'hospital-based blood establishment'.

Hospital-based blood establishment A hospital unit which is responsible for the collection of homologous blood, testing for transfusion-transmissible infections and blood group, processing into blood components and storage. Please compare 'hospital blood bank'.

Inactive donor Someone who has made at least one donation. This donor has made the last donation NOT within the last 24 months, but is still registered in the donor data base.

Lapsing donor Someone who has made at least one donation within the last 24 months, but NOT within the last 12 months.

Mobile site A location where blood session materials are not permanently present; materials have to be transported to and from the location.

Mobile vehicle site A location visited by a mobile vehicle. The donor donates inside this vehicle. The mobile vehicle is a truck/trailer with all blood session materials inside.

Newly registered donor A donor who has been registered as a donor but who has not donated yet.

Nurse An employee with a nursing qualification.

Patients with special transfusion needs	Patients who need special (e.g. multiple, long-term, specified antigen typing) transfusions, such as thalassaemic patients, patients with leukaemia or sickle cell anaemia.
Prospective donor	Someone who states his/her wish to give blood or plasma but is not registered as a donor yet.
Registered donor	Someone who is registered in the donor data base (newly registered donors, first time donors, regular donors, returning donors, lapsing donors and inactive donors).
Regular donor	Someone who made at least two donations within the last 24 months. The last donation has been made within the last 12 months.
Response rate	Number of invited donors attending a blood session divided by the total number of invited donors.
Repeat donation	Any non-autologous donation other than first time donations
Replacement donor	A donor recruited by a patient to enable the patient to undergo therapy which requires blood transfusion.
Returning donor	Someone who has made at least two donations. This donor has made only one donation within the last 12 months AND the interval between the last and the before last donation is more than 24 months.
Self-deferral	The donor himself decides before donation that he is not eligible to donate. Please compare: self-exclusion.
Self-exclusion	The donor himself decides after donation that his donation should not be used for transfusion. Please compare: self-deferral.
Serious adverse event	Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood and blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.
Serious adverse reaction	An unintended response in donor associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity.
Stopped donor	Someone who was registered as a donor and may or may not have made one or more donations, but has subsequently been deregistered as a donor from the donor data base for any reason.
Successful donation	A donation where the puncture of the donor skin did result into whole blood or blood components suitable for processing
Unsuccessful donation	A donation where the puncture of the donor skin did not result into whole blood or blood components suitable for processing

Abbreviations

CoE	Council of Europe
EU	European Union
Fte	Full time equivalent
ISBT	International Society of Blood Transfusion
SOP	Standard Operating Procedure
PI	Performance Indicator