

Development of Safe and Sustainable National Blood Programmes

Manual

GAP **Global Advisory Panel**
on Corporate Governance and Risk Management of Blood Services in Red Cross and Red Crescent Societies



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Inside cover:

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Contents

Preface	5
Acknowledgements	5
1. Introduction	6
2. Overview of National Society involvement in blood programmes	8
2.1 <i>Levels of National Society engagement</i>	8
2.2 <i>Promoting a safe and sustainable blood system</i>	16
3. Fundamental Principles	17
3.1 <i>Promoting voluntary, non-remunerated blood donation (VNRBD)</i>	17
3.2 <i>Ensuring safety for donors and recipients</i>	18
3.3 <i>Promoting equity of access to blood and blood products</i>	18
3.4 <i>Serving the community and patient interest</i>	19
4. Blood programme management	20
4.1 <i>Organizational models</i>	20
4.2 <i>Governance</i>	21
4.3 <i>Corporate management</i>	22
4.4 <i>Financial management</i>	22
4.5 <i>Risk management</i>	24
4.6 <i>Balanced decision-making</i>	25
5. Building a sustainable donor base	26
5.1 <i>Voluntary, non-remunerated blood collection</i>	26
5.2 <i>Attracting and retaining donors</i>	27
5.3 <i>Long-term donor commitment</i>	27
5.4 <i>Donor health and counselling</i>	28
6. Blood Safety	30
6.1 <i>Strategy development</i>	30
6.2 <i>Programme implementation</i>	31
6.2.1 <i>Minimum screening requirements</i>	31
6.2.2 <i>Additional screening test requirements</i>	32
6.2.3 <i>Testing algorithms</i>	33
6.2.4 <i>Test systems</i>	33
6.2.5 <i>Quality system</i>	33
6.2.6 <i>Result, donor and product management</i>	34
6.2.7 <i>Emergency provision of blood</i>	34
7. Quality management	35
7.1 <i>The quality system</i>	35
7.2 <i>Good manufacturing practice (GMP)</i>	36
7.3 <i>Standards</i>	38
7.4 <i>Auditing</i>	38
8. Partnerships	39
8.1 <i>Government</i>	39
8.2 <i>Community engagement</i>	40
8.3 <i>Blood sector networks</i>	40
8.4 <i>Hospitals and clinicians</i>	41
8.5 <i>National Societies</i>	42
9. Sustainability	43
9.1 <i>Adoption of new technologies and practices</i>	43
9.2 <i>Contingency planning and disaster preparedness</i>	43
9.3 <i>Environmental sustainability</i>	45
10. Transition and exit strategies	46
Appendices	51
Appendix 1: <i>International Federation's blood policy</i>	51
Appendix 2: <i>National Society blood risk summary</i>	57
Appendix 3: <i>Framework of a Memorandum of Understanding</i>	58
Appendix 4: <i>ISBT Code of Ethics</i>	61
Appendix 5: <i>Blood Safety, WHO Aide-Mémoire for National Blood Programmes</i>	62

<i>Appendix 6: The Clinical Use of Blood, WHO Aide-Mémoire for National Health Programmes</i>	64
<i>Appendix 7: Quality Systems for Blood Safety, WHO Aide-Mémoire for National Blood Programmes.....</i>	64
<i>Appendix 8: Safe Blood Components, WHO Aide-Mémoire for National Health Authorities</i>	66

Preface

The safety and integrity of a nation's blood supply is fundamental to a secure health system. People in all societies should have the right to expect that the blood and blood products supplied to them are gathered and provided in a safe and sustainable way. While the World Health Organization (WHO) recognizes that it is the responsibility of governments to ensure a safe and adequate supply of blood¹, the International Federation of Red Cross and Red Crescent Societies (IFRC) expects its member National Societies that are involved in blood programmes to meet these obligations to the community.

This manual supercedes the IFRC 1998 Blood Programme Development Manual and is informed by the expertise of the Global Advisory Panel (GAP) on Corporate Governance and Risk Management of Blood Services in Red Cross and Red Crescent Societies. It identifies the features of an effective and sustainable blood programme and directs member societies to relevant resources on blood programme management.

By developing this manual the GAP seeks to support National Societies to manage their involvement in blood programmes in accordance with the International Federation's blood policy and principles and in the best interests of donors and recipients.

This publication describes the Red Cross Red Crescent minimal requirements and international blood service standards that National Societies need to meet in order to maintain a blood programme. It also includes generic guidelines to assist them in assessing the risks of blood service provision, and in transitioning to a lesser involvement in blood programme delivery if this is considered appropriate.

Ultimately, it is the responsibility of individual societies involved in blood programmes to ensure that they establish sound governance and their programmes comply with the safety and quality requirements and the necessary risk management mechanisms described in this manual and the GAP Self-assessment. It is important that National Societies are aware of their responsibilities and exposure to risk that arise with undertaking blood service activities.

Acknowledgements

The members of the GAP (the blood services of the American Red Cross, Australian Red Cross, Red Cross Society of China (Hong Kong), Ethiopian Red Cross Society, Finnish Red Cross, Honduran Red Cross, Japanese Red Cross Society, Magen David Adom in Israel, Swiss Red Cross and the Thai Red Cross Society) would like to thank the IFRC's Health Department for their collaboration in the development and publication of this Manual. The International Federation's contribution of expertise in voluntary blood donor recruitment, and their support with translations and funding assistance are gratefully acknowledged.

The GAP would also like to express its thanks to both the International Society of Blood Transfusion (ISBT) and the World Health Organization (WHO) for their important work in supporting national blood programmes as well as their specific contributions to this manual. ISBT's helpful feedback on the draft document has enabled the GAP to develop a better, more useful Manual for the use of National Societies, while the GAP would like to thank WHO for allowing us to reference their excellent materials. Finally, the members would like to thank the Singapore Red Cross for their valuable assistance in bringing a blood donor recruitment perspective to appendix 3.

¹ *Aide-Mémoire: Blood Safety*. Geneva, WHO, 2002

1. Introduction

The International Federation's mission is to improve the lives of vulnerable people by mobilizing the power of humanity. The IFRC recognizes that health security is fundamental to global, national and individual development and is committed to capacity building and promoting sustainability.² Priorities in its Global Agenda are to improve local, regional and international capacity to respond to disasters and public health emergencies; scale up actions with vulnerable communities in health promotion, disease prevention and disaster risk reduction; and to significantly increase HIV/AIDS programming and advocacy.

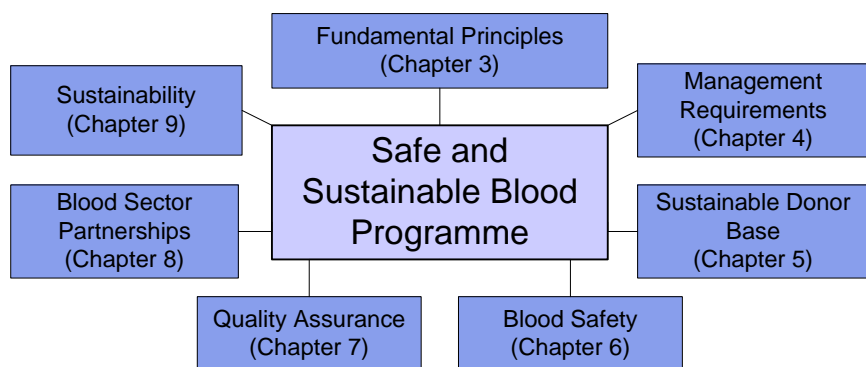
The safety and integrity of national blood supplies are fundamental to health security. Blood and blood products are vital for health care and the achievement of the United Nations' Millennium Development Goals to:

1. reduce child mortality (Goal 4)
2. improve maternal health (Goal 5)
3. combat HIV/AIDS, malaria and other diseases (Goal 6)

Recognizing that voluntary, non-remunerated blood donation (VNRBD)³ provides the foundation for safe and sustainable blood systems, the International Federation has partnered with WHO to create a global framework for action for 100 per cent voluntary blood donation⁴. Approximately 60 nations, including resource-limited countries, have now achieved a national blood supply sourced from voluntary donors. The aim of the global framework is to eliminate paid or family replacement donation and help shift the responsibility for the provision of blood from patients' relatives (in the case of family replacement donation) to the health care system.

The International Federation through the GAP supports the establishment of safe and sustainable blood systems through leadership, advocacy and guidance to National Societies and their blood programmes. This manual has been developed by the GAP with the assistance of IFRC's health department. Since its establishment in 2001, the GAP has provided advice to member societies on corporate governance and risk management. It

promotes the adoption of best practice, knowledge exchange and the mobilization of resources across blood services. The areas highlighted in this publication, as illustrated in the diagram on the right, are based on feedback from National Societies and their partners.



² Health policy adopted at the XV Session of the IFRC General Assembly, Seoul, November 2005.

³ "Voluntary, non-remunerated blood donors are persons who give blood, plasma or other blood components of their own free will and receive no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This includes time off work, other than reasonably needed for the donation and travel. Small tokens, refreshments and reimbursement of direct travel costs are compatible with voluntary, non-remunerated donation." Decision 34 of the VIII Session of the IFRC General Assembly, Budapest, 1991

⁴ For the purposes of this manual, any reference to voluntary blood donors or voluntary blood donation assumes the donation is non-remunerated, as per the description in the footnote above.

The International Federation's blood policy (appendix one) states that National Societies must implement the GAP Self-assessment and adhere to the requirements set out in this manual. National Societies operating full blood transfusion services (Level A) should find all sections of the manual relevant. For those societies involved only in promotion and advocacy of voluntary blood donation (Level C), Chapter 3 on the fundamental principles underpinning involvement in blood activities will be of particular interest. It is worth noting here that for the purposes of this manual, any reference to voluntary blood donors or voluntary blood donation assumes the donation is non-remunerated.

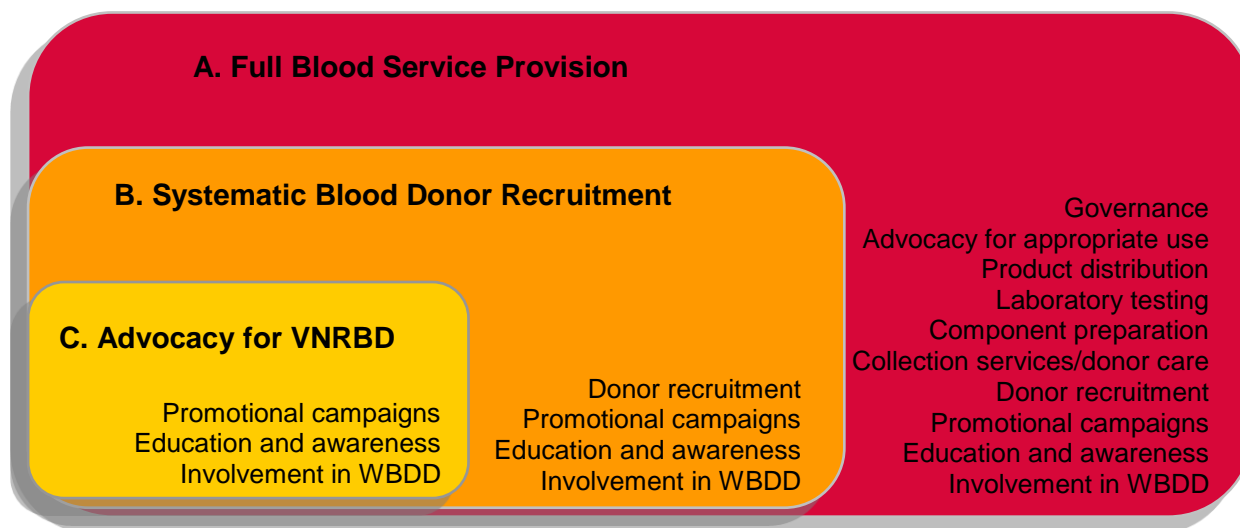
National Societies that are also involved in the systematic recruitment of voluntary blood donors should especially focus on the sections covering sustainability of the donor base (Chapter 5), tracking of donations for safety and quality assurance (Chapters 6 and 7), partnerships to support a culture of voluntary blood donation and to share best practice in donor recruitment (Chapter 8), and transition strategies (Chapter 10).

The GAP and the International Federation are mindful that member societies are at different stages of development in their blood programmes and acknowledges their efforts to date towards meeting their obligations. This manual is intended to serve as a resource to assist members in achieving a safe and sustainable blood system, maintaining the high standing and trust that the community places in Red Cross and Red Crescent societies.

2. Overview of National Society involvement in blood programmes

The extent of National Society engagement in blood programmes ranges from non-involvement through to extensive responsibility for blood collection and supply. Around a quarter of member societies have some responsibility for blood service delivery in their national blood programmes, while around 63 per cent are engaged in either systematic blood donor recruitment activities or advocacy and promotion of VNRBD.⁵

2.1 Levels of National Society engagement



The greater the level of engagement and responsibility that National Societies have in relation to blood programmes, the more extensive are their requirements, obligations and level of risk.

Most National Societies are best suited to contribute towards *predisposing* the community to donate blood, such as through education programmes and advocacy campaigns. Feedback from many governments also suggests that support for their blood services from a society and its volunteers can be of most assistance in this area. The GAP regards this level of involvement as presenting the lowest risk for any National Society.

National Societies at all levels are not encouraged to expand their existing blood programme activities unless they have received a mandate from the appropriate government authority, and have sufficient resources, capacity and expertise to do so. Should National Societies wish to move between levels, undertake more extensive involvement in donor recruitment, or significantly increase or reduce their involvement in Level A activities, it is recommended that advice be sought from the GAP at the outset. Considerations include the capacity of a National Society to undertake additional blood programme activities, the provision of sufficient government funding, access to suitable training and personnel, an appropriate governance structure and risk management expertise.

To assist National Societies in understanding the extent of their commitment and associated requirements, an overview of recommendations for each level of engagement in blood programme activities is provided on the following pages for their consideration. A list of the minimal conditions recommended for undertaking a National Society blood programme can also be found in the GAP Self-assessment under key issue one.⁶

⁵ *Global Mapping of Red Cross/Red Crescent involvement in blood programmes 2009/2010 (updated August 2011)*, GAP, 2011; p. 3. For more information contact the GAP secretariat (gapsecretariat@redcrossblood.org.au)

⁶ The latest GAP Self-assessment questionnaire is available on the IFRC's internal web site <https://fednet.ifrc.org>



Level A: Full blood service provision

National Societies involved in providing blood collection, storage and distribution services require strong governance and risk management structures. These societies can reinforce positive attitudes to blood donation through excellent service, recognition and valuing of the donor gift. Those involved at Level A must also meet the requirements set out for Level B and C.

<p>National Society blood service checklist</p>	<p>Fundamentals</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Adherence to IFRC blood policy and the minimal conditions described in the GAP Self-assessment (Level A). <input checked="" type="checkbox"/> The blood service is integrated as part of a national health policy and plan. <input checked="" type="checkbox"/> The blood service operates under a quality assurance programme and adheres to a national regulatory framework or, if necessary, an international regulatory framework. For example, the AABB's '<i>Standards for Blood Banks and Transfusion Services</i>', or the Council of Europe's '<i>Guide to the preparation, use and quality assurance of blood components</i>'. <input checked="" type="checkbox"/> The blood service is based upon voluntary, non-remunerated blood donation. <input checked="" type="checkbox"/> Roles and responsibilities between the blood service, the National Society, the government and other stakeholders are formally documented in a service agreement, and are being adhered to. <input checked="" type="checkbox"/> Government protection/indemnity and/or appropriate insurance cover have been secured for blood service activities, including clinical advice. (Please refer to the GAP Self-assessment for the types of insurance cover required). <input checked="" type="checkbox"/> The blood service has a long-term and sustainable source of revenue. <input checked="" type="checkbox"/> The blood service has sufficient facilities, supplies, equipment and trained staff and volunteers to meet operational and regulatory requirements. <input checked="" type="checkbox"/> Training programmes are in place to develop and maintain operational skills for all staff. <input checked="" type="checkbox"/> The donor is treated ethically and his or her privacy and confidentiality are assured. <p>Blood programme management</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> There is a separate corporate governance structure for the blood service, including a professional blood service board with the appropriate skills and knowledge to manage corporate governance effectively. <input checked="" type="checkbox"/> There is a well-defined system of delegation that provides clarity on authority and accountability between the: <ul style="list-style-type: none"> • National Society council and blood service board • blood service board and blood service management <input checked="" type="checkbox"/> A policy is in place to ensure there are no conflicts of interest for board members, senior staff and major suppliers. <input checked="" type="checkbox"/> The blood service is under the direction of an appropriately qualified professional who has authority over the necessary resources. <input checked="" type="checkbox"/> A separate corporate structure for the administration of the blood service has been established. <input checked="" type="checkbox"/> There is a nationwide organizational model for the blood service.
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- ☑ The blood service has a **clear vision and mission**, and a **strategic plan** that meets the needs of donors, recipients and clinicians.
- ☑ **Performance goals** and **key performance indicators** have been established to monitor progress against the strategic plan.
- ☑ **Training programmes** are in place to develop and maintain management and leadership skills.

Financial management

- ☑ The blood service has an **independent budget** with a **service level agreement** for the transfer of funds between the National Society and the blood service.

Risk management

- ☑ There is a **risk management framework** in place to identify, prioritize and manage risks relevant to the local environment. The framework should include regular completion of the **GAP Self-assessment**.
- ☑ Systems are in place to identify **emerging threats** to the safety of the blood supply relevant to the local environment.
- ☑ Mechanisms are in place for **supporting recipients of infected blood**, including record-keeping policies for potential future claims.
- ☑ If undertaking **fractionation**, the appropriate risk management measures described in the GAP Self-assessment are in place.

Donor care and counselling

- ☑ The **health and well-being** of the donor and recipient are paramount.
- ☑ The blood service maintains **donor records** and a donor register.
- ☑ National **donor selection and deferral criteria** are defined and a deferral system relevant to the local environment has been implemented.
- ☑ A **counselling** system for donors, especially those that have been deferred, is in place.

Blood Safety

- ☑ A **national screening strategy** is developed and implemented by the blood service that:
 - reflects **international good practice** and takes into account **local variables** and **national regulations**;
 - describes **minimal requirements** for pre-donation screening (including donor eligibility), laboratory testing and product management;
 - ensures **100%** of blood donations are **tested** and only those found **negative** for specified transfusion transmitted infections (TTIs) are released; and
 - includes a **system** to manage the **disposal of 'at risk' product** in accordance with national regulations for bio-hazardous waste

Quality assurance

- ☑ The blood service adheres to a **national regulatory framework**, or there is national acknowledgement that an **international regulatory framework** (such as AABB, Council of Europe) should be applied.
- ☑ The blood service adheres to **quality assurance standards** and **good manufacturing practice (GMP)** to ensure the quality and safety of blood and blood components in accordance with WHO and international or local regulatory requirements.

	<ul style="list-style-type: none"> <input checked="" type="checkbox"/> Systems of quality assurance, monitoring, evaluation and accountability are in place for all aspects of blood service provision, including collection, preparation, testing, storage and distribution. <input checked="" type="checkbox"/> Staff are continually trained in all aspects of quality assurance. <p>Stakeholder partnerships</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> The blood service participates with government in the development of national regulatory standards. <input checked="" type="checkbox"/> A system is in place for performing a cost-benefit analysis, with government, on all safety-enhancement proposals. <input checked="" type="checkbox"/> The government is educated on the importance of adequately funding blood safety. <input checked="" type="checkbox"/> A national system is established to report Haemovigilance/serious adverse events to the National Society blood programme where a donor might be implicated. If there is no national system, hospital-based reporting should be encouraged. <input checked="" type="checkbox"/> There are systems in place to educate the public on the safety of the blood supply and the risks of blood transfusion. <input checked="" type="checkbox"/> Clinicians are educated on the appropriate use of blood and blood components, the risks of blood transfusion and relevant aspects of Patient Blood Management <input checked="" type="checkbox"/> Hospitals are encouraged to develop a system that monitors and works towards reducing wastage and advocates appropriate blood product use. <input checked="" type="checkbox"/> The blood service has formal agreements with end users (e.g., hospitals) on inventory holdings, ordering and supply systems. <input checked="" type="checkbox"/> Hospitals are encouraged to set up multidisciplinary transfusion committees. <input checked="" type="checkbox"/> The blood service has developed a ‘supply plan’ with stakeholders (including end users) to ensure that recruitment and collection activities produce sufficient blood and blood components to meet the needs of the health system. <p>Sustainability</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> A clear disaster preparedness and contingency plan is in place. <input checked="" type="checkbox"/> The blood service has an appropriate environmental and hazardous waste management policy.
Level of Risk	High (refer to Chapter 4, Appendix 2, and the GAP Self-assessment Level A).
Key Resources for Level A blood programmes⁷	<ul style="list-style-type: none"> • <i>Promoting Safe and Sustainable Blood Systems Policy</i> (draft). Geneva, IFRC, 2011 (see Appendix 1). • GAP Self-assessment Level A. GAP, current version. • WHA 63.12, <i>Availability, safety and quality of blood products</i>. Sixty-Third World Health Assembly, Geneva, 21 May 2010, Geneva, WHO 2010 (also WHA 28.72 and WHA 63.12). • <i>Aide-Mémoire: Blood Safety</i>. Geneva, WHO, 2002 (attached as Appendix 5)

⁷ GAP recommends that National Societies and their blood services keep a copy of all key resources with the GAP manual for easy reference

- *Aide-Mémoire: The Clinical Use of Blood*. Geneva, WHO, 2003 (attached as Appendix 6)
- *Aide-Mémoire: Developing a National Blood System*, Geneva, WHO, 2011
- *Aide-Mémoire: Good Policy Process for Blood Safety and Availability*. Geneva, WHO, 2008
- *Aide-Mémoire: Quality Systems for Blood Safety*. Geneva, WHO, 2002 (attached as Appendix 7)
- *Aide-Mémoire, Safe Blood Components*. Geneva, WHO, 2005 (attached as Appendix 8)
- *Aide-Mémoire: Safe health-care waste management*. Geneva, WHO, September 2000
- *Blood Cold Chain: Selection and Procurement of Equipment and Accessories*. Geneva, WHO, 2002.
- *Costing Blood Transfusion Services*. Geneva, WHO, 1998.
- *Manual on the Management, Maintenance and Use of Blood Cold Chain Equipment*. Geneva, WHO, 2005
- *Screening Donated Blood for Transfusion-Transmissible Infections*. Geneva, WHO, 2009
- *Safe management of wastes from healthcare activities*. Geneva, WHO, 1999
- *Code of Ethics for Blood Donation and Transfusion*. International Society of Blood Transfusion (ISBT), General Assembly, 12 July 2000; amended by the ISBT General Assembly, 5 September 2006 (attached as Appendix 4).
- *Australian Code of Good Manufacturing Practice for Human Blood and Tissues*. Canberra, Therapeutic Goods Administration, 2000
- *Guide to the Preparation, Use and Quality Assurance of Blood Components*. European Directorate for the Quality of Medicine (EDQM), Council of Europe, current edition.
- *Standards for Blood Banks and Transfusion Services*. AABB, current edition
- *Making a difference...Recruiting voluntary, non-remunerated blood donors*. Toolkit, Geneva, IFRC, 2008
- *Towards 100 per cent voluntary blood donation: A global framework for action*. Geneva, WHO/IFRC, 2010

Please note: References relevant to the content in each manual chapter are listed under the Resources heading found at the end of most sections.



Level B: Systematic recruitment of voluntary blood donors

Some National Societies support their domestic blood programme and blood services by recruiting blood donors and providing access to blood donation centres. These societies act in partnership with a blood service, actively promote non-remunerated donation, and motivate donors through information and recruitment campaigns. National Societies at Level B need to enter into a dialogue with the blood services to which they recruit donors to ensure that the blood service has the appropriate standards in donor care and quality assurance.

<p>National Society VNRBD Recruitment programme checklist</p>	<p>Fundamentals</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Adherence to the IFRC's blood policy and the minimal conditions described in the GAP Self-assessment (Level B). <input checked="" type="checkbox"/> Ensuring that the blood service the National Society recruits blood donors to meets local regulatory requirements and/or WHO and international standards recommended for national blood programmes (see Level A information on pages 8-11). <input checked="" type="checkbox"/> The blood donor recruitment programme is based on VNRBD. <input checked="" type="checkbox"/> Roles and responsibilities between the National Society and government have been clarified and there is a documented service agreement for VNRBD recruitment activities. <input checked="" type="checkbox"/> A long-term and sustainable source of revenue for the donor recruitment programme has been secured. <input checked="" type="checkbox"/> The donor recruitment programme is evaluated regularly to assess whether a) it is meeting demands or b) it is grossly exceeding requirements. <input checked="" type="checkbox"/> The donor is treated ethically and his or her privacy and confidentiality are assured. <input checked="" type="checkbox"/> The IFRC toolkit <i>Making a difference...Recruiting VNRBD</i> is used. <p>Blood donor recruitment programme management</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> There is a clear vision, mission and strategic plan for the donor recruitment programme. <input checked="" type="checkbox"/> Performance goals and key performance indicators have been established to monitor progress against the strategic plan. <input checked="" type="checkbox"/> The programme is under the direction of a professional director with authority over the necessary resources, who is part of the National Society's senior management team. <input checked="" type="checkbox"/> The director organizes, manages, trains, monitors and evaluates the staff, volunteers and procedures involved in blood donor recruitment and retention. <input checked="" type="checkbox"/> Staff are continually trained in all aspects of blood donor recruitment and retention. <p>Donor care and counselling</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> A donor register and records are maintained. <input checked="" type="checkbox"/> The National Society's donor recruitment and deferral practices reflect national donor selection and deferral criteria. <input checked="" type="checkbox"/> Counselling for donors, especially those that have been deferred, is provided by
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	<p>the National Society or blood service, as appropriate.</p> <ul style="list-style-type: none"> ☑ Good customer service and donor care is the responsibility of all staff members. ☑ Staff performance is subject to monitoring and evaluation. <p>Promotion</p> <ul style="list-style-type: none"> ☑ A community education programme develops positive attitudes to VNRBD. ☑ Donor populations at low risk of transfusion-transmitted infections (TTIs) are targeted. ☑ The worth of blood donations and blood donors is recognized. ☑ The National Society works with clinicians (through education, awareness, etc.) to promote VNRBD. <p>Sustainability</p> <ul style="list-style-type: none"> ☑ There is a risk management framework in place to identify, prioritize and manage risks relevant to the local environment. ☑ A clear disaster preparedness and contingency plan is in place.
Level of Risk	Medium (refer to Chapter 4, Appendix 2, and the GAP Self-assessment Level B).
Key Resources	<ul style="list-style-type: none"> • <i>Promoting Safe and Sustainable Blood Systems Policy</i> (draft). Geneva, IFRC, 2011 (see Appendix 1). • GAP Self-assessment Level B. GAP, current version. • <i>Towards 100 per cent voluntary blood donation: A global framework for action</i>. Geneva, WHO and IFRC, 2010. • <i>Making a difference...Recruiting voluntary, non-remunerated blood donors</i>. Toolkit, Geneva, IFRC, 2008. • <i>Developing a Voluntary Blood Donor Programme for Blood Safety (DONOR)</i>. Geneva, WHO and IFRC. • <i>Aide-Mémoire: Blood Safety</i>. Geneva, WHO, 2002. • <i>Aide-Mémoire: Safe Blood Components</i>. Geneva, WHO, 2005. • <i>New blood for the world</i>, DVD and leaflet. Geneva, IFRC, 2009. • Proceedings of the international colloquia on the recruitment of VNRBD. • <i>Making the most of World Blood Donor Day</i>. WHO/IFRC/FIODS/ISBT, www.wbdd.org <p>Please note: References relevant to the content in each manual chapter are listed under the Resources heading found at the end of most sections.</p>



Level C: Motivation and advocacy for voluntary, non-remunerated blood donation

Many National Societies report they play a significant role in promoting VNRBD for blood programmes in their countries and in generating positive attitudes to blood donation through volunteer networks, education programmes and advocacy campaigns. These activities predispose a population to donate blood. All National Societies are encouraged to be involved at this level, if practicable and appropriate.

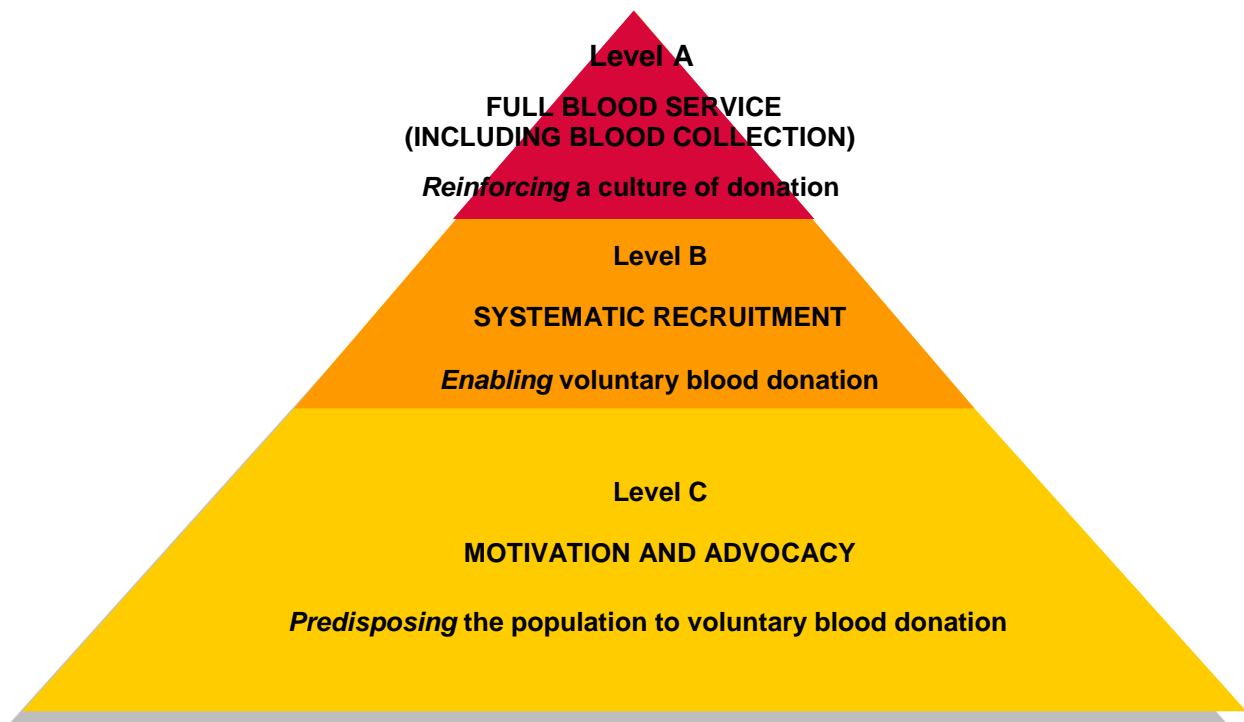
National Society Expectations	<p>Bring to public attention the role of voluntary blood donors in meeting the needs of the most vulnerable.</p> <p>Undertake occasional, broad-based community education and awareness programmes.</p> <p>Participate in World Blood Donor Day events (14 June).</p>
Level of Risk	Low.
Basic Checklist	<p>National Societies involved in the occasional promotion and advocacy of blood donation should:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> have a general agreement with national and local government authorities to use World Blood Donor Day, 14 June, as an opportunity to pay tribute to voluntary blood donors <input checked="" type="checkbox"/> remind its own membership about the need for securing a safe blood supply through voluntary and unpaid blood donation <input checked="" type="checkbox"/> have clarified its roles and responsibilities and those of other stakeholders in setting up viable Club 25 Programmes, whereby youth assist by giving blood on a regular basis and also help with peer education in health promotion <input checked="" type="checkbox"/> explore with the government ways to phase out family replacement donation and move towards 100 per cent voluntary blood donation
Key Resources	<ul style="list-style-type: none"> • <i>Promoting Safe and Sustainable Blood Systems Policy</i>. Geneva, IFRC, draft. (see Appendix 1). • GAP Self-assessment Level C. GAP, current version. • <i>Making a difference...Recruiting voluntary, non-remunerated blood donors</i>. Toolkit, Geneva, IFRC, 2008. • <i>Towards 100 per cent voluntary blood donation: A global framework for action</i>. Geneva, WHO and IFRC, 2010. • <i>Developing a Voluntary Blood Donor Programme for Blood Safety (DONOR)</i>. Geneva, WHO and IFRC, 2010. • <i>New blood for the world</i>, DVD and leaflet. Geneva, IFRC, 2009. • <i>Making the most of World Blood Donor Day</i>. WHO/IFRC/FIODS/ISBT. Available from www.wbdd.org <p>Please note: References relevant to the content in each manual chapter are listed under the <i>Resources</i> heading found at the end of most sections.</p>

2.2 Promoting a safe and sustainable blood system

All National Societies, irrespective of whether they are directly or indirectly involved in the administration of their national blood programmes, can contribute towards the development of a safe and sustainable national blood system. Advocacy and promotion of VNRBD builds the foundations of global blood safety, which ultimately saves lives.

National Societies with no formal involvement in blood programmes (Level C) can support the process of changing attitudes and beliefs towards blood donation in their countries through advocacy, education campaigns and participating in blood donor recognition events, notably World Blood Donor Day on 14 June each year. Also, community health programmes supported by the International Federation and its member societies, such as strategies to prevent AIDS or hepatitis and to control diseases such as measles or cholera, promote healthy lifestyles in local communities and provide the basis for a low-risk blood donor population.

Societies involved in blood donor recruitment activities (Level B) can further build participation in voluntary blood donation through campaigns and providing access to donation centres. Those extensively involved in blood services (Level A) can promote a culture of donation by valuing and recognizing the commitment of donors, and can encourage regular donation by providing effective, accessible services to donors.



3. Fundamental Principles

The International Federation expects that National Societies engaging in blood programmes adhere to and promote the Fundamental Principles of humanity, impartiality, neutrality, independence, voluntary service, unity and universality. National Societies are also expected to demonstrate and uphold IFRC core values when engaging with blood service partners and the community. These are:

- the protection of life, health and human dignity
- respect for the human being
- non-discrimination on the basis of nationality, race, gender, religious beliefs, class or political opinions
- mutual understanding, friendship, cooperation and lasting peace among people
- service by volunteers

These principles and values are reflected in the following commitments that underpin safe, equitable and sustainable national blood programmes. National Societies should also comply with the International Society of Blood Transfusion (ISBT) *Code of Ethics for Blood Donation and Transfusion* (2006), which has been adopted by WHO and is included in this manual as appendix four. The Code is available in different languages on the ISBT web site (www.isbtweb.org).

3.1 Promoting voluntary, non-remunerated blood donation (VNRBD)

VNRBD has been viewed as critical to the international health effort since the 1975 World Health Assembly (WHA) resolution⁸ called for member states to “promote the development of national blood services based on voluntary, non-remunerated donation of blood”, a principle reasserted by the WHA in 2005.⁹ Voluntary, non-remunerated blood donors, particularly those who donate blood regularly, provide the foundation for a safe, sustainable blood supply that can meet the needs of all patients requiring blood transfusion. The International Red Cross and Red Crescent Movement has been a strong advocate for VNRBD and continues to work towards this objective internationally.

A number of studies have shown that blood derived from altruistic, voluntary donors is safer than that sourced from paid donors or family replacement donors, with the lowest rates of transfusion-transmissible infection among regular donors.¹⁰ The recognition of donor contribution to the well-being of others, rather than payment, supports the integrity of the blood system and maintains human dignity. Sourcing blood from voluntary blood donation will help eliminate paid and family replacement donation and support universal and equitable access to safer blood transfusion.

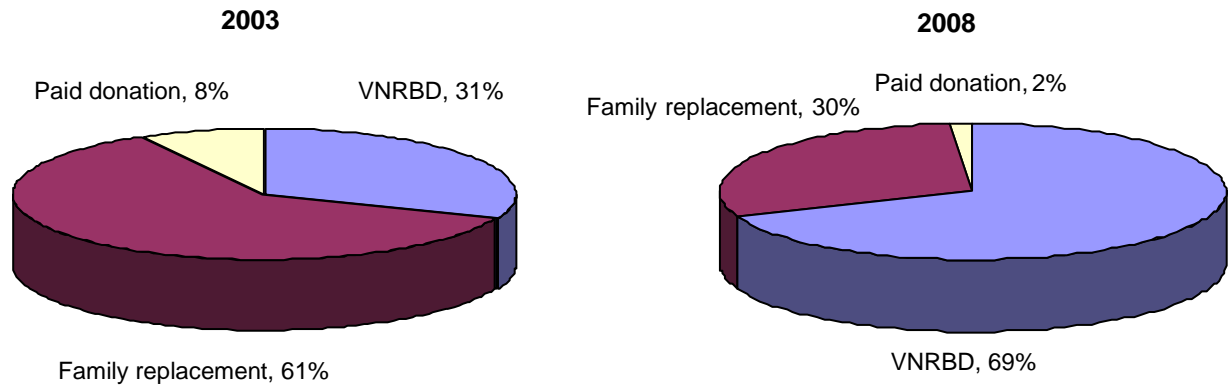
A safe and sustainable blood supply is underpinned by programmes aimed at recruiting and retaining voluntary blood donors from low-risk populations. Many countries have achieved the transition from paid and family replacement donation to VNRBD and, as illustrated overleaf, many others have made significant progress towards this objective.

⁸ WHA 28.72, *Utilization and supply of human blood and blood products*. Twenty-Eighth World Health Assembly, 13-30 May 1975. Geneva, WHO, 1975

⁹ WHA 58.13, *Blood safety: proposal to establish World Blood Donor Day*. Fifty-Eighth World Health Assembly, Geneva, WHO, 2005

¹⁰ *Towards 100 per cent voluntary blood donation: A global framework for action*. Geneva, WHO/IFRC, 2010, p. 18.

Developing (Low HDI) Countries' Progression towards VNRBD



Source: World Health Organization Global Data Base, 2009

3.2 Ensuring safety for donors and recipients

Those National Societies involved in blood donor recruitment, collection or service delivery are entrusted by their community and government to act as good stewards of the blood supply and to safeguard its integrity. This requires mechanisms for oversight of blood management and processes that ensure high standards of safety and quality, as will be outlined in subsequent chapters.

National Societies have a responsibility to maintain the well-being of both donors and the recipients of blood products. To meet this obligation, recruitment should focus on attracting low-risk donors, with effective donor screening and deferral processes. Donor welfare should be supported through arrangements for donor health and counselling. The quality and safety of blood and blood components is further ensured by laboratory testing of donated blood, systems to trace and recall potentially contaminated blood components; standards for inventory storage, handling and distribution; and guidelines and training for appropriate clinical use.

3.3 Promoting equity of access to blood and blood products

Blood transfusion is a life-saving function that should be available in a first-referral level of a health care facility providing comprehensive emergency obstetric and newborn care.¹¹ Access to safe blood for all patients reduces morbidity and mortality, supporting the International Federation's global agenda goals and the Millennium Development Goals. The timely availability of safe blood and blood products is essential for blood transfusion in emergency situations, such as from road accidents or haemorrhage during childbirth. Haemorrhage accounts for over 25 per cent of the 530,000 maternal deaths each year. Almost all of these are in the developing world. Access to safe blood could help prevent up to a quarter of maternal deaths.¹² A large proportion of traffic accident victims need blood transfusion during the first 24 hours of treatment. Road accidents are projected to become the third largest contributor to the global burden of disease.¹³ Children under the age of five suffering from life-threatening anaemia, often as a result of malaria or malnutrition, also require transfusion support.¹⁴

¹¹ *Towards 100 per cent voluntary blood donation: A global framework for action*. Geneva, WHO/IFRC, 2010, p. 9.

¹² *Ibid*

¹³ *Ibid*

¹⁴ *Towards 100 per cent voluntary blood donation: A global framework for action*. Geneva, WHO/IFRC, 2010, p. 9.

It is important that all patients have access to life-saving blood on the basis of their clinical need. In systems supported by an established voluntary donor base, patients generally have improved access to safe blood transfusion in both routine and emergency situations. Hospitals, patients and patient families should not be placed under pressure to find blood donors. Family replacement donors do not provide for the community's blood supply needs and hospitals dependent on such donors usually have insufficient inventory to administer transfusions when needed.

It is more appropriate that the community takes ownership for the blood system through voluntary, non-directed donations. With altruistic blood donation, patients experience a sense of being cared for by others in the community, which can generate a reciprocal spirit of generosity and engagement. A VNRBD system supports equity of access by providing a regular, reliable supply of safe blood.

3.4 *Serving the community and patient interest*

A strong commitment to humanity is the basis of National Society involvement in blood programme activities. Engagement in blood services and promotion of safe blood donation provides tangible and occasionally life-saving benefits to members of the community.

Humanitarian values also motivate individuals to generously and unconditionally donate their blood. This humanitarian spirit is core to the International Federation's work and is reflected by the many volunteers who give freely of their time. Societies have an obligation to respect this commitment by recognizing and valuing the gift of blood donation. For those societies directly involved in blood programme delivery, serving the patient and community interest also requires maintaining the integrity of donated blood by ensuring its quality and safety, and striving to make best use of scarce blood to achieve the best outcomes for patients.

Chapter resources

A Code of Ethics for Blood Donation and Transfusion. International Society of Blood Transfusion (ISBT), 2000, amended 2006.

4. Blood programme management

4.1 Organizational models

Blood programmes can be national, regional or hospital-based. National Societies can range from being the sole provider of the national blood programme to undertaking large or small-scale blood collection at a regional or district level, or providing support to the national blood service through the recruitment of donors or the promotion of VNRBD. Regardless of the structure of blood service delivery arrangements, the IFRC and GAP support WHO recommendations that blood service provision be guided by national regulations and a national blood policy to promote consistency in practice, accessibility and equity of access.¹⁵

WHO recommends that a national blood system should be organized and coordinated to ensure the most efficient and cost effective use of all resources¹⁶. A centralized structure supports a safe and sustainable blood supply by improving safety and quality, ensuring a consistent, regular blood supply which is less dependent on local contingencies, and providing flexibility when responding to emergency situations. Centralization of blood processing and testing provides for increased cost-efficiency and uniformity of standards.

Blood transfusion services should be coordinated at national regional and provincial levels, with critical activities such as blood screening and processing consolidated in strategic locations¹⁷. The GAP recommends that, where possible, National Society blood programmes should function under a nationwide operational model¹⁸ in which district and regional services form part of a central blood service managed by a national blood service director. The director should be responsible for ensuring the blood service adheres to national standards in quality assurance and good manufacturing practice (GMP) and for setting internal organizational policies and procedures in line with national regulations.

Whatever model is used, it is important that the blood service has a clear organizational structure, and that the roles and responsibilities at national, regional and district level (if applicable) are clear, and accountabilities between the different levels, if any, are clearly defined. Individual Blood Transfusion Services (BTS) should be structured, staffed and managed in accordance with national regulations with suitable medical, technical and quality processes for the provision of safe blood and blood components to patients. BTSs should be accessible and sustainable with:

- suitable premises that comply with GMP
- sufficient numbers of appropriately trained staff
- specialized equipment for blood collection, processing, testing, storage and transportation and a preventative maintenance system
- a reliable supply of blood collection bags and reagents¹⁹

The GAP can facilitate collaboration with partners such as WHO and government health agencies and provide guidance to National Societies on which organizational structure may be most appropriate. This would be informed by a situation analysis that looked at the local context, availability of resources, and so on.

¹⁵ *Aide-Mémoire: Safe Blood Components*. Geneva, WHO, 2005

¹⁶ *Aide-Mémoire: Developing a National Blood System*. Geneva, WHO, 2011

¹⁷ *Ibid*

¹⁸ *Key Issue two: GAP Self-assessment Level A*. GAP, current version.

¹⁹ *Aide-Mémoire: Safe Blood Components*. Geneva, WHO, 2005

Resources

- *Aide-Mémoire: Safe Blood Components*, Geneva, WHO, 2005
- *Aide-Mémoire: Developing a National Blood System*, Geneva, WHO, 2011
- *GAP Self-assessment Level A*. GAP, current version

4.2 Governance

National Societies are expected to apply principles of good corporate governance in respect of their blood programmes. Blood programme management is complex and requires specialist medical, technical, and financial expertise. The GAP recommends that National Societies delivering blood programmes establish a separate, professional board that comprises members with blood sector, clinical and business management experience. The separate board should have delegated responsibility to govern the blood programme, including the appointment of the director of the blood programme and authority over dedicated blood programme resources. There should be clearly defined roles and accountability between the blood service director and the blood service board.

The chairman of the blood service board and the majority of its members should be independent of the blood service management team. The board's role includes to:

- ensure the blood service has an effective system of corporate governance and that the board also operates in accord with corporate governance standards
- establish the strategic direction and ensure sufficient resources are available for the blood service to achieve its strategic objectives
- monitor performance and approve budgets, new business proposals and major items of capital expenditure
- oversee operations and ensure effective management
- ensure major policies are established with appropriate support systems
- ensure procedures for risk management, internal control and compliance are adhered to
- appoint and monitor the performance of the director of the blood programme and develop succession planning
- ensure that the blood service has appropriate interaction with external stakeholders²⁰

The functions of a blood service board can be supported by the establishment of more specialized oversight committees, such as finance, audit and risk, and clinical governance committees. Each committee should comprise the relevant managers responsible for that function of the blood service and board members with appropriate experience and technical expertise.²¹

While a separate board can provide National Societies with additional expertise with which to manage blood service risks, National Societies may still be exposed to financial and reputational risks. It is important that there are clearly defined lines of authority and accountability between the National Society's blood service board and the society's governing council. A National Society might also consider establishing an advisory committee to provide independent advice to the blood service board on medical, scientific and research matters and to provide assurance to the governing council that high standards are being maintained.

Resources

GAP Self-assessment Level A. GAP, current version.

²⁰ Informed by the official description for an Australian Red Cross blood service board member, November 2008

²¹ Informed by the Australian Red Cross blood service's terms of reference for their advisory committees, 2008-2009.

4.3 Corporate management

The GAP recommends that a National Society blood service has a separate corporate structure for the administration of the blood programme, with an independent budget. The roles and responsibilities of the National Society and the blood service should be discussed and clarified, and then documented and respected. A service level agreement should be in place for the transfer of funds between the National Society and blood service, and measures established so the National Society does not have access to financial contributions (unless prior approval from donors has been given) and personal information from blood donors.

A blood service director should be appointed who is well qualified to manage the blood service and accountable to the National Society, the board and the wider community. The blood service director should be accountable nationally for ensuring that all blood service operations are carried out properly and competently, as required by the relevant health acts, regulations and standards. He or she could be supported by a management committee comprising the managers of the various departments including clinical, donor recruitment, quality, finance, risk and audit, etc.

Staff roles and responsibilities should be clearly defined in job descriptions and there should be sufficient staff to meet regulatory requirements and support the organization and its activities. Blood service staff should have the appropriate experience and training for their positions.²²

A clear vision and mission should be in place for the blood service or blood donor recruitment programme and stakeholders should be consulted in the development of a strategic plan. Performance goals and key performance indicators need to be established to measure progress against the strategic plan, which should be reviewed regularly to ensure that it remains relevant.

Resources:

GAP Self-assessment Levels A and B. GAP, current versions.

4.4 Financial management

National Societies involved in blood programmes at any level should develop and implement a financial management system. It should be appropriately costed, effectively managed, supported by government and ensure the ongoing financial sustainability of their blood programme. WHO in its Aide-Mémoire on Blood Safety notes that the responsibility for adequately funding the blood service to ensure a safe and adequate supply of blood rests with the government.²³ It is critical that there should be transparent financial arrangements, including a service level agreement for the transfer of funds, between the National Society and blood service so the government or other funding body is assured that the funds are being used for relevant blood programme activities.

The WHO and IFRC Global Framework²⁴ provides National Societies operating Level B or C blood programmes (recruitment and motivation only) with information and action points to secure sustainable financing for their blood programmes. National Societies operating at Level A may also use this resource to help in budgeting for their donor recruitment activities.

One of the key challenges for National Society blood services is advocacy to funders around the cost of

²² *Aide-Mémoire: Blood Safety*. Geneva, WHO, 2002

²³ *Ibid.*

²⁴ *Towards 100 per cent voluntary blood donation: A global framework for action*. Geneva, WHO/IFRC, 2010, pp. 40-41.

blood. The time and resources that inform the final cost of blood are often not known or misunderstood by funders, and therefore they can be unwilling to support fully the seemingly high cost of blood. Therefore, it is very important that National Societies actively engage and advocate with funders on the issue of sustainable blood service funding.

National Societies may seek sustainable financing for their blood services either through cost recovery or annual budget allocation. Whatever the method of financing, in order to be sustainable the level of funding must cover capital and recurrent costs²⁵ and the financial model must allow for potential future increases in the cost of blood service delivery (for example, the introduction of new tests, staff increases, building renovations, inflation, devaluation, etc.). The WHO Blood Costing Model is an example of a tool that can be used by National Societies with full blood programmes for costing their blood services.²⁶

National Societies should seek to develop and implement a funding agreement with their government (or other funder) which outlines the financing arrangements for their blood service, including reporting requirements, and which allows for regular renegotiation of future funding levels should the blood service cost increase.

It is recommended that there should be a dedicated resource person (chief financial officer) for blood service financial management who is accountable to the blood programme director. Blood services may also wish to establish a finance and audit committee, which may comprise the chief financial officer and suitably qualified members of the blood service board and also provides for oversight of financial practice. National Societies should aim to conduct regular audits (either annually or in line with government requirements) to demonstrate transparency to funders and as an opportunity to review financial practices to identify areas for improvement.

Minimum checklist for financial management of blood services:

- Advocate to potential funders (e.g., government) on the resources required for blood transfusion services, and the associated costs.
- Develop a realistic costing of blood service activities – the WHO model is recommended.
- Negotiate an agreement with government for the ongoing provision of blood service financing (cost recovery or budget allocation).
- Establish a service level agreement for the transfer of funds between the National Society and the blood service, including overhead costs if applicable.
- Implement an appropriate financial management model, with a focus on transparency and sustainability, in line with any government requirements.
- Implement regular (at least annually, or as required by government) financial reporting to the funder and other appropriate authorities (e.g., the National Society and the blood service board).
- Appoint a dedicated financial manager, responsible to the blood service director.
- Undertake annual budgeting, including a review of blood service costs – capital and recurrent.
- Undertake an annual audit of the financial management systems, including expenditure.

Resources

Costing Blood Transfusion Services. Geneva, WHO, 1998

²⁵ Capital costs are those incurred during start-up, expansion or improvement phases of a blood programme, such as for buildings, vehicles, equipment, furniture, and also training costs. Recurrent costs include staff remuneration, heating and lighting, insurance, travel, consumables and administration.

²⁶ *Costing Blood Transfusion Services*. Geneva, WHO, 1998

4.5 Risk management

There are inherent risks in collecting and supplying blood and blood components. Blood services need to ensure the health of donors, to manage the risk of transfusion-transmitted infection and other transfusion-related complications, to ensure blood and blood components are stored and handled appropriately, and that they are delivered in time and to order. Communities also expect National Societies to operate with professional integrity and to maintain high ethical standards. Appropriately managing risks involved in the delivery of blood programmes results in improved consequences for donors or recipients, and has a positive impact on the reputation and financial stability of a National Society.

A brief list of the main risks facing National Societies involved in blood services (Level A) and VNRBD recruitment (Level B) can be found in Appendix 2, while a more exhaustive checklist can be found in the GAP Self-assessments. It should be recognized, however, that while compliance with the standards described in the GAP Self-assessment and this manual will significantly reduce National Societies' exposure to risk, securing government indemnity and/or adequate insurance cover is essential in the eventuality of compensation or other legal claims arising from blood service delivery.

GAP recommends that National Societies consult with local legal experts to clarify the risk management benefits of securing government assurance for its blood programme activities, particularly against blood borne disease liabilities, or acquiring appropriate insurance cover as a last resort. Any recommendations made as a result of those consultations should be implemented by the National Society as a matter of priority.

It is important that National Societies establish systems for the identification, prioritization and management of risks that are relevant to the local context. ISO 31000 provides generic principles and guidelines for risk management. These recommend a risk management framework that integrates risk management into the culture of the organization, including governance, planning, decision-making and reporting. A risk management framework promotes understanding of the context in which the organization operates, sets out a risk management policy and processes to address and manage risk, and assign responsibilities and accountability. There should be consultation with management, staff and external stakeholders when identifying actual and potential risks. These risks can then be assessed and plans developed to manage them. Risk management processes and decisions should be well documented. As with other quality assurance processes, a National Society's approach to risk management needs to be monitored and reviewed for continuous improvement.

To illustrate, a risk framework might begin with workshops attended by board members and senior management to determine the blood service's risk tolerance and its key strategic risks.²⁷ A risk matrix can then be developed to categorize risks, and criteria agreed for which type of risk would need to be escalated for the attention of senior management and the board. Strategic risks are passed on to the appropriate operational areas, which are responsible for ensuring actions are in place to manage each risk. The risks are then prioritized and recorded on an organizational risk register, which is monitored according to agreed risk and control indicators. High-risk actions would be included in business planning processes and progress against actions regularly monitored.

The GAP provides information and advice to National Societies on appropriate risk management structures and processes. The GAP Self-assessment questionnaire includes a checklist to guide National Societies in understanding their exposure to potential risks and to signal areas requiring attention. It enables National Societies to ascertain:

²⁷ This example is informed by the Australian Red Cross Blood Service's risk management framework.

- their own performance against international benchmarks
- where they are performing well and where improvements can be made
- whether it is appropriate they continue their involvement in blood service activities (see Chapter 10)

National Societies' engagement should in general be aimed for long-term provision and support. Any considerations to reduce the National Societies' level of involvement in blood activities should clearly follow the recommendations detailed in Chapter 10 (transition and exit strategies). GAP Self-assessments are available for National Societies involved at all levels of blood programme activity. Participating Level A blood services receive an individual feedback report from the GAP that analyses their Self-assessment results and provides them with specific risk management recommendations. Depending upon the number of Self-assessments received by the GAP, blood services may receive an additional report comparing their Self-assessment results with those of other Level A blood services in their region. Level B National Societies may complete the Self-assessment and receive a feedback report upon request, according to the GAP's capacity.

It should be noted that only the National Society that completed the Self-assessment is identified in its individual report - the anonymity of other participating National Societies is maintained to encourage accurate self-reporting.

The GAP endeavours to respond to the many requests for corporate governance and risk management assistance received from National Society blood services. However, specific technical support can only be offered to two or three societies a year. Those seeking assistance should first contact the GAP secretariat to discuss what assistance is required before submitting a written request from their secretary general to the GAP chair.

Resources

- *GAP Self-assessment, Level A, B and C*. GAP, current version
- *International Standard ISO 31000 Risk Management — Principles and Guidelines*. International Organization for Standardisation (ISO), 2009. Available from the ISO web site, www.iso.org
- *Aide-Mémoire: Good Policy Process for Blood Safety and Availability*. Geneva, WHO, 2008

4.6 Balanced decision-making

There is a public expectation that blood services not only respond to established risks to blood safety but also anticipate potential or emerging risks and act accordingly. Under the precautionary principle, where there is reason to believe that a potential threat to public health may occur, preventative action should be undertaken and not delayed until definitive evidence is available.

Balanced decision-making encompasses both evidence-based and precautionary approaches to guide investment and safety decisions. This is supported by engagement with blood sector decision-makers, regulators and the community to ascertain blood-related risks and inform decisions on investment towards safety, taking into account all relevant scientific, financial and social considerations and ensuring that a balance is maintained between safety and cost. Increased blood safety should be weighed up against any potential costs, for example a decrease in the availability of blood or blood products.

Resources

- *GAP Self-assessments Level A, B and C*. GAP, current versions
- *Aide-Mémoire: Good Policy Process for Blood Safety and Availability*. Geneva, WHO, 2008

5. Building a sustainable donor base

The capacity of a blood programme to provide sufficient blood and blood products is ultimately determined by the availability and commitment of healthy, regular VNRBD donors and the appropriate use of blood and blood products by the clinical community. In building a sustainable donor base, blood services need to establish a positive, long-term relationship with donors that recognizes their commitment, promotes good donor health, fosters repeat donation and encourages referrals of colleagues, family and friends.

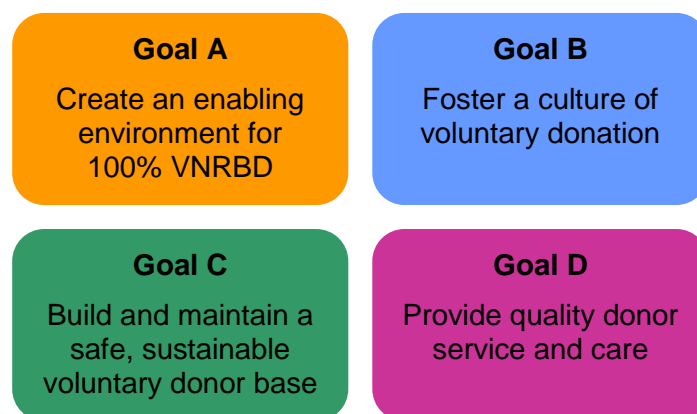
5.1 *Voluntary, non-remunerated blood collection*

Voluntary, non-remunerated donors who regularly give blood are the foundation of a safe and adequate blood supply. Blood collection with well-selected voluntary donors from low-risk populations provides the first line of defense in minimizing the risk of transfusion-transmitted infection.²⁸

The International Federation shares the belief of WHO that it is morally unacceptable for health care to be based on the purchase of body parts, including blood. Blood services have an obligation to safeguard the health of donors and no coercion should be brought to bear upon an individual to donate.²⁹ People who give blood for monetary reward or in response to pressure from others may conceal information that would otherwise cause them to be deferred, either temporarily or permanently. For people in these circumstances, donation may not only be potentially harmful to a recipient, it may also have negative health consequences for the donors themselves.

A system of voluntary, non-remunerated blood donation can reduce the risk of patient exposure to contaminated blood and blood products. Non-paid blood donors invariably have a lower prevalence of transfusion-transmissible infection than paid donors because they have no reason to withhold any information about their health status that may make them unacceptable as donors.

The International Federation is working in partnership with WHO to promote a global framework for action in achieving VNRBD blood programmes internationally.³⁰ The global framework outlines strategies for progressing towards this goal in each of the areas illustrated in the figure below.



²⁸ *Screening Donated Blood for Transfusion-Transmissible Infections*. Geneva. WHO, 2009, p. 6.

²⁹ *Towards 100 per cent voluntary blood donation: A global framework for action*. Geneva, WHO/IFRC, 2010, p. 14.

³⁰ *Ibid.*

5.2 Attracting and retaining donors

To provide for even the most basic blood supply requirements a country needs at least 1 per cent of the population to donate, with requirements in most countries far exceeding this.³¹ WHO asserts that regular donation by suitable donors requires effective donor recruitment, call-up and retention strategies. This is supported by national donor selection and deferral criteria that factor in the maintenance of donor health, and blood collection targets informed by clinical demand.³²

Blood services are encouraged to appoint an officer responsible for the national blood donor programme to lead a group trained in relevant aspects of donor education, motivation, recruitment and retention. A register of VNBRD donors should be established and efforts made to identify and attract donor populations with low risk of transfusion-transmitted infection. It is also appropriate to monitor transfusion-transmitted infection in the donor population.³³

The IFRC toolkit *Making a difference...Recruiting voluntary, non-remunerated blood donors* presents practical international examples to inform all aspects of blood donor recruitment. The toolkit covers planning and implementation of education and social marketing programmes, recruiting and retaining target groups, engaging young people, approaches to quality service provision, and national and global partnerships in support of donor recruitment.

Resources

- *Making a difference...Recruiting voluntary, non-remunerated blood donors*. Toolkit, Geneva, IFRC, 2008
- *Towards 100 per cent voluntary blood donation: A global framework for action*. Geneva, WHO/IFRC, 2010
- *Aide-Mémoire: Safe Blood Components*. Geneva, WHO, 2005
- *Aide-Mémoire: Blood Safety*. Geneva, WHO, 2002

5.3 Long-term donor commitment

Repeat donors are generally safer than new donors because they are better informed about the importance of low-risk behaviour and understand the need for self-deferral should their donation potentially be harmful to a recipient. Testing for transfusion transmissible infections like HIV, HCV and HBV of repeat donors at each donation additionally decreases the risk for recipients of blood components. It is also more cost-effective to retain existing or former donors than to recruit first-time donors. The retention of existing donors is therefore crucial to achieving an adequate, safe and sustainable blood supply.

Quality management starts with blood donor recruitment and donor care. This includes valuing and caring for donors and considering how their needs can better be met. Opening times and locations of donor centres and mobile sites should be convenient for donors while ensuring that adequate staffing is available. Surveys of donors can provide feedback on convenience and customer service. Blood services should also have a mechanism to receive and address customer complaints.

A customer service ethos should be reflected in:

- the mission statement of the blood service
- job descriptions of every employee

³¹ *Towards 100 per cent voluntary blood donation: A global framework for action*. Geneva, WHO/IFRC, 2010, p. 10.

³² *Aide-Mémoire: Safe Blood Components*. Geneva, WHO, 2005

³³ *Aide-Mémoire: Blood Safety*. Geneva, WHO, 2002

- an effective quality system, including standard operating procedures for each process
- standing agenda items for staff meetings
- systematic monitoring and evaluations
- acknowledgement and rewards for staff that provide the best customer service
- communication with the public

The higher the quality of interaction between a blood service and its donors, the more likely it is to succeed. Expectations of customer service need to be clearly communicated to staff and volunteers. Staff motivation is a primary factor in the provision of excellent service to donors. A good working environment, job security, opportunities for promotion, regular training and appropriate remuneration all contribute to job satisfaction, which will support positive attitudes towards customer service.

5.4 Donor health and counselling

Blood services should have in place a counselling and support system for their donors. Counselling of donors includes the provision of information before an individual registers to donate, a donor interview before donation, making available blood collection and testing information during blood donation, and providing post-donation information, counselling and referral when appropriate.³⁴

Counselling is particularly important when a donor is found to be ineligible to donate because of a temporary deferral, as this can affect a donor's morale and potentially discourage future donation. Particular care must be taken in post-donation counselling of donors whose screening tests are confirmed positive for a transfusion-transmitted infection or where they have been implicated in a transfusion reaction. Temporary and permanently deferred donors require professional and sympathetic attention from an appropriately trained staff member. The health needs of a deferred donor should be addressed through referral to a medical practitioner or a counselling service.

Integral to the trust relationship between blood services and donors is an understanding that the results of blood tests and any information they divulge will be regarded as strictly confidential. Donor interviews should be conducted in an environment in which the conversation cannot be overheard. Donor records need to be kept secure. This confidentiality is critical so that donors are truthful about their health status or recent behaviours that might contribute to an increased risk to blood safety, and so deferred donors are not subjected to victimization from their community.

Minimum checklist for blood donor counselling:³⁵

- Provide counselling to individuals who are temporarily or permanently deferred from blood donation under national donor selection criteria.
- Provide oral or simple written pre-donation information that educates donors about donor selection, testing, deferral/referral and self-deferral. Give as a first step with the medical questionnaire.
 - Give donors that have medical conditions information on healthy lifestyles and/or encourage them to see their doctors.
 - Ensure donors are given a forward appointment at the end of the deferral period to motivate their return.
- Provide pre-donation counselling just before blood donation. Blood service staff should conduct a confidential interview with the donor to ensure they have and understand the pre-donation information, go over the medical questionnaire, allow the donor to ask questions and secure their informed consent to donate. Measure blood donors' blood pressure and haemoglobin.

³⁴ *Implementation Guidelines on Donor Counselling*. Geneva, WHO-CDC-IFRC, 2012

³⁵ *Ibid.*

- Advise donors deferred for low haemoglobin how to improve their haemoglobin levels.
- Refer donors deferred for anaemia for medical treatment and review their donation frequency.
- Encourage donors that have been permanently deferred to advocate VNRBD to others.
- ☑ Provide the donor with information on the type of screening tests conducted during the blood donation and the fate of components should any of the tests show abnormal results.
- ☑ Offer post-donation counselling to all donors that return positive results. Counselling should:
 - be handled tactfully, with understanding and empathy
 - be conducted as soon as results are available
 - be conducted one-on-one by a trained and knowledgeable staff member
 - be held in privacy and the donor assured that his or her information will be kept confidential
 - discuss the test results and the implications for the donor's health
 - be conducted at a reasonable and understandable pace and offer the donor the opportunity to ask questions and clarify doubts and concerns
 - explore risk behaviour and reinforce cessation/prevention of unsafe behaviour refer the donor to an appropriate medical specialist for further management, care and treatment
 - advise the donor to inform contacts that might be at risk of infection so they can be tested and treated
 - be used to identify any weaknesses in the pre-donation screening process i.e. the donor questionnaire and interview

Resources

- *Implementation Guidelines on Donor Counselling*. Geneva, WHO-CDC-IFRC, 2012
- *Screening Donated Blood for Transfusion-Transmissible Infections*. Geneva, WHO, 2009 (Section 6.3)

6. Blood Safety

This section discusses the principles and requirements for screening of donated blood to ensure the safety of the blood supply. Transfusion of an incompatible blood product or a blood product carrying transfusion-transmissible infections (TTIs) has the potential for significant harm to the recipient, and also provides significant reputational and financial risk to the National Society providing the blood service. National Societies should implement rigorous donor and donation screening strategies into blood programmes to minimize these risks.

A primary aim of blood safety screening is to safeguard recipients of blood and blood components from the risk of TTI. Effective blood safety screening strategies target the identification and exclusion of risk from the blood supply through screening of both the donor and the donation. Blood safety screening begins with the recruitment of voluntary, non-remunerated blood donors from low risk populations, and continues with the pre-donation assessment of prospective donors against established selection criteria. Provision for the voluntary and confidential self exclusion of blood donors either at the time of assessment or post donation is an important safeguard to exclude donations with a previously undisclosed risk factor. Finally donated blood is laboratory tested for markers of transfusion-transmissible infections prior to release.

Blood Safety strategies should also target the processes and tests that safeguard recipients from the risk of transfusion with incompatible blood. Appropriate strategies include testing of all blood donations for specified blood groups and screening for the presence of antibodies, prior to their release. Further laboratory testing with the intended recipient is conducted pre-transfusion to confirm the appropriateness of the selected donor unit for transfusion, and exclude incompatibility between the intended recipient and donor blood.

6.1 *Strategy development*

To ensure the provision of safe blood to the community, an overall blood safety screening strategy to manage blood safety and specifically reduce the risk of TTIs must be developed and implemented. The strategy should:

- Be nationally consistent and described in national policy and regulations
- Reflect international good practice (WHO, Council of Europe, AABB etc) and take into account local variables
- Ensure the ethical assessment and management of blood donors including appropriate donor counseling (in accordance with WHO recommendations)
- Identify the mandatory screening requirements for blood donations and any additional or selective screening requirements.
- Prescribe the universal screening of all donations for TTIs.
- Be based on appropriate risk assessment and analysis. The risk assessment must consider the geographic epidemiology, incidence and prevalence of blood borne infection in the country and the residual risk estimates for the local donor population.
- Be reviewed periodically. Changes in the epidemiology of current TTIs and the potential for emergence of new TTIs may require the strategy to be updated to ensure its ongoing effectiveness and appropriateness.
- Clearly define the responsibilities for pre-transfusion compatibility testing (hospital or blood service).

Resources

- *Screening Donated Blood for Transfusion-Transmissible Infections*. Geneva WHO, 2009
- *Aide-Mémoire: Blood Safety*. Geneva, WHO, 2002
- *Aide-Mémoire: Safe Blood Components*. Geneva, WHO, 2005

6.2 Programme implementation

The effectiveness of the screening strategy depends upon the consistent implementation of all aspects of the strategy into blood programmes at the local level. During the implementation process National Societies must ensure that:

- ☑ All prospective donors, including repeat donors, complete a pre-donation assessment
- ☑ 100% of blood donations are screened and only those found negative for TTIs are released
- ☑ blood screening programmes are operated within the context of a well supported and well managed quality system
- ☑ the screening programme incorporates all blood screening requirements specified in country-specific regulations/standards (where these exist) or other internationally recognized regulations/standards, and must also address the minimum screening requirements outlined in 6.2.1.
- ☑ where pre-transfusion compatibility testing occurs outside of the National Society, actively promote the use of relevant testing standards to ensure the blood safety pre-transfusion testing is conducted appropriately.

Resources

The resources listed below apply to all the remaining sections of this chapter (6.2.1-6.2.7). Additional resources are listed at the end of each section, where applicable.

- *Screening Donated Blood for Transfusion-Transmissible Infections*. Geneva, WHO, 2009
- *Guide to the Preparation, Use and Quality Assurance of Blood Components*. European Directorate for the Quality of Medicine (EDQM), Council of Europe, current edition.
- *Standards for Blood Banks and Transfusion Services*. AABB, current edition
- *Australian Code of Good Manufacturing Practice for Human Blood and Tissues*. Canberra, Therapeutic Goods Administration, 2000
- *Aide-Mémoire: Blood Safety*. Geneva, WHO, 2002
- *Aide-Mémoire: Safe Blood Components*. Geneva, WHO, 2005
- *Aide-Mémoire: Quality Systems for Blood Safety*. Geneva, WHO, 2002

6.2.1 Minimum screening requirements

a.) Pre-donation screening – Donor Assessment

All prospective blood donors must undergo a pre-donation assessment including completion of a donor questionnaire, confidential interview and medical assessment against established donor selection criteria. If not already in place, national standardised selection and deferral criteria should be developed that reflect international best practice (e.g. Council of Europe, AABB guidelines) as well as national and local epidemiological data on infectious diseases, prevalent risk behaviours and other local variables³⁶.

The donor questionnaire must be designed to obtain the donor's medical and travel history, and any behaviours that may result in increased risk to blood safety. The donor selection criteria must be designed specifically to identify and manage donors with risk factors that could indicate infection with a transfusion transmissible agent. Donors unable to fulfill the donor selection criteria must be excluded from blood donation via permanent or temporary deferral and appropriately counselled.

³⁶ *Towards 100 per cent voluntary blood donation: A global framework for action*. Geneva, WHO/IFRC, 2010; P102

b.) Laboratory screening of blood donations

Testing for markers of transfusion-transmissible infections:

The blood screening programme must ensure that 100% of blood donations are screened by appropriate laboratory screening test systems for at least one marker for each of the following TTIs:

- HIV HIV-1 and HIV-2 Antibody or combination antigen-antibody assay (test)
- HCV HCV antibody or combination HCV Antigen-antibody assay
- HBV Hepatitis B surface antigen (HBsAg)
- Syphilis Screening for specific antibodies to *treponema pallidum*

Testing for blood group and antibody screening

- Every blood donation must be typed for ABO and Rh(D) blood groups.
- All first time donors must be tested for clinically significant irregular red cell antibodies.
- The ABO and Rh(D) typing result on each donation must be verified with the historically determined blood type for repeat donors. For first time donors, the ABO and Rh(D) typing must be based on two independent ABO and Rh(D) tests.

Pre-transfusion compatibility testing with intended recipient (this testing may occur outside the blood service in hospital transfusion laboratories)

- ABO and Rh(D) typing of both the donation and recipient red cells.
- Recipient serum or plasma tested for irregular antibodies.
- Compatibility testing of donation red cells and recipient plasma for all cases with irregular red cell antibodies.

6.2.2 Additional screening test requirements

All National Society blood services should adhere to the minimum screening requirements listed in section 6.2.1 however additional screening tests may also be applied depending on local risk profiles and blood safety management strategies (or donor selection guidelines). Consideration should be given to extending the screening programme beyond the minimum requirements for TTIs based on the local incidence and prevalence of blood borne disease in the country and the associated risk of these infections to the blood supply.

In some countries, additional screening for *Trypanosoma cruzii* [Chagas disease], West Nile virus, HTLV/II and malaria may be considered. For example, in malaria endemic areas, it would be appropriate to consider the implementation of malaria-specific donor selection and deferral guidelines aimed at identifying donors at least risk of malaria infection, in addition to the implementation of laboratory screening of donations for parasitaemia.

The practice of additional pre-donation testing of prospective blood donors for TTIs should be considered carefully as pre-donation testing is generally not cost-effective (except in some countries where the prevalence of TTIs is extremely high), and the associated inconvenience to the donor and increased risk of stigmatization may undermine the development of a base of regular VNRBD donors, all of which can adversely affect the sustainability of the blood programme³⁷. Post donation screening (as per the minimum screening requirements) is essential to allow release labeling of the final product.

³⁷ *Screening donated blood for transfusion transmissible infections*. Geneva, WHO, 2009, section 5.8

6.2.3 Testing algorithms

National testing algorithms should be developed to describe the specific process of testing and result management for each individual TTI. These algorithms ensure consistency in blood screening and result interpretation by describing:

- the precise sequence of testing (i.e. initial screening, repeat testing, and any additional supplemental or confirmatory testing)
- the resulting component fate depending on the test result outcome

They should also describe actions to be undertaken regarding donor management (i.e. donor deferral, notification, counseling and, where applicable re-instatement testing), again to ensure consistency of application.

6.2.4 Test systems

There are a number of considerations that should be taken into account when selecting a test system for blood screening including effectiveness, cost, availability and ease of use. Assays selected must be designed specifically for blood donor screening, and must have both high sensitivity and specificity. Screening assays must be adequately validated prior to use to ensure that the test system consistently performs as intended in the local environment where it will be used, and systems must be used in accordance with the manufacturer's instructions.

The use of rapid/simple assays is not recommended for large scale blood screening as they are designed for the immediate and rapid testing of small numbers of samples, mainly for diagnostic purposes, and in general have inferior sensitivity compared to assays optimised for blood screening.

Apart from the technical assay specifications (including rates of biological false positives and period of detection), other factors such as availability of ongoing supply of associated test kits/reagents, as well as complexity and the level of operator expertise required to use the system should also be considered.

Regardless of the type of screening test system selected, having an adequate number of suitably trained operators with the appropriate level of technical expertise to perform the required testing and result interpretation in accordance with the national testing algorithms and procedural instructions is essential.

6.2.5 Quality system

The blood screening programme must be supported by, and operated within a well managed quality system. Quality system oversight of the screening programme provides assurance that the blood screening processes are implemented as intended and are regularly monitored for their effectiveness.

Quality assurance in blood screening processes should include:

- the implementation of good laboratory practice,
- the appropriate use of internal quality control processes in addition to the use of external or reference controls for the purpose of monitoring testing performance (eg from national reference laboratories),
- the participation in independent quality assurance panels.

Quality systems are discussed in further detail in section 6.

6.2.6 Result, donor and product management

Only blood donations that have been screened and found negative for TTIs are suitable for release for supply and ultimately transfusion. The blood service must implement systems of quarantine and segregation to ensure that components/donations cannot be released until the full complement of screening tests have confirmed that the unit is negative for known TTIs and the required testing for blood grouping and antibody screening is complete.

Blood donations found to be reactive or indeterminate as a result of the screening test should be considered to be infectious and immediately quarantined, to prevent accidental release. Quarantined blood donations must be easily identifiable, be physically segregated from the blood inventory, and should wherever possible be safely discarded without delay. Disposal of quarantined units must be in accordance with national regulations for bio-hazardous waste and should reflect the WHO recommendations on healthcare waste management³⁸.

Staff should be safeguarded from risk from handling potentially infectious blood through the establishment of appropriate training in universal/standard precautions and the implementation of Good Laboratory Practices.

Screening test results must remain confidential and the blood service should have systems in place to ensure that access to this information is highly restricted. Only nominated individuals within the blood service should be permitted access to the donor screening records.

Processes for ethical donor management should be established including donor confirmatory testing and counseling and, where appropriate, processes for undertaking lookback (i.e. tracing/testing recipients of blood components from donors with TTI positive results).

Additional resources

- *Safe management of wastes from healthcare activities*. Geneva, WHO, 1999
- *Aide-Memoire: Safe health-care waste management*. Geneva, WHO, 2000

6.2.7 Emergency provision of blood

The blood screening strategy should include provision for the emergency release of blood under reduced screening arrangements in response to specific defined emergency conditions. The types of emergency conditions should be agreed in consultation with relevant regulatory authorities, governments and stakeholders, and be based on appropriate risk assessment where failure to provide blood would result in greater adverse health outcomes than the risk of issuing partially, or in extreme circumstances, wholly unscreened blood. In such circumstances, the use of rapid test systems and individual labeling specifying the limitations of testing may be appropriate. Blood samples of any units issued under the emergency provisions must be tested as soon as possible by appropriate blood screening tests, and the results communicated to the recipient's treating physician.

³⁸ *Safe management of wastes from healthcare activities*. Geneva, WHO, 1999

7. Quality management

National Societies engaged in the provision of blood services should have a quality management framework in place which ensures that the blood and blood components produced are fit and safe for clinical use.

An effective quality management framework ensures that a blood service produces blood and blood components that are safe and clinically effective in a way that does not cause harm to patients, donors or staff. The framework should meet regulatory and legal requirements and allow opportunities for improvement in quality and safety to be identified.

There are three essential aspects that must be considered by a blood service when implementing a quality management framework:

- the quality system
- good manufacturing practice
- standards

7.1 *The quality system*

WHO recommends that a quality system should cover all aspects of blood service activities and ensure traceability, from donor recruitment through to the transfusion of blood and blood components to patients, and should take into account the structure, needs and capabilities of the blood service.³⁹ It should be guided by a quality policy (preferably national) and operate under the direction of a national manager.

An effective system should ensure that policies and procedures are in place to define and control all activities that have the potential to affect the quality of blood components and the safety of donors, staff and patients. For each activity, procedures should be in place covering:

- establishment of specifications
- management of resources
- monitoring and analysis of activities against specifications to confirm quality and identify improvements
- identifying and resolving situations where the required standards are not met
- management responsibility for reviewing the effectiveness of the quality system and driving continuous improvement

The quality policy and procedures should form the basis of a manual which sets out the system structure and clear accountability. The manual should be read and understood by all staff.

There are a number of resources that are available to guide National Societies in the implementation of a quality system, including the International Organization for Standardization's ISO 9001 Standard which is generic to all industries. The AABB, the Council of Europe, and the Australian Therapeutic Goods Administration (TGA) have regulatory frameworks for blood services. It is important that a National Society, if it does not have local regulatory requirements in place or they are not up to international standards, selects and adopts one of these international standards for its blood service.

³⁹ *Aide-Mémoire: Quality Systems for Blood Safety*. Geneva, WHO, 2002

Resources

- *Aide-Mémoire: Quality Systems for Blood Safety.*, Geneva, WHO, July 2002
- *Aide-Mémoire: Safe Blood Components.* Geneva, WHO, 2005
- ISO 9001 *Quality Management Systems – Requirements.* ISO, 2008. Available from the ISO web site, www.iso.org
- *Guide to the Preparation, Use and Quality Assurance of Blood Components.* European Directorate for the Quality of Medicine (EDQM), Council of Europe, current edition.
- *Standards for Blood Banks and Transfusion Services.* AABB, current edition
- *Australian Code of Good Manufacturing Practice for Human Blood and Tissues.* Canberra, Therapeutic Goods Administration, 2000

7.2 Good manufacturing practice (GMP)

The blood service quality system should be based on good manufacturing practice (GMP). This incorporates all activities performed by the blood service that ensure a finished component or delivered service consistently meets the required specifications. GMP requirements are usually set out in 'Codes of GMP' that are developed by blood services in conjunction with regulatory or government authorities or are adopted from any existing documents. With respect to blood service-related activities, Codes of GMP include a very strong emphasis on checking and controlling all steps of manufacturing and control to show that the component or service is suitable for its intended use – i.e., fit for purpose – and that this can be repeated. Principles of GMP should apply to the whole manufacturing process, from donor selection to release of blood components for use. Key requirements include:

- **Implementation (or introduction) of a quality system:** Quality system structures and procedures should be in place and a quality manager who is independent of the manufacturing process should be appointed.
- **Monitoring the effectiveness of the quality system:** An internal audit programme should be in place to review existing activities regularly and a system be set up to identify, report, monitor and analyse incidents when errors occur or the final component or service is not 'fit for use' (i.e., a continuous improvement system to monitor non-conforming components and services).
- **Management review:** The staff within the senior management level should regularly review the results of activity monitoring such as internal audits, corrective actions, non-conformances and customer complaints or adverse event reports to identify improvement opportunities.
- **Staff training and performance:** Staff should be trained in and be able to follow the quality system requirements and GMP principles applicable to their role, and their work performance evaluated regularly. This should be documented and the records should be made available to staff and for audit or monitoring purposes. Lines of accountability should be clearly documented and understood by all staff, including senior management.
- **Suitable premises:** Buildings should be suitable for the activities performed by the blood service. All areas, especially those used for production and manufacturing, should be constructed and organized in a way that reduces errors and allows for easy cleaning. The working environment (e.g., air temperature, humidity, etc.) should be appropriate for the activities and, where critical, should be monitored and alarmed.
- **Equipment suitable for intended use:** Equipment important (or critical) to any blood service activity, from recruitment through to distribution, should be fit for its purpose and validated (i.e., tested to make sure it performs as expected) before use. A regular maintenance programme should be in place, including testing of equipment performance against known standards (calibration), especially for refrigeration and bar code equipment.
- **Document control:** There should be a system for controlling the content of documents (a document control system) to ensure that instructional documents, such as standard operating procedures, are always current. The system should make sure there is a regular review and update of the

documents and that obsolete documents are removed from use. A copy should be kept for archiving purposes.

- **Record management:** The blood service should establish specifications for the storage, retention, archiving and disposal or destruction of any records holding information on the blood service's manufacturing activities, including determining which records to keep. The retention period should be based on regulatory or legislative requirements.
- **Control of materials:** Materials used in the manufacturing chain should be purchased from reliable suppliers wherever possible and assessed against specifications for their performance and quality prior to release for use. Critical materials should be traceable to components in the event of a recall due to defective material. Suppliers of critical materials should be audited regularly to ensure compliance with quality requirements.
- **Donor recruitment, selection, collection and testing:** Donors should be assessed for suitability according to defined donor selection criteria that are appropriate for the local environment and ensure the safety of the donor, the staff and the patient or recipient. Records should exist to demonstrate full traceability of the steps taken from donor to component, and each donation should be screened for infectious agents. The donor selection criteria and testing/screening requirements are stipulated in the standards adopted by the blood service.
- **Quality control monitoring and process control:** Procedures should be established to ensure that all activities, processes, materials, equipment, etc. are 'tested' or validated before being implemented for use. Blood components should be regularly monitored by a quality control testing programme and the results checked against the agreed specifications of the quality system. Any changes to established systems should be managed via a 'change control process' that includes any re-validation or re-testing that needs to occur before the change is implemented. The status of materials, equipment and blood components should be clearly demonstrated by status labelling or physical location where status could mean 'fit for use', in quarantine, not tested, failed test results, under-validation, etc. Where possible, physical segregation is best and any non-conforming material or blood components that have not been assessed as 'fit for use' should be securely segregated. There should be documented procedures for the release of blood components by an authorized person where the component has been assessed as 'fit for use' and rapid recall of released components if required.
- **Storage and Transport:** Materials and blood components should be stored and transported in equipment or facilities that maintain the required storage conditions (temperature, etc.). There should be clear differentiation between in process/unfinished/quarantined/non-conforming components and finished 'fit for use' components. Transport containers should be validated for the component type, the temperature at which they are to be transported, and the distance or time of transport. Where possible, the transport should also be monitored, using a data logger.
- **Computer systems:** Computer systems, where used in the blood service operations, should be validated to demonstrate that they perform as required. Strict data control should be applied to computer records.
- **Contracted suppliers:** Where services are sub-contracted, there is a responsibility to ensure that the sub-contractor follows all the relevant standards that apply to the blood service and provides services as detailed in a contract.

The World Health Organization has established GMP guidelines and provides training workshops and seminars on the assessment of compliance with GMP at manufacturing sites, details of which can be provided by local or regional WHO offices.

Resources: As per Section 7.1, plus:

- WHO *Guide to Good Manufacturing Practice (GMP) Requirements*. Geneva, WHO, 1997
- *Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials*, Volume 2, Good Manufacturing Practices and Inspection. Geneva, WHO, 2007
- *Blood Cold Chain: Selection and Procurement of Equipment and Accessories*. Geneva, WHO, 2002
- *Manual on the Management, Maintenance and Use of Blood Cold Chain Equipment*. Geneva, WHO, 2005
- *Safe Blood and Blood Products Distance Learning Material*. Geneva, WHO, 2002
- *Principles of Good Manufacturing Practice in Respect of Medicinal Products for Human Use and Investigational Medicinal Products for Human Use*. European Commission Directive 2003/94/EC

7.3 Standards

While the adoption of GMP can provide confidence that a blood service's blood components will meet specifications, Codes of GMP generally do not set out the required specifications for those components. These are contained in Standards.

Standards detail the minimum acceptable specifications or criteria for the most important (or critical) steps in the blood service's activities, and for the services and finished blood components provided by the blood service. Standards can either be used as guidelines for practice, or set as minimum regulatory requirements that must be met depending on the regulatory and legislative requirements of the country. Standards are often seen as the minimum requirement and a blood service may choose to exceed them in practice.

Appropriate Standards for blood and blood components should be selected by the National Society, the regulator or government authority, or both in consultation, and may include the selection of an existing Industry Standard such as the AABB *Standards for Blood Banks and Transfusion Services* or Council of Europe *Guide to the preparation, use and quality assurance of blood components*, or the development of a set of locally specific Standards.

Resources: As per Section 6.2, plus:

- *Screening Donated Blood for Transfusion-Transmissible Infections*. Geneva, WHO, 2009

7.4 Auditing

An internal audit programme should be established to review periodically the operation and effectiveness of the quality system. The audit programme should ensure that all activities and manufacturing steps are covered, and that the level of compliance with internal and regulatory requirements is assessed. Internal audits also provide opportunities to identify areas that need improvement. External audits may also be conducted by a regulatory agency or a third party.

There should be a procedure that describes the frequency and the requirements for conducting internal audits, including time frames for reporting and responding to audits. The scope of each audit should be clearly defined and the audit conducted by a trained auditor who is independent of the activity being audited. Corrective action taken in response to audit outcomes should be reviewed and verified before closing out the audit.

Audit outcomes should be regularly reviewed as part of management review.

Resources:

- *ISO 19011: Guidelines for quality and/or environmental management systems auditing*. ISO, 2002. Available from the ISO web site, www.iso.org

8. Partnerships

Fostering global partnerships and collaboration is a United Nations' Millennium Development Goal. There are limits to the capacity of individual organizations to generate a culture of voluntary donation and build sustainable blood systems. Achieving a safe and sustainable blood system requires the cooperation and assistance of government, as well as communication and engagement with other blood services and National Societies.

8.1 Government

As blood transfusion services are an essential part of modern health care provision, governments have a strong interest in maintaining a healthy, sustainable, self-sufficient national blood programme. WHO recognizes that it is ultimately the responsibility of the Ministries of Health to ensure a safe and sufficient supply of blood and blood products and their safe and rational use. Even if this responsibility has been delegated to a nongovernmental blood service organization, governments should provide effective leadership and governance and sufficient resources to establish and maintain a sustainable national blood system⁴⁰. This should include:

- providing adequate financial resources with which to develop and maintain a viable blood programme
- formalising government support and commitment to the blood programme
- enabling the blood transfusion service to operate with a discrete budget, separate management and appropriately trained staff
- establishing appropriate support systems and structures for the national blood system, including a national blood policy and strategic plan which emphasizes the principle of VNRBD⁴¹
- developing a legislative and regulatory framework based upon international standards to encourage and enforce appropriate blood service standards and behaviour (if not in place)
- supporting national clinical guidelines for blood transfusion
- creating a broadly representative national blood commission⁴² or national blood authority with executive functions⁴³

National Society blood services and voluntary blood donor recruitment activities should, therefore, be fully integrated into the government's health plans. Any roles and responsibilities delegated to a National Society by a government should be defined in a legal agreement⁴⁴ such as a service agreement or Memorandum of Understanding that also defines the source of financial support and the cost-recovery system. An example framework for a Memorandum of Understanding is included as Appendix 3. Any agreement for blood service provision should also include government indemnity or protection for the National Society's blood service activities acknowledging that there are risks associated with undertaking a blood programme.

National Societies and their blood services have a responsibility to practice humanitarian diplomacy⁴⁵ to ensure that the government appreciates the role that safe blood and a sufficient supply of such blood and blood products play in national health security, and the benefits to public health that will come from

⁴⁰ *Aide-Mémoire: Developing a National Blood System*. Geneva, WHO, 2011

⁴¹ Processes for effective blood policy and policy considerations are outlined in *Aide-Mémoire: Good Policy Process for Blood Safety and Availability*. Geneva, WHO, 2008

⁴² *Aide-Mémoire: Blood Safety*. Geneva, WHO, 2002

⁴³ *Aide-Mémoire: Developing a National Blood System*. Geneva, WHO, 2011

⁴⁴ *Ibid*

⁴⁵ *IFRC Humanitarian Diplomacy Policy*, adopted by the 19th session of the IFRC Governing Board in Paris, May 2009.

appropriately funding and supporting the national blood programme. National Society communications and interactions with government should stress the need for a national policy of VNRBD, action to minimize risk in blood services and the importance of adequately funding blood safety measures, the need for balancing blood safety and accessibility, and the importance of donor care and donor and recipient safety. Governments should also be reminded of their responsibilities in maintaining a national blood system that is fully integrated into the health care system (as described by WHO in *Aide-Mémoire* for Ministries of Health, *Developing a National Blood System*⁴⁶).

Because of their strong ties to the community and their extensive volunteer networks, some National Societies may find that the government would like them to increase their engagement in blood programme activities, particularly blood donor recruitment. Any increase in blood activities comes with an increase in risk to the National Society, so it is recommended that any society considering a change to its level of engagement in its national blood programme first contacts the GAP and/or the International Federation for advice.

Resources

- *Aide-Mémoire: Developing a National Blood System*. Geneva, WHO, 2011
- *Aide-Mémoire: Good Policy Process for Blood Safety and Availability*. Geneva, WHO, 2008
- *Aide-Mémoire: Blood Safety*. Geneva, WHO, 2002
- *Blood Transfusion Safety*, Information Sheet for National Health Authorities. Geneva, WHO, current version

8.2 Community engagement

Blood services are encouraged to engage with government health, education and community agencies, the media, other voluntary and educational organizations and the business community in promoting VNRBD and community support for the national blood programme. These networks and channels of communication can improve public understanding of the role of blood in health care, influence attitudes to blood donation, and convey the importance of blood safety. Government and business employers can also support blood services by providing opportunities for their employees to donate blood and by forming corporate donor groups.

Resources

- *Towards 100 per cent voluntary blood donation: A global framework for action*. Geneva, WHO/IFRC, 2010

8.3 Blood sector networks

International collaboration supports resilience in blood systems and the capacity of blood services to adapt in response to uncertainty and change. Collaboration assists national blood services in emergency preparedness and pandemic planning. Sharing of best practice examples, emerging technologies and investments in safety supports blood services in pursuing continuous improvement. It can also inform discussions with government on investment in new technology and appropriate safety measures.

National and regional blood services recognize that there are significant benefits in engaging in blood sector networks such as the international Alliance of Blood Operators (ABO), the European Blood Alliance (EBA), Asia-Pacific Blood Network (APBN), AABB, ISBT, the International Plasma Fractionation Association (IPFA), the International Haemovigilance Network (IHN), the International Society of Thrombosis and Haemostasis (ISTH), and the International Federation of Blood Donor Organizations

⁴⁶ *Aide-Mémoire: Developing a National Blood System*. Geneva, WHO, 2011

(FIODS). Blood sector networks support performance improvement and operational efficiency through benchmarking, the exchange of knowledge, and the development of consistent policies, standards and processes across countries and regions.

Benchmarking operational performance against other comparable blood services provides identification of best practice, quality assurance and continuous improvement. Blood services affiliated with ABO participate in an annual Balanced Scorecard that allows for comparison of performance and practice in the areas of donor attraction and retention, blood component demand and issue rates, clinic efficiency, collection and processing efficiency, and workforce turnover. The scorecard gives participating blood services a clear indication of where they are positioned relative to other (non-identified) countries in each aspect of blood service delivery. Data from the benchmarking informs discussions among network members on best practice and collaborative approaches such as sharing information.

Information from the ABO and APBN Balanced Scorecards is shared among participating blood services. National Societies interested in learning more about benchmarking using a scorecard are advised to contact the ABO or the APBN secretariats.

The Global Blood Safety Network (GBSN) forum, convened by WHO, involves international organizations, agencies and experts from developing and developed countries in sharing expertise in support of global blood safety. The forum promotes information exchange, consensus on appropriate blood safety standards and practices, and fosters cooperative arrangements between institutions to support the safety of blood donors and recipients in all countries. Further information on the aims and outcomes of the GBSN is available on the WHO web site.

8.4 Hospitals and clinicians

The implementation of appropriate patient blood management (PBM) systems during blood storage, handling, use and administration by hospitals is important in ensuring that the quality and safety of blood and blood components is maintained and that scarce blood resources are used to best effect with respect to patient outcome. While National Society blood services may not have any direct involvement in the treatment of patients by blood transfusion, they do have a responsibility to patients to ensure that blood is collected while maintaining both the quality and safety of the units, and to their blood donors to ensure that donated blood is not wasted and that it is used appropriately.

Blood services should have in place formal agreements for the supply of blood to hospitals that include provisions such as:

- a commitment from the hospital that it adheres to WHO recommendations on the clinical transfusion process and patient safety⁴⁷ and PBM⁴⁸
- the appropriate levels of stock
- systems for ordering and supply
- monitoring and reporting of appropriate use and wastage and expiry
- monitoring and reporting of patient adverse events

It is recommended that blood services engage with transfusion medicine experts, hospital administrators, and government stakeholders (e.g., military representatives and national contingency or disaster management teams) to establish a national or local inventory management and supply plan. This should be aimed at ensuring sufficient supplies to meet routine demands and respond to surges if additional blood is required, for example in emergency situations (see Section 9.2), while minimizing wastage from

⁴⁷ *Aide-Mémoire: Clinical Transfusion Process and Patient Safety*. Geneva, WHO, 2010

⁴⁸ *Aide-Mémoire: The Clinical Use of Blood*. Geneva, WHO, 2003

expiry and inappropriate use. It is recommended that blood services and hospitals also establish arrangements for priority supply and transportation.

Blood services should encourage hospitals to establish multidisciplinary transfusion committees responsible for implementing the national policy and guidelines in a local context and monitoring how blood components are being used, as described by WHO in its *Clinical Use of Blood, Aide-Mémoire for National Health Programmes* (2003). Blood services should work with hospital transfusion committees in determining current and anticipated blood supply needs, and in promoting leading transfusion practice.

National Society blood services should work to educate clinicians as well as medical and nursing students on aspects of blood transfusion safety, the risks of blood transfusion, alternatives and prevention strategies, the importance of appropriate product use, and the benefits of voluntarily donated blood. Level B and C National Societies could also focus on hospitals and clinicians in their advocacy efforts to change family replacement donation to 100 per cent VNRBD.

Resources

- Aide-Mémoire: *Clinical Transfusion Process and Patient Safety*. Geneva, WHO, 2010
- Aide-Mémoire: *The Clinical Use of Blood*. Geneva, WHO, 2003
- Aide-Mémoire: *Safe Blood Components*. Geneva, WHO, 2005
- WHA 63.12, *Availability, safety and quality of blood products*. Sixty-Third World Health Assembly, Geneva, 21 May 2010, Geneva, WHO 2010

8.5 National Societies

The GAP supports cooperation between National Societies involved in blood programme delivery through regional meetings and the establishment of twinning or buddying relationships between blood services.

GAP regional meetings allow National Society blood services to discuss issues arising from the GAP Self-assessment and provide societies from similar environments the opportunity to share corporate governance and risk management experiences, challenges and successful approaches. The GAP's zonal coordinators can also hold in-depth discussions with societies seeking priority assistance with the organization of their blood programme.

Upon request the GAP and/or the International Federation can help National Societies establish twinning or buddying relationships with other National Societies that have expertise and experience in areas of need, and can also provide them with direct advice as to the appropriate level of engagement in their national blood programme (see Chapter 10).

The International Federation encourages National Societies involved in donor recruitment to share their experiences and some zones and regions hold regular meetings for societies involved in blood programme activities, including VNRBD recruitment. National Societies should contact their Federation zone office for more information.

9. Sustainability

9.1 Adoption of new technologies and practices

Blood services benefit from shared learning with other blood services on best practice in blood management, testing, manufacturing and distribution. This includes evaluations of new technologies and equipment, and comparisons of operational approaches and performance. Information exchange can occur through blood sector networks, visits to other blood services, attending conferences or engaging in partnering arrangements.

Equipment needs to be appropriate to the defined task and meet specified standards. In determining the suitability of new equipment, blood services should consider factors such as performance in local conditions, operating requirements (e.g., power, water), staff training and maintenance. Coordinating equipment purchases across a blood service can assist in standardization, provide for economies of scale, and simplify processes for training, maintenance and support.

When considering receipt of donated equipment it is important to assess how the equipment will integrate with the existing system, whether trained operators are available, and if replacement parts and maintenance services are obtainable.

The transition to new technologies or systems should be planned to minimize disruption, with a process of monitoring, evaluation and review. Time should be allowed to ensure appropriate training of staff using the equipment. Blood services should also consider whether outmoded equipment that still operates to specified standards might be of use to other National Society blood services. Equipment should otherwise be appropriately disposed of.

9.2 Contingency planning and disaster preparedness

Disruption of blood services as a result of a natural disaster, pandemics, war or terrorism can potentially impact upon the lives of patients in need of blood transfusion. After a disaster, demand for blood may suddenly escalate at the same time as blood collection sites become unusable and the public's response and willingness to donate increase. A significant issue will be managing the influx of donors. Power cuts may cause stored blood and blood products to become unsafe as they fall outside of prescribed storage temperatures. A crisis situation may also be caused by publicity concerning contaminated blood products. Delivery of blood services entails responsibility to ensure an adequate and timely supply of blood and blood components. A lack of preparation and contingency for adverse events could result in a loss of confidence and reputational damage to a National Society. A disaster plan is therefore essential to manage a response, so that blood service staff and other partners are clear on what should be done, by whom, and in what order.

A comprehensive plan for disaster management includes actions for mitigation, preparedness, response and recovery. Mitigation actions might include relocating facilities to alternate sites or designing facilities to reduce the impact of recurring natural disasters. Preparedness addresses the risks that cannot be sufficiently reduced by mitigation strategies and involves a risk analysis of potential disasters and those areas of operation most likely to be adversely affected. Preparatory actions should be routinely reviewed to ensure that they address these risks and, where possible, a test run or exercise included to monitor preparedness and the accuracy of key information such as contact numbers.

Response during a disaster includes critical actions initiated by staff to protect life and property but the safety of staff must be the primary consideration. These actions include establishing internal and external communication, conducting emergency evacuations, and re-establishing operations at an alternate site (if required). This requires clearly defined, understood and practised processes, emergency operating procedures, and a leadership succession plan. Recovery operations focus on the restoration of critical infrastructure to re-establish important functions, such as communications, power, water, sewage and transportation. Identifying areas that may require additional mitigation actions in the event of future disasters is also an aspect of recovery.

Contingency and disaster planning involves identifying recurring natural disasters and events that are endemic to the region – e.g., earthquakes and seasonal disease patterns. Information regarding man-made threats can also be provided by government agencies responsible for health, defence and utilities, or from the private sector. A National Society's blood service disaster plan should be integrated with any national disaster plan and should detail:

- membership of the crisis management team with their roles and responsibilities
- names, roles and contact information of key contact persons plus back-up personnel
- internal communication management for staff and volunteers
- external communication management, including names and roles of official spokespersons and responsibilities for communication with donors, the media, and other stakeholders (e.g., hospitals)
- information on alternative collection sites
- information on alternative finished product storage sites (e.g., have established agreements with hospitals to increase on-site stock should blood service storage equipment fail)
- information on alternative supplies of equipment and consumables
- information and procedures for recruitment, collection, processing, testing, storage and distribution activity continuation in the event of a disaster
- names, addresses and contact details for all staff
- responsibilities of individual staff in relation to contingency and disaster planning
- arrangements for back-up storage of all donor and sponsor records
- arrangements for computer back-up systems, where in use

The disaster plan needs to be well practiced, so that staff know exactly what to do and can act immediately in assuming their designated role. Disaster management responses should be rehearsed on a regular basis as part of staff training.

Resources

- *Maintaining a Safe and Adequate Blood Supply during Pandemic Influenza: Guidelines for Blood Transfusion Services*. WHO, July 2011.
- *Pandemic Influenza Planning for Blood Organizations*. European Blood Alliance Emergency Planning Action Group, 2009
- *Disaster Operations Handbook: Coordinating the Nation's Blood Supply during Disasters and Biological Events*. AABB, 2008. Available from the AABB's web site, www.aabb.org
- *The John Hopkins and Red Cross Red Crescent Public health guide in emergencies*. John Hopkins Bloomberg School of Public Health and IFRC, 2008, second edition.

9.3 Environmental sustainability

Sound environmental management helps to minimize the impact of blood service operations upon the environment and public health. It not only supports compliance with regulatory standards but also demonstrates to the public and employees that their National Society is acting in an environmentally responsible way. Good environmental management practices can also deliver savings through lower energy usage, less consumption of materials, and reduced waste management and distribution costs.⁴⁹

The requirements and guidelines for an environmental management system are set out in the ISO 14000 Standards, which complement the ISO Standards for quality management (ISO 9000). ISO 14000 provides a holistic framework with which blood services can develop an environmental policy and plans. An effective management system will enable the blood service to manage hazardous waste, identify and control environmental impacts, set environmental objectives and targets, plan actions to achieve these, and continually improve environmental performance.

A blood service's environmental approach should be conveyed in an environmental policy made available to the government, suppliers, contractors and the community. This will:

- comply fully with all applicable environmental and hazardous waste management laws and regulations, and reflect international good practice, including WHO recommendations on health-care waste management
- seek to minimize or control (to the extent possible) environmental impacts from operations
- set objectives and targets for continuous improvement in environmental performance
- promote staff awareness of environmental objectives and responsibilities, and their active involvement
- communicate the environmental policy and environmental requirements to contractors and suppliers and seek to influence, as far as possible, their environmental practices⁵⁰

Resources

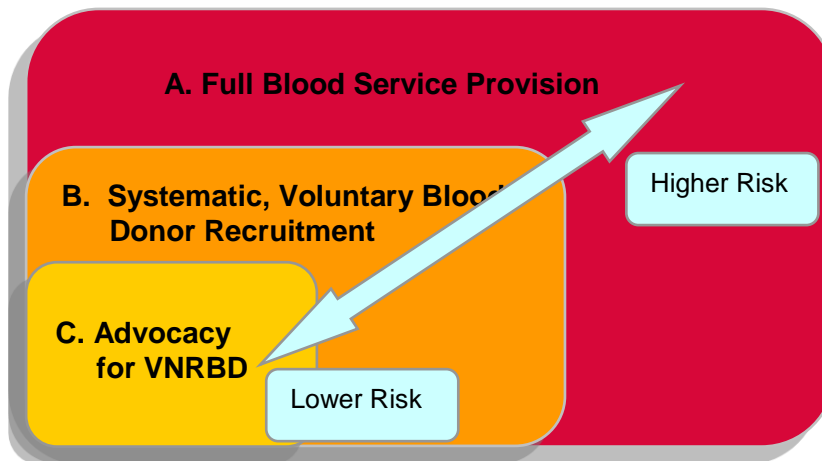
- ISO 14000, *Environmental Management*. ISO, 2007. Available from the ISO web site, www.iso.org
- *Safe management of wastes from healthcare activities*. Geneva, WHO, 1999
- *Aide-Memoire: Safe health-care waste management*. Geneva, WHO, September 2000

⁴⁹ See ISO web site, www.iso.org.

⁵⁰ These areas are informed by the environmental policy of the Hong Kong Red Cross blood transfusion service.

10. Transition and exit strategies

As previously highlighted, involvement in blood service delivery (Level A) entails a high degree of responsibility and compliance to manage National Society exposure to blood-related risks. These risks can be reduced through adherence to the standards outlined in this document (refer to the tables in Section 2.1). If a National Society involved in blood programmes determines that it has insufficient capacity to manage the associated risks or if the government is prepared to take over the blood programme, it could consider reducing its level of involvement in blood activities, as in the diagram below.



National Societies that are considering either building their capacity and ability to operate their blood services in a safe and sustainable manner or withdrawing to a lesser involvement in blood activities are encouraged to contact the GAP or the International Federation for advice. Decisions to reduce involvement in blood programmes are not made lightly, and it is important to consider and mitigate the consequences to the community of a National Society's withdrawal from blood service provision.

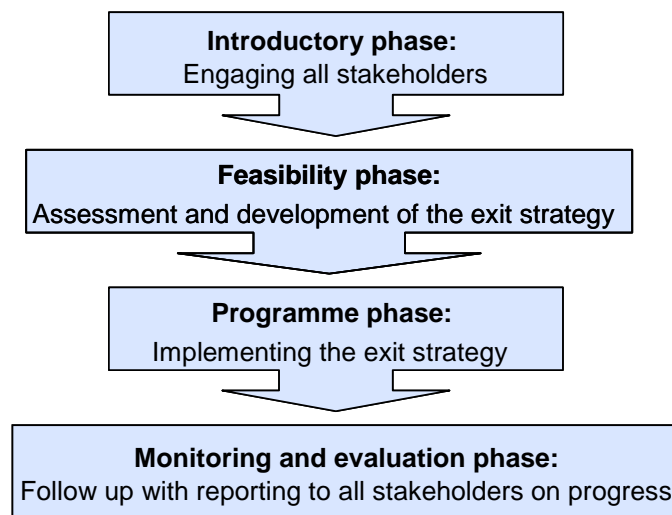
It is important that the National Society engages key stakeholders (the government, the International Federation, WHO, the GAP and others) before it initiates action to exit from its blood service. The result of the negotiations might be that an alternative provider is identified, making it easier for the National Society to withdraw strategically from its blood service activities. However, in some cases the government might decide to increase resources to the National Society and, with technical support from international agencies such as the GAP or WHO, the blood service can improve its operations to meet the required standards and remain the national blood programme provider.

The following pages present generic guidelines for blood service National Societies contemplating a transition from Level A to a lesser degree of involvement. The guidelines are broad, so they can be adapted to local circumstances and conditions.

The guidelines may also serve as a tool for engagement with government regarding the requirements for an effective and sustainable national blood programme. Blood services cannot function effectively without adequate financing and appropriate infrastructure. The GAP can provide guidance to National Societies when engaging with government and other stakeholders regarding the extent of their involvement in blood programme activities.

Exit Strategy Framework

This framework and its guidelines are designed to assist National Societies that have decided that their best course of action is to exit from their blood service activities. It includes strategies to ensure appropriate consultation and processes are undertaken during the transition phase, when the blood service transfers from the National Society to another entity (as determined by the appropriate government body). The following phased change plan is recommended:



The following guidelines are intended to assist National Societies designing an effective exit or transition plan. It includes objectives, considerations and potential activities.

Phase 1: Introductory phase
<p>Objective: To facilitate the gradual implementation of an exit strategy by consulting key stakeholders and identifying requirements for effective transition.</p> <p>Activities:</p> <ul style="list-style-type: none"> • Hold discussions between a) the National Society blood service and the ministry of health, b) the National Society blood service, the ministry of health and the appropriate GAP zonal coordinator (focal point), if necessary. • Share information arising from the GAP Self-assessment report. • Clarify the new role of the National Society (Level B or C). • Discuss options and a time frame for the exit strategy/change plan (recommended minimum of two years). • Appoint a project team involving all stakeholders and establish its terms of reference, taking into consideration any additional fund-raising that might be needed to manage the implementation of the exit strategy.
Phase 2: Feasibility phase
<p>Objective: To develop a project/exit plan for the handover of blood service activities that ensures: A smooth transition to the new authority, security for the blood service and its stakeholders, and the maintenance of optimal blood safety and levels of donor care.</p>

Activities

- Perform a detailed **risk analysis** of the impacts of the National Society's exit from blood services in the local situation (see Section 4.5).
- The project team (including government authorities) should develop a project/exit plan that ensures:
 - a clear **governance regime** for the handover, and for **each area** of blood service operations the following are identified:
 - *what* is required to properly effect a handover
 - *who* is responsible
 - *how* those tasks will be done by the responsible party
 - *when* those tasks will be done by the responsible party
 - the following are incorporated as areas for attention (as applicable):
 - **the operational transition of products and services**. May include: transfer of assets, equipment, hardware and software, personnel, knowledge exchange/training, transfer of databases, provision of statement of third party contracts, and insurance information
 - **blood service functions**. May include: donor management and recruitment, collections, testing, processing, inventory management and distribution, operations support, transfusion medicine, research and development, corporate support and planning
 - the **safety** of blood donors and blood recipients through the application of the **fundamental principles** of VNRBD and equity in access to blood and blood products (see Section 3)
 - the **integration** of international standards in quality assurance and good manufacturing practice (GMP) (see Section 6) into **national regulations** as recommended by WHO
 - **blood donors** are aware of and **confident** in the transition process, so they continue to donate blood
 - a **costing analysis** is completed to ensure that the future blood programme operation is **financially sustainable** (see Section 4.2)
 - appropriate **compensation** is given to the National Society for the **transfer of any assets**
 - **risks** are identified and managed throughout the process of transition and beyond (see Section 4.5)
 - sufficient resources are put towards **communicating** with government, key stakeholders (e.g., media, regulators, suppliers, hospital staff and clinicians), donors and the general public
 - a **contingency plan** is in place to manage either:
 - lack of preparedness to exit according to the initial time frame
 - a local disaster which may result in the necessity to re-establish the National Society blood service temporarily to deal with the crisis
- Agree on a **Memorandum of Understanding** that clarifies each party's role and responsibilities subsequent to the handover (see Appendix 3).
- **A GAP review**⁵¹ of the project/exit plan proposal with recommendations to ensure that any possible risk management issues for IFRC have been considered (e.g., reputational risk).

⁵¹ Subject to the availability of resources

Phase 3: Programme phase

Objective: To implement the project/exit plan within the agreed time frame while maintaining a service that meets all the needs of both the donor and patient populations.

Activities:

- Implementation of the project/exit plan and Memorandum of Understanding with scaling down of National Society involvement during the transition, ensuring:
 - the **systematic transfer** of blood service functions and operational products and services
 - the establishment of **national regulations** for the blood programme based upon international standards, if they are not in place already
 - blood safety is maintained through the **application of quality assurance and GMP systems** (as per WHO recommendations)
 - progress is being made towards **100 per cent VNRBD**
 - ongoing **collaboration** with partners, patient organizations, professional societies and other stakeholders to ensure supply plans are set up to meet the nation's need for blood
 - the supply of blood and blood products is on a **non-for-profit** basis
 - changes and updates are **communicated** to stakeholders through key spokespersons
 - a system and process is established to manage the ongoing requirement for **donor lookback and counselling** once the exit is complete
- If withdrawing to Level B or C, in parallel, the National Society should consider:
 - appointing a **team** with a focus on **donor recruitment** or **community education** and setting up training programmes based on:
 - the IFRC toolkit *Making a difference...Recruiting voluntary, non-remunerated blood donors*
 - the workshop materials compiled jointly by WHO and IFRC, entitled *DONOR*
 - *Towards 100 per cent voluntary blood donation: A global framework for action*
 - the requirements basic checklists found in this manual in Section 2.1 (pages 12-14)
 - establishing a **sub-committee** to address legal responsibilities to blood donors and blood recipients in order to comply with World Health Assembly recommendation 28.72, which calls for member states to enact effective legislation governing the operations of blood services and to take any other necessary action to protect and promote the health of blood donors and recipients⁵²
 - providing ongoing **capacity building and mentoring** to the new blood service operator
- Liaise with **WHO** to ensure requirements are being met in all areas of blood service operations and to secure access to the full Basic Operational Framework for Blood Transfusion Safety.

⁵² Subsequent WHA resolutions (WHA58.13, 2005 and WHA60.18, 2007) have called upon all member states to establish or strengthen systems for the recruitment of voluntary, non-remunerated donors and the implementation of stringent criteria for donor selection.

Phase 4: Monitoring and Evaluation phase

Objective: To report on a regular basis on all matters of accountability to the new services' donors, the funding agencies, users of blood and blood products, and the community at large.

Potential activities:

- Report on **agreed targets** (e.g., blood donation, blood component production).
- Review the new **system's impact**, if any, on wider health and care priorities (maternal health, child mortality).
- **Benchmark** progress with key partners (see Section 7.3). Access to safe blood and blood components cannot be achieved without cost but an unsafe or inadequate blood supply is even more costly in both human and economic terms. Benchmarking with key partners can assist in quality improvements at all levels of service delivery and is a useful tool for monitoring progress in a cost-efficient way.
- Report back to the **GAP** with full '**case study**' details for the benefit of other National Societies and ministries of health.
- Conduct a '**Learning Review**' to identify what:
 - was done well and would be done again
 - was not done well and would be improved on next time

The review could report back to the GAP for the benefit of other National Societies and ministries of health.

Appendices

Appendix 1: International Federation's blood policy



POLICY

Promoting Safe and Sustainable National Blood Systems

Introduction:

Blood safety is a critical underpinning for safe blood transfusion and health systems. People in all countries have a right to expect that the blood and blood products supplied to them are gathered, produced and provided in a safe and sustainable way that supports their communities and their health systems.

The International Federation recognises that “health security is a fundamental and indispensable prerequisite to global, national and individual development”⁵³ and it supports the advancement of global health security by promoting voluntary non-remunerated blood donation (VNRBD), and advocating for the safe provision of blood and products⁵⁴.

While the World Health Organisation (WHO) recognises that it is the responsibility of governments to ensure a safe and adequate supply of blood⁵⁵, Red Cross/Red Crescent Societies in many countries, as auxiliaries to their governments, play an important role in promoting safe and sustainable blood programmes. National Society activities range from the provision of the national blood service, to systematic recruitment of voluntary blood donors, to promotion of blood donation and advocacy for VNRBD, for example annual participation in World Blood Donor Day.

Scope of policy

This policy sets out the International Federation and member National Societies' position on advancing health security through safe and sustainable blood systems.

Importance of blood services

Sustainable and quality blood services play a critical role in the health of any society, and in terms of disaster preparedness the existence of a quality blood service is critical. While the availability of blood could be a major concern in the event of a disaster, the safety is also always of paramount concern to any emergency/disaster response. Blood is used for a multitude of life saving purposes including: assisting patients undergoing surgery; treating diseases including anaemia and malaria; caring for patients on chemotherapy; supporting women with complications during childbirth (postpartum haemorrhage) and patients on Antiretroviral (ARV) treatments. The unavailability of safe blood can lead to serious health consequences such as death from haemorrhage or the transmission of life threatening infections HIV/AIDS, hepatitis B and C, syphilis and other infections.

There should be preparedness plans to provide rapid response to emergency situations and for post-disaster reconstruction of blood transfusion services.

The availability of safe blood contributes directly to three of the United Nations Millennium Development Goals:

4. the reduction of child mortality;
5. the improvement of maternal health; and
6. combating HIV/AIDS, malaria and other diseases.

⁵³ Health Policy adopted at the 15 session of the General Assembly of the IFRC, Seoul, November 2005.

⁵⁴ *Strategy 2020*, p 15, IFRC

⁵⁵ *Blood Safety*, Aide-Memoire for National Blood programme, WHO, 2002

It is recognised that a sufficient supply of safe blood and blood components based on voluntary nonremunerated blood donation (VNRBD), and the security of that supply, are important national goals to prevent blood shortages and meet the transfusion needs of the patient population⁵⁶.

VNRBD is a critical component in ensuring a safe and sustainable blood supply that meets the needs of all recipients. VNRBD was enshrined as a fundamental principle of blood service when the 1975 World Health Assembly (WHA) resolution called for member states to “promote the development of national blood services based upon voluntary non-remunerated donation of blood”⁵⁷.

Patients must have equitable access to safe transfusion on the basis of their clinical needs, and the safety of the donor and patient must be considered paramount. The International Federation and its member National Societies promote equity, access, quality and safety of blood and blood components so that citizens can have confidence in the security and integrity of their blood system.

While the benefits of blood transfusion are widely acknowledged, there are also some risks inherent in the blood transfusion process, including accidental exposure to transfusion transmitted infections such as HIV. To secure the safety of the blood supply, blood services must ensure that appropriate donor screening and quality management processes are in place, and that they remain vigilant against new threats to the blood supply.

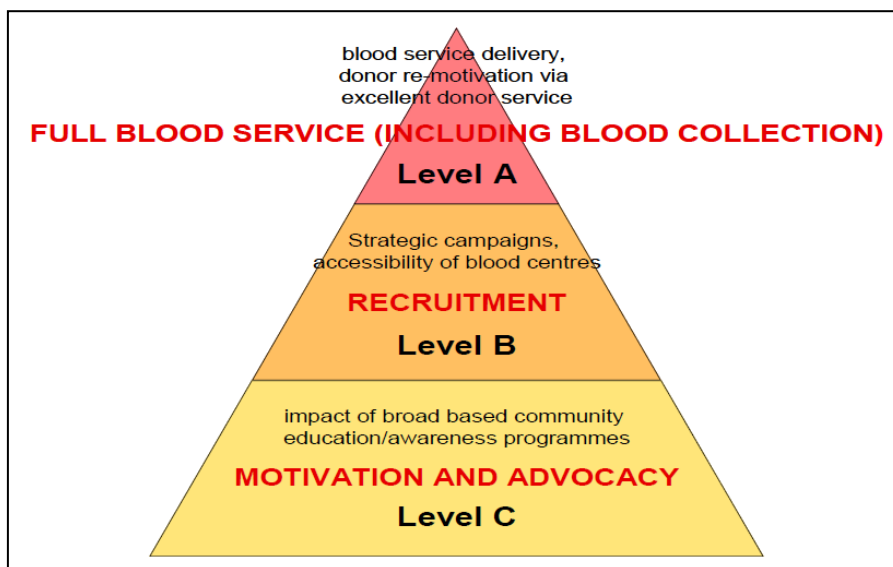
Characteristics of well-functioning RC/RC blood programmes

While it is the responsibility of a country’s government to ensure an adequate and safe blood supply, many National Societies play an important role in supporting their government to achieve that objective. National Societies may be involved in blood-related activities at three levels:

- A: Full blood services (collecting, testing, processing, distribution)
- B: Systematic recruitment of blood donors to a blood service
- C: Promotion and advocacy of blood donation

These levels are reflected in the figure below.

Figure 1: Red Cross/Red Crescent role in blood activities



Each level of National Society involvement in blood services is characterised by different requirements regarding capacity and risk management. While Level A requires the most resources and has the highest level of risk, a well run National Society blood service can contribute enormously to the health and well-being of the community in which it is based. However, all National Societies can contribute

⁵⁶ WHA resolution 63.12.

⁵⁷ WHA resolution 28.72 This principle was reasserted again by the WHA in 2005 (WHA58.13) and 2010 (WHA28.72)

towards the development of a safe and sustainable blood system through the advocacy and promotion of VNRBD.

For a full description of the characteristics of each level, please refer to the Global Advisory Panel on Corporate Governance and Risk Management of Blood Services in Red Cross and Red Crescent Societies' (GAP) blood manual 'Development of Safe and Sustainable Blood Programmes'. A summary of the main characteristics of a well-functioning level A or B blood programme is provided below.

For both Levels A and B:

- Systems are in place to ensure that the health and well-being of the donor and recipient are protected
- There is national blood policy in place which reflects WHO recommendations, including VNRBD, and it is supported by a legislative framework
- The blood programme is integrated as part of a national health policy and plan
- The allocation of roles and responsibilities between the Government, the blood programme, and the National Society reflect the overall responsibility of the Government to ensure an adequate and safe blood supply and are formally documented in a service agreement
- Long-term and sustainable funding allows the blood programme to:
 - meet operational and regulatory requirements with regards to facilities, supplies, equipment and trained staff and volunteers; and
 - implement appropriate donor care and risk management systems leading to high quality, safe and effective blood products.
- The blood programme is nationally coordinated to ensure uniformity of standards and cost efficiency
- Donor selection criteria are in place to identify low risk donors and counselling is provided in cases of deferral
- There is a risk management framework in place, to identify, prioritise and manage risks

At Level A:

- The National Society has secured government protection/indemnity and/or insurance cover for its blood service activities, including clinical advice.
- The National Society should assure that adequate external assessments are conducted regularly to ensure that the Blood services operate under the necessary quality assurance programme and adheres to a national regulatory framework based upon internationally recognised standards.
- The blood service is involved in collaborations and partnerships to ensure a safe and adequate blood supply and appropriate product use.

At Level B:

- The blood service to which the National Society recruits donors operates under a quality assurance programme and adheres to a national regulatory framework based upon internationally recognised standards.
- There are agreements in place whereby the roles and responsibilities of the National Societies and the Blood Service are clearly defined.

It is therefore important that National Societies consider carefully the level of blood activity which is most appropriate for their engagement. The global burden of disease due to unsafe blood can be eliminated or substantially reduced through an integrated approach to blood safety, requiring,

- The establishment of a nationally coordinated blood service
- Formalization of government commitment and support.
- Contribute where appropriate to the Development of National blood policy and plans.
- Advocacy of necessary legislation/regulation for the Blood Transfusion Service .
- Establishment of nationwide quality systems, including guidelines, standard operating procedures, accurate records, monitoring and evaluation aligning to Government policy.
- Collection of blood only from vnrbd from low risk populations

- Haemovigilance system for monitoring, reporting and investigating adverse events.
- Trained staff and continuing professional development and upgrading for latest technology as a prerequisite.
- Ensure efficient and good laboratory practices in screening for transfusion transmissible infections, blood grouping, compatibility testing, blood component production, storage and transportation
- Reduction of unnecessary transfusions through effective clinical use of blood

But a National Society needs to consider carefully all aspects of a sustainable and quality programme, and if it is contemplating a commitment to undertake activities at Level A the National Society:

1. Should have a clear mandate from their government to do so;
 2. Should have the capacity to adhere to regulatory requirements and implement appropriate blood safety measures;
 3. is able to manage any legal liabilities, possibly by considering whether a separate legal entity is required to separate the assets of the National Society from the blood business.
- Independence with its own director, board of management and budget may also lead to increased public trust and confidence, crucial to a successful national blood programme.

Framework of support to RC/RC blood programmes

Together with WHO the IFRC is committed to the achievement of 100 per cent voluntary blood donation, in keeping with our Fundamental Principles, and we have a long history of collaboration in the area of blood safety and availability. The strength of the partnership lies in its complimentary and synergistic approach at national as well as global level. Three key milestones have marked our strategic collaboration, each providing a global framework of support:

- (1) the designation of Blood Safety as the theme of WHO's World Health Day 7 April 2000, supported by IFRC
- (2) the foundation and establishment of World Blood Donor Day in 2004-5 which is now celebrated each year on 14 June to raise awareness of the importance of blood donation and recognize the contribution of voluntary non-remunerated blood donors in saving lives and improving health.
- (3) the 2009-10 release of the WHO/IFRC *Global Framework for action-towards 100 per cent voluntary blood donation*

The International Federation's main toolkit, designed to assist key stakeholders in best practice, in donor recruitment and advocacy for 100 per cent vnrbd is the package "*Making a Difference...recruiting voluntary, non-remunerated blood donors*". This is a self-help manual empowering personnel in the field to motivate, recruit and retain vnrbd and to phase-out any dependence on family/replacement donors.

National Societies and the International Federation have created an expert's group (GAP) to generally assist and advise National Societies on the governance and risk management issues relevant to blood services, as resources allow. GAP's main tool in working with National Societies is the Self-assessment, a questionnaire that:

- enables National Societies to identify potential problem areas where their blood programme activities may be exposing them to risk; and
- offers strategies for improving corporate governance and risk management.

Meanwhile, as ongoing support to sister societies and in accordance with the spirit of the International Federation, the sharing of best practice between National Societies is encouraged in order to maintain and expand on the competitive advantage which the International Federation and its member National Societies have in this specialized field of health care.

It is clearly acknowledged and understood that each National Society is fully responsible for its own blood activities. The support provided by either the International Federation, GAP or assisting National Societies does not in any way dilute or transmit this responsibility.

Specific Responsibilities – arising out of this policy:

The International Federation, GAP and National Societies engage to:

- support and advocate the principle of voluntary, non-remunerated blood donation (VNRBD)
- advocate a balanced decision-making approach to blood safety that addresses both evidence-based considerations and the precautionary principle
- promote and uphold high ethical standards, integrity and accountability consistent with the *Code of Ethics for Blood Donation and Transfusion* of the International Society of Blood Transfusion, as adopted by the International Conference of Red Cross and Red Crescent Societies, 1981, and supported by the World Health Organization

National Societies have a responsibility to:

- work to ensure their Governments accept their responsibility to ensure a safe and adequate blood supply within their jurisdictions
- identify their role in the overall strategy of blood service delivery in their country in accordance with their capacity, technical know-how, available resources, local priorities and in liaison with government
- promote safe, sustainable and equitable practices in the development and administration of blood programmes
- ensure their blood programme has an adequate governance structure with a well-defined system for delegation of authority and accountability.
- support the aspiration of national self-sufficiency, including ensuring adequate blood and blood products to meet domestic health needs
- undertake Humanitarian Diplomacy as necessary to seek government action to minimise risk in blood services and to help ensure that Government alerts the public to any reasonably preventable inadequacy in blood service delivery which places them at risk
- implement the GAP Self-assessment and adhere to the *Development of Safe and Sustainable National Blood Programmes Manual*, which may necessitate a more detailed analysis, assessment and development of an exit strategy
- respect the confidentiality and privacy of all information relating to blood donors and blood donation
- administer any blood programmes in compliance with this position; inform all staff, volunteers and blood sector partners participating in blood programmes of this position
- where practical, provide support to other National Societies and blood services in achieving a safe and sustainable blood system in ways that enable self-empowerment and long-term sustainability
- take steps in consultation with GAP and other partners to ensure that appropriate risk management measures are implemented; this includes ensuring that its senior management and governing leaders are alerted to any material risks and that appropriate action is subsequently taken
- ensure that all blood programmes comply with this policy

The International Federation has a responsibility to:

- focus on the promotion of voluntary blood donor recruitment and to liaise and work in close collaboration with GAP, WHO and other partners in implementing the WHO/IFRC Global Framework for action-towards 100 per cent voluntary blood donation
- share knowledge and exchange information with GAP at a strategic, regional and country level.

- ensure this policy is reviewed after five years
- work with the GAP membership to help ensure necessary GAP resourcing
- keep – through the International Federation Secretary General – International Federation Governance appropriately informed of major material risks for the International Federation it becomes aware of

The GAP has a responsibility to:

- share knowledge and provide advice to National Societies on governance and management of risk associated with blood programmes, as resources allow
- ensure any lessons learned from the implementation of the GAP manual “Development of Safe and Sustainable National Blood Programmes” are incorporated into an update of the manual at same time as the policy review
- inform both the International Federation Secretariat and the concerned National Societies of major material risks for the International Federation discovered through the GAP National Society self-assessment program in blood service delivery and any other GAP work

Review and Reference:

This policy was drawn up in 2010 and it is designed to replace the previously established policy on Quality Provision in Blood Services. IFRC will ensure this policy is reviewed after five years, with any proposed amendments to be submitted to the Federation for approval. The review is to be initiated no later than 30 Dec 2014.

This policy is submitted to Governing Board Dec 2010 for its approval and submission to the General Assembly in Nov 2011.

Further Reference Texts:

Decision 34, 8th session of the General Assembly, Budapest, 25-28 Nov 1991. Voluntary nonremunerated blood donors are persons who give blood, plasma or other blood components of their own free will and receive no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This includes time off work, other than reasonably needed for the donation and travel. Small tokens, refreshments and reimbursement of direct travel costs are compatible with voluntary, non-remunerated donation

Code of Ethics for Blood Donation and Transfusion. International Society of Blood Transfusion, General Assembly, Montreal, 1980 and XXIVth International Conference of the Red Cross, Manila, 1981.

Code of Ethics for Blood Donation and Transfusion. International Society of Blood Transfusion, General Assembly, 12 July 2000; amended by the ISBT General Assembly, 5 September 2006.
Decision 36, Blood Quality Programme. Seville, Spain: 11th Session of the General Assembly, November 1997.

Melbourne Declaration 2009, arising from WHO/IFRC global consultation on 100 per cent vnrbd whereby participants (more than 65 experts in transfusion medicine, policy makers, government and non-government representatives from 38 countries across WHO/IFRC regions) agreed, *inter alia*, to work in collaboration in international efforts to promote safe and sustainable vnrbd programmes that foster community engagement and benefit the recipients of blood and blood products.

Decision, World Health Assembly, 2010, *Availability, safety and quality of blood products* (WHA63:12)

Appendix 2: National Society blood risk summary

There are a number of risk issues facing Level A and Level B National Societies. For a full list of risk management recommendations, see the GAP Self-assessment.

Main risks for National Society blood services (Level A)

Below is a list of the main risk issues the GAP has identified for National Society blood services (Level A) in order of priority:

Risk issue	Consequence
Lack of government protection and/or appropriate insurance cover for blood-borne disease transmission	Exposes the National Society to financial risks beyond its capacity to resolve should an incident occur
The inability to meet either regulatory or national standards	Should be minimum requirements of any blood service – blame for a lack of achievement can be clearly laid at the feet of the National Society
Lack of funding and resources	Fundamental risk management and donor and product safety systems/processes are prejudiced
The lack of systematic identification, analysis, evaluation and prioritization of risks and their management	Lack of appreciation of risks and therefore identification of those which are the most imperative to reduce
Ineffective governance	Significant risks in lack of assurance and leadership
Lack of systems of monitoring emerging threats to the blood supply	Lack of risk management measures in place to deal with blood-borne diseases
Failure to provide meaningful, practical support for 'victims' of blood-borne disease transmission	Risks the very reputation of Red Cross Red Crescent as a humanitarian organization

Main risks for National Societies involved in blood donor recruitment (Level B)

- Without clear Memoranda of Understanding with either the ministry of health or blood service, the National Society may recruit to a blood service without appropriate standards to ensure blood safety and blood donor care and safety.
- Without adequate knowledge of the criteria for blood donor selection, there is a risk of mobilizing groups of people, some of whom may not be eligible to donate blood, which could result in the National Society being criticized as unprofessional.
- With pressure from government, some societies may participate in recruiting donors to potentially 'unsafe' blood services and expose themselves to potential risks including a) victims of blood-borne diseases seeking meaningful and practical support from the societies due to their involvement in the recruitment of the donor and b) a donor seeking compensation from the societies for injuries related to blood donation at the blood service.

Appendix 3: Framework of a Memorandum of Understanding

When a National Society agrees to undertake the provision of part (Level B) or all (Level A) of a national blood programme on behalf of the government or health authority, GAP recommends that this is supported by a Memorandum of Understanding (MoU) or service agreement between the two parties. A MoU provides clarity on respective roles and responsibilities and facilitates a cooperative working relationship based on expectations that have been agreed to by both parties. It can also be used to document and reaffirm the government's responsibility to assist the National Society in managing its blood programme risks both financially and with regards to assurance.

MoU's are established for a clearly specified period (such as 1-3 years) however they should be reviewed annually. It is in the interest of both parties that a formal contract be negotiated each year (perhaps as an addendum to the MoU) that specifies the volume/number of products to be provided and the funding that will be provided by, or funding arrangements that are supported by, the government.

MoU formats may vary but generally they will include the following:

A **title** which describes clearly the parties and the purpose of the MoU, for example: 'Memorandum of Understanding (MoU) between [*the Country government or health authority*] and [*the National Society/blood service*] for the [*Specific programme of work e.g. implementation of the national blood programme/provision of the blood donor recruitment programme*]'

I. Mission/Objective

A preamble which includes a brief description of the missions of both the National Society/blood service and the government, and the area which the partnership will promote e.g. the adequate supply of safe blood and blood products to patients, through a national blood programme based on voluntary blood donation.

II. Purpose and Scope

A description of the intended results that both parties hope to achieve in forming the partnership, and the area(s) that the specific activities listed later will cover.

Delegations could be covered in this section. If a National Society is delegated as the national blood service, the National Society should seek an assurance that it will have autonomy and independence in the technical management of the programme. Funding arrangements and the provision of assurance could also be covered here.

III. Responsibilities

A list of the specific responsibilities and/or tasks of each party, and any joint obligations, that have been agreed as part of the negotiation process including annual operations and budget plans with agreed Key Performance Indicators. Below is a list of government and National Society responsibilities that could be considered for inclusion in a MoU for a **Level A** blood programme.

<p>Government obligations:</p> <ul style="list-style-type: none"> The implementation of a clear blood policy which spells out the agreed roles and functions of all parties, including the National Society, and establishes VNRBD as the basis for the national blood programme <p>Government obligations (cont.):</p>	<p>National Society/blood service obligations:</p> <ul style="list-style-type: none"> Comply strictly with all laws, regulations and guidelines issued by government Provide the population with access to the safest possible blood and blood products, equitably and appropriately <p>National Society/blood service obligations (cont.):</p>
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<ul style="list-style-type: none"> • The provision of an appropriate legislative framework for the blood programme and regulatory oversight • The provision of sufficient resources to enable the National Society to undertake the task at the required level of quality and competence without compromising standards or diminishing its own resources • The provision of an adequate level of protection/assurance to the National Society for undertaking the blood programme on its behalf, particularly regarding incidents of 'no fault' transfusion transmitted infection. 	<ul style="list-style-type: none"> • Recruit VNRB donors, provide appropriate donor care, and collect, test, process and distribute blood and blood components • Retain competent staff, including an appropriately skilled director with the responsibility and authority for planning, coordinating and managing the blood programme • Provide a technical, financial and administrative structure to ensure the appropriate management of the blood programme • Maintain an appropriate quality management system for its activities and production processes • Submit agreed financial and quality reports to the government in a timely manner
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A number of the examples above could also apply for **Level B** National Society's entering into partnership with a blood centre. Additional suggestions are included below:

<p>Government/Blood Centre obligations:</p> <ul style="list-style-type: none"> • The implementation of appropriate donor care systems and of quality standards in the collection, testing and processing and distribution of blood and blood components to ensure the population has access to the safest possible blood and blood products, equitably and appropriately • The provision of professional expertise for the development of the public awareness programme, in liaison with those responsible for donor recruitment programme (including RC/RC) • Assistance in the orientation and training of RC/RC volunteers • Management of a dedicated budget for the blood service allocating appropriate resources to those responsible for donor recruitment (including RC/RC) 	<p>National Society/blood donor recruitment programme obligations:</p> <ul style="list-style-type: none"> • Work in partnership with Blood Centre to ensure an adequate supply of safe blood • Recruit and build a team to implement the blood donor recruitment and management programme, implementing wherever possible the IFRC's standard toolkit 'Making a Difference ...recruiting voluntary , non-remunerated blood donors' • Develop and implement a continuous national awareness programme to heighten the importance of blood donation • Develop and manage education, publicity and promotion activities to promote, recruit and retain blood donors to the level as agreed with the blood service. • Develop recognition programmes for regular blood donors, in partnership with the blood service, including World Blood Donor Day on 14 June. • Motivate and enlist the support of the community to organize and host blood mobile sessions and to coordinate the activities for the blood mobile drives with the blood service. • Recruit, train and manage a pool of volunteers to maximize the impact of the donor recruitment programme
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IV. Terms of Understanding

Describes the terms of length for the MoU and the effective date from which the agreement will start (usually when it is signed). A review period, usually annually, should be included to ensure that the MoU is meeting its purpose and that any necessary revisions can be made. The option to extend the MoU upon mutual agreement could also be written into this section.

The process for termination of the MoU and for resolving disputes should be clarified. A confidentiality clause could also be incorporated to ensure that information and documents received or acquired are treated as strictly confidential.

The MoU should end with the signatures of the duly authorised representatives of both the government and National Society and the date upon which the document was signed. The signatures of at least two witnesses, one from each party, should also be included.

GAP may be able to assist in providing example MoU's for National Societies to consider. Please contact the GAP Secretariat or the IFRC, if further information is required.



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 haemapheresis 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.

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

Appendix 5: Blood Safety, WHO Aide-Mémoire for National Blood Programmes



World Health
Organization

Blood Safety

AIDE-MEMOIRE for National Health Programmes

A well-organized blood transfusion service (BTS), with quality systems in all areas, is a prerequisite for safe and effective use of blood and blood products.

The HIV/AIDS pandemic has focused particular attention on the importance of preventing transfusion-transmitted infections (TTIs). Up to 3% of HIV infections worldwide are transmitted through the transfusion of contaminated blood and blood products. Many more recipients of blood products are infected by hepatitis B and C viruses, syphilis and other infectious agents, such as Chagas disease.

The global burden of disease due to unsafe blood transfusion can be eliminated or substantially reduced through an integrated strategy for blood safety which includes:

- Establishment of a nationally-coordinated blood transfusion service
- Collection of blood only from voluntary non-remunerated blood donors from low-risk populations
- Testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing
- Reduction in unnecessary transfusions through the effective clinical use of blood, including the use of simple alternatives to transfusion (crystalloids and colloids), wherever possible.

Words of advice

- Secure government commitment and support for the national blood programme
- Establish a blood transfusion service as a separate unit with responsibility and authority, an adequate budget, a management team and trained staff
- Educate, motivate, recruit and retain voluntary nonremunerated blood donors from low-risk populations
- Ensure good laboratory practice in screening for transfusion-transmissible infections, blood grouping, compatibility testing, blood component production and the storage and transportation of blood products
- Reduce unnecessary transfusions through the effective clinical use of blood, including alternatives to transfusion
- Establish a quality system for the BTS
- Train all BTS and clinical staff to ensure the provision of safe blood and its effective clinical use



Checklist

Blood transfusion service

- Government commitment and support
- National blood policy and plan
- Legislation/regulation
- Organization with responsibility and authority for the BTS
- BTS management committee
- BTS medical director
- BTS quality manager
- Specialist BTS advisory groups
- Trained BTS administrative and technical staff
- Adequate budget
- National quality system

Blood donors

- National blood donor programme officer
- Blood donor unit
- Blood donor recruitment officer
- Standard operating procedures
- Training of staff in blood donor unit
- Low-risk donor populations
- Educational materials
- Register of voluntary non-remunerated blood donors
- Donor selection, deferral, care and confidentiality
- Donor notification and referral
- Monitoring of TTIs

Testing of donated blood

- Technical officer
- Screening strategies and protocols
- Training of laboratory technical staff
- Screening of all donated blood for TTIs
- Blood grouping and compatibility testing
- Good laboratory practice, including standard operating procedures (SOPs)
- Continuity in testing
- Effective blood cold chain

Clinical use of blood

- National policy and guidelines on the clinical use of blood
- Training of clinicians and BTS staff
- Prevention, early diagnosis and treatment
- Alternatives to transfusion (crystalloids and colloids)
- Effective clinical use of blood
- Monitoring and evaluation

Key elements

Establish a blood transfusion service

It is the responsibility of governments to ensure a safe and adequate supply of blood. This responsibility may be delegated to a non-profit non-governmental organization, but the BTS should be developed within the framework of the country's health care infrastructure.

The BTS requires government commitment and support and recognition as a separate unit with an adequate budget, management team and trained staff.

Important activities in establishing a blood transfusion service include:

- Formalization of government commitment and support
- Development of a national blood policy and plan
- Development of necessary legislation/regulation for the BTS
- Formation of an organization with responsibility and authority for the BTS
- Formation of a BTS management committee
- Appointment of a medical director
- Appointment of a quality manager
- Appointment, when necessary, of specialist BTS advisory groups
- Appointment and training of staff experienced in each key aspect of the BTS
- Development and implementation of a budgeting and finance system to ensure a sustainable blood programme through cost recovery and/or annual budget allocation
- Establishment of national quality system, including guidelines, standard operating procedures, accurate records, monitoring and evaluation.

Educate, motivate, recruit and retain low-risk blood donors

High priority should be given to the elimination of family/replacement and paid blood donor systems, which are associated with a significantly higher prevalence of TTIs.

Voluntary non-remunerated blood donors from low-risk populations who give blood regularly are the foundation of a safe and adequate blood supply.

Important activities include:

- Appointment of an officer responsible for the national blood donor programme
- Establishment of a BTS unit responsible for donor education, motivation, recruitment and retention
- Appointment of a designated blood donor recruitment officer
- Preparation of SOPs in accordance with BTS guidelines
- Training of staff in the blood donor unit
- Identification of donor populations at low risk for TTIs
- Development of educational materials
- Establishment of a register of voluntary non-remunerated blood donors
- Assurance of safe blood collection procedures, including donor selection and deferral, donor care and confidentiality

- Donor notification and referral for counselling
- Monitoring of TTIs in the donor population.

Test all donated blood

The BTS should develop and maintain a national strategy for the testing of all donated blood and blood products, using the most appropriate and effective tests, and for good laboratory practice. Important activities include:

- Appointment of a designated technical officer
- Development of protocols for the testing, selection and evaluation of appropriate screening assays to be used at each site
- Training of BTS laboratory technical staff
- Screening of all donated blood for TTIs, including HIV, hepatitis viruses, syphilis and other infectious agents, such as Chagas disease
- Blood grouping and compatibility testing
- Good laboratory practice, with effective documentation, including standard operating procedures
- Procurement, supply, central storage and distribution of reagents and materials to ensure continuity in testing at all sites
- Maintenance of an effective blood cold chain for the storage and transportation of blood and blood products.

Reduce unnecessary transfusions by effective clinical use of blood

Blood transfusion has the potential for acute or delayed complications and the transmission of infection. The risks associated with transfusion can be reduced by minimizing unnecessary transfusions through the effective clinical use of blood and blood products and the appropriate use of simple alternatives to transfusion which are safer and more cost-effective.

Important activities include:

- Development of a national policy and guidelines on the clinical use of blood
- Training in the clinical use of blood for all clinicians involved in the transfusion process and for BTS staff
- Commitment to the prevention, early diagnosis and treatment of conditions that could result in the need for transfusion (obstetrical complications, trauma and other causes of anaemia)
- Availability of intravenous replacement fluids (crystalloids and colloids) for the correction of hypovolaemia
- Availability of pharmaceuticals and devices to minimize the need for blood
- Effective clinical use of blood and blood products in accordance with national guidelines
- Monitoring and evaluation of the clinical use of blood.

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Appendix 6: The Clinical Use of Blood, WHO Aide-Mémoire for National Health Programmes



World Health Organization

The Clinical Use of Blood

AIDE-MEMOIRE

for National Health Programmes

Blood transfusion is an essential part of patient care. When used correctly, it saves lives and improves health. However, blood transfusion carries a potential risk of acute or delayed complications and transfusion-transmitted infections and should be prescribed only to treat conditions associated with significant morbidity or mortality that cannot be prevented or managed effectively by other means.

Blood is a scarce human resource and ensuring its safety and clinical effectiveness requires investment – both human and financial.

The national blood transfusion service (BTS) is responsible for ensuring the provision of an adequate supply of safe blood for all patients requiring transfusion. The national health programme should develop policies and strategies to reduce the need for transfusion, minimize unnecessary transfusions and ensure the safe and appropriate use of blood and blood products. These strategies should include:

- Prevention, early diagnosis and effective treatment of conditions that could result in the need for transfusion
- Use of good surgical and anaesthetic techniques, pharmaceuticals and medical devices to reduce blood loss
- Availability and use of simple alternatives for volume replacement, including intravenous replacement fluids (crystalloids and colloids)
- Appropriate prescribing of blood and blood products in accordance with national guidelines
- Safe pre-transfusion procedures
- Safe administration of blood and blood products.

The national blood programme and clinical users of blood and blood products should work together to implement these policies and strategies.

Words of advice

- Secure government commitment and support for the development and implementation of a policy to promote the safe, appropriate use of blood
- Ensure a safe and adequate supply of blood and blood products
- Ensure the availability and use of simple alternatives to transfusion
- Establish a national committee on the clinical use of blood
- Develop national guidelines on the clinical use of blood
- Involve professional bodies and patient associations in the establishment of systems to ensure the safe and appropriate use of blood
- Provide training for all clinicians, nurses, BTS/hospital blood bank staff and other personnel involved in the transfusion process
- Establish transfusion committees in each hospital in which transfusion takes place
- Establish a system to monitor and evaluate blood usage
- Establish a national haemovigilance system to monitor, report and investigate adverse events associated with transfusion



Checklist

Prerequisites

- Well organized, nationally coordinated blood transfusion service
- National blood policy and plan incorporating the clinical use of blood
- National committee on the clinical use of blood
- Quality system for the BTS, hospital blood banks and clinical departments
- Adequate resources

National guidelines

- Clinical and laboratory indications for the use of blood, blood products and alternatives to transfusion
- Information about available blood products and alternatives to transfusion
- Standard blood request form
- Guidance on the development of blood ordering schedule and standard operating procedures at hospital level

Education and training

- Training of clinicians, nurses and BTS/ blood bank staff in:
 - Undergraduate and postgraduate programmes
 - In-service training
 - Continuing medical education

Hospital transfusion committees

- Effective implementation of national guidelines
- Training of hospital staff
- Hospital blood ordering schedule
- Hospital standard operating procedures
- Monitoring and evaluation at hospital level

Monitoring and evaluation

- Safety and adequacy of available blood and blood products and alternatives to transfusion
- Traceability of blood and blood products
- Compliance with national transfusion guidelines
- Patterns of blood usage and clinical transfusion practice
- Adverse events related to transfusion

Key elements

Requirements for the appropriate clinical use of blood

The national blood programme has the responsibility to ensure that blood and blood products provided for clinical use are safe, adequate to meet demand, clinically effective and produced consistently to appropriate standards.

While responsibility for the decision to transfuse ultimately rests with individual clinicians, consistently effective clinical transfusion practice cannot be achieved unless the following are in place:

- A well organized, nationally coordinated blood transfusion service

to ensure the availability of, and access to, safe blood and blood products

- National blood policy and plan incorporating the clinical use of blood, with appropriate supportive regulations
- National committee on the clinical use of blood within the national blood programme
- Availability of intravenous replacement fluids, and medical devices and pharmaceuticals to reduce blood loss

- Quality system for the BTS, hospital blood banks and all clinical departments involved in transfusion, including:
 - Standard operating procedures
 - Documentation of requests for blood, blood sampling, the administration of blood and monitoring the transfused patient
 - Systems to monitor adverse events and errors related to transfusion
 - Clinical audit.

National clinical guidelines

Transfusion guidelines should represent a consensus by clinical specialists, the BTS, pharmacists and professional bodies on the most effective treatments for specific conditions. They should be practical, comprehensive and relevant to local conditions. They should include:

- Clinical and laboratory indications for the use of blood, blood products and alternatives to transfusion
- Information on available blood products and alternatives to transfusion: dosage, storage conditions, risk of transfusion-transmissible infection, means of administration, contraindications and precautions
- Standard blood request form to provide full information about the patient and the need for transfusion
- Blood ordering schedule, as a guide to the number of units of blood and blood products that should normally be requested for each type of operation, with guidance on its adaptation by each hospital
- Instructions for the development of standard operating procedures at hospital level.

The national committee on the clinical use of blood should work to ensure the effective implementation of the guidelines.

Education and training

The effective implementation of the national policy and guidelines requires education and training in clinical blood use and safe clinical transfusion procedures for clinicians, nurses, BTS/blood bank staff and other personnel involved in transfusion, including:

- Undergraduate and postgraduate programmes in:
 - Medical schools and teaching hospitals
 - Medical laboratory technology training institutions
 - Schools of nursing
 - Paramedical schools
- In-service training for:
 - Clinicians
 - Nurses
 - Blood transfusion service and hospital blood bank staff
- Continuing medical education:
 - Hospital clinical meetings
 - Seminars and conferences
 - Medical publications.

Hospital transfusion committees

A transfusion committee should be established in each hospital to implement the national policy and guidelines and monitor the use of blood and blood products at the local level. The committee should have authority within the hospital structure to determine hospital policy in relation to transfusion and resolve any identified problems.

The main functions of a hospital transfusion committee include:

- Developing systems for the implementation of the national guidelines within the hospital
- Liaison with the BTS to ensure the availability of required blood and blood products at all times
- Liaison with the relevant department to ensure a reliable supply of intravenous replacement fluids and other alternatives to transfusion at all times
- Developing a hospital blood ordering schedule

- Developing hospital standard operating procedures for all steps in the transfusion process
- Training all hospital staff involved in transfusion
- Monitoring the usage of blood and blood products within the hospital
- Monitoring and investigation of severe adverse effects or errors associated with transfusion, taking any corrective and preventive action required and reporting through the haemovigilance system to the national committee on the clinical use of blood.

Monitoring and evaluation

At national level, responsibility for monitoring and evaluation should be shared by the BTS, the national committee on the clinical use of blood and the department responsible for the supply of intravenous replacement fluids and other alternatives to transfusion.

The monitoring system should cover:

- The safety, adequacy and reliability of the supply of blood, blood products and alternatives to transfusion
- The traceability of all blood and blood products, from blood collection to transfusion
- Compliance with the national guidelines on transfusion and the impact on prescribing practice
- Differences in blood usage within hospitals and between similar hospitals at regional, provincial and district level
- Haemovigilance – the monitoring, reporting and investigation of all adverse events related to transfusion.

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Appendix 7: Quality Systems for Blood Safety, WHO Aide-Mémoire for National Blood Programmes



AIDE-MEMOIRE for National Blood Programmes

Blood transfusion is a key part of modern health care. It is the responsibility of the national blood programme to provide an adequate supply of blood for all patients requiring transfusion and to ensure the quality of blood and blood products for clinical use. All products must be safe, clinically effective and of appropriate and consistent quality.

The strategies for achieving this are:

- A well-organized, nationally-coordinated blood transfusion service (BTS)
- Blood collected from regular, voluntary non-remunerated blood donors from low-risk populations
- Testing of all donated blood, including screening for transfusion-transmissible infections, blood grouping and compatibility testing
- Appropriate clinical use of blood.

Every blood transfusion service should develop an effective quality system to ensure the implementation of these strategies. The quality system should cover all aspects of its activities and ensure traceability, from the recruitment and selection of blood donors to the transfusion of blood and blood products to patients. It should also reflect the structure, needs and capabilities of the BTS, as well as the needs of the hospitals and patients that it serves.

Key elements of quality systems include:

- Organizational management
- Standards
- Documentation
- Training
- Assessment.

Management commitment and support are essential for the development, implementation and monitoring of a national quality system in order to ensure continuous quality improvement. All staff should understand the importance of quality and the consequences of failure in the quality system.

Words of advice

- Secure the commitment and support of management at all levels
- Identify the need for quality in the national blood policy
- Develop a national quality policy and plan
- Secure adequate resources
- Designate a national quality manager with overall responsibility for the implementation of quality systems in BTSs at all levels
- Develop a quality section, with appropriate staffing and expertise, in each blood centre and hospital blood bank
- Provide training in quality for all BTS staff and other health care professionals involved in blood transfusion
- Assess the effectiveness of the quality system continually



Checklist

Prerequisites

- Nationally-coordinated BTS
- Management commitment and support
- Integration of quality in the national blood policy
- National quality policy and plan
- National quality manager
- Adequate resources

Organizational management

- Clearly defined organizational structure
- Quality manager in each blood centre and hospital blood bank
- Quality section in each blood centre and hospital blood bank
- Culture of quality
- Commitment and support of all staff
- Identification of processes and procedures and their critical control points

Standards for quality systems

- Regulatory or legislative framework
- Appropriate national or international standards
- Standards relevant to BTSs

Documentation

- Appropriate, comprehensive documents, including a quality manual and standard operating procedures (SOPs)
- Complete, accurate records
- System for controlling documents

Training

- Training policy and plan
- Training of all BTS staff in quality and quality systems
- Training of other health care professionals involved in blood transfusion
- Evaluation of training and its impact

Assessment

- Validation
- Ongoing data collection and analysis
- Haemovigilance
- Regular review of all activities
- Internal and external audits
- Error management, corrective and preventive action
- External quality assessment schemes

Key elements

Requirements for quality systems in blood transfusion

It is the responsibility of governments to ensure that the blood and blood products provided for clinical use by the national blood programme are safe, adequate to meet demand, effective and produced consistently to the appropriate standards.

To achieve this, the blood transfusion service must develop an effective quality system. This should provide a framework within which BTS activities are established, performed in a quality-focused way and continuously monitored to improve outcomes.

The establishment of a quality system will ensure the collection of adequate supplies of blood from regular, voluntary non-remunerated donors, the testing of all blood before use and the appropriate clinical use of blood.

Prerequisites for developing a quality system within the national blood programme include:

- Nationally-coordinated blood transfusion service
- Commitment and support of management at all levels
- Recognition of the importance of quality in the national blood policy

- National quality policy and quality plan detailing the strategy, mechanism and resources for their implementation
- Designation of a national quality manager with the necessary responsibility and authority for the development, implementation and monitoring of the quality system
- Provision of appropriate, adequate and sustainable resources to support the development and maintenance of the quality system.

Organizational management

Central to an effective quality system is commitment and support from management at all levels, including:

- Clearly defined organizational structure that defines accountability, authority and responsibility
- Designation of a quality manager, with the necessary skills and expertise, in each blood centre and hospital blood bank
- Formation of a quality section or identified work area in each blood centre and hospital blood bank from which quality activities can be coordinated
- Development of a culture of quality through a management focus on building quality into all activities
- Motivation of staff to ensure their commitment and support for the quality system
- Identification of specific processes and procedures and their critical control points.

Standards for quality systems

Relevant and appropriate standards are required to provide the framework for the development of the quality system:

- The existence of any relevant national legislation or regulations must be acknowledged and incorporated into the framework for quality
- Standards may be national or international: e.g. International Organization for Standardization (ISO) and Good Manufacturing Practice (GMP)

- The standards adopted must be relevant to the BTS and its activities.

Documentation

An effective and accurate documentation system that ensures traceability of all BTS activities is the foundation of good quality management.

Important activities include:

- Development of a quality manual: a document describing the quality system, including the organization's quality policy, standards and procedures
- Production and use of appropriate, comprehensive documents for all activities, including standard operating procedures, forms, labels and any other documents required
- Generation and maintenance of complete and accurate records
- Development of a system to manage the issue, use and retrieval of documents.

Training

Comprehensive, appropriate and effective training is required for all BTS staff and other health care professionals involved in blood transfusion.

Important activities include:

- Training policy and plan
- Training for all BTS staff in general principles of quality, the quality system, documentation and the use of quality monitoring tools

- Training programmes for other health care professionals involved in blood transfusion

- Clear understanding of the role of the individual in the quality system and the consequences of quality failures
- Ongoing monitoring and evaluation of training and its impact.

Assessment

Ensuring quality is a continual process. Ongoing assessment of the effectiveness of the quality system is essential through:

- Validation of all processes, procedures, equipment and reagents
- Ongoing collection and analysis of data generated from key activities and their use in quality improvement
- Establishment of haemovigilance through a system of monitoring, reporting and investigation of adverse incidents related to all blood transfusion activities
- Regular review of all activities to assess the overall effectiveness of the quality system and ensure continuous improvement
- Programme of regular internal and external audits of the quality system
- Reporting and analysis of errors with effective corrective and preventive action
- Active participation in appropriate external quality assessment schemes to improve laboratory performance.



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Appendix 8: Safe Blood Components, WHO Aide-Mémoire for National Health Authorities



World Health
Organization

Safe Blood Components

AIDE-MÉMOIRE

for National Health Authorities

Safe blood may be used most effectively if it is divided into components prepared from whole blood donations or obtained by apheresis procedures. One unit of whole blood can be used to meet the needs of more than one patient and provide only that component that is required. In addition, the availability of blood components enables the provision of therapeutic support for patients with conditions such as disorders of haemoglobin, coagulation and bone marrow.

An effective blood component programme requires a sustainable national blood programme, including a well-organized, nationally coordinated blood transfusion service (BTS), a stable base of suitable, voluntary non-remunerated blood donors, accurate testing systems, quality systems and a suitable regulatory mechanism. For this, the commitment and support of national health authorities and additional human, financial and technological resources are needed.

Requirements for a blood component programme include:

- Effective strategies for the recruitment and retention of voluntary non-remunerated blood donors, including apheresis donors, where applicable, to ensure a safe, adequate and reliable source of blood for component preparation
- Centralization or regionalization of blood processing and testing to permit economies of scale and uniform standards of performance
- Systems and standardized procedures for donor selection, blood collection, processing, testing, storage and transportation to ensure the consistent quality, safety and efficacy of blood components
- Training of BTS staff in all activities related to the provision of safe blood components
- Training in appropriate blood component therapy for staff involved in the clinical transfusion process.

Consideration should be given to the use of surplus plasma for the production of plasma-derived medicinal products through fractionation, utilizing facilities either within or outside the country.

Words of advice

- Assess the clinical demand for blood components and the feasibility of a component preparation programme
- Develop a programme that complies with regulatory requirements and is appropriate to the level of the health care system, including the diagnostic and medical services available
- Allocate adequate human and financial resources to ensure the sustainability of the programme
- Build a stable base of regular, voluntary non-remunerated blood donors to meet collection targets for blood components
- Consolidate blood processing and testing within major centres
- Strengthen the interaction between the BTS and hospitals and promote appropriate blood component therapy



Checklist

Organizational requirements

- Nationally-coordinated BTS with centralized/regionalized processing and testing
- Assessment of clinical demand and feasibility of blood component programme
- Adequate, sustainable finances
- Suitable premises, working environment and waste management system
- Appropriate infrastructure
- Suitable regulatory mechanism
- Sufficient number of trained staff
- Appropriate technology, equipment and materials for blood collection, testing and processing
- Effective quality systems, including standardized procedures and good manufacturing practices
- Documentation of all processes and accurate labelling

Blood donors and blood collection

- Panel of regular voluntary blood donors
- National criteria for donor selection and deferral
- Donor call-up and blood collection planned to meet component preparation targets
- Suitable blood collection bag systems

Component preparation, testing and distribution

- Specifications for blood components, equipment and materials
- System for quarantine, release and recall, including labelling
- Quality monitoring of blood components

Storage and transportation

- Correct storage and transportation of blood bags, donor specimens, collected units, blood components, reagents and materials
- Separate storage areas for untested, quarantined and available units
- Suitable temperature-monitored equipment

Blood component stock management

- Agreements between the BTS and hospitals on stocks, order and supply
- Monitoring and evaluation of availability, utilization and outdating of components

Blood component therapy

- Guidelines on use of blood and blood products
- Hospital transfusion committees
- Training of clinical staff involved in transfusion
- Accurate transfusion records
- Haemovigilance system
- Ongoing assessment of need for components

Key elements

Organizational requirements for an effective blood component programme

Before a blood component programme is established, a systematic assessment of its feasibility and scope is required. The scale and level of development of the programme should be determined by the clinical demand for components, including the availability of medical and diagnostic services, and the capacity of the BTS.

If the clinical demand for component therapy cannot fully be met from components prepared from whole blood, consideration might be given to developing an apheresis programme.

A blood component programme should be accessible and sustainable. The BTS should be allocated adequate financial resources to meet the additional costs of component preparation, including:

- Suitable premises that comply with good manufacturing practices

- Sufficient number of trained staff
- Specialized equipment for blood collection, processing, testing, storage and transportation and a preventive maintenance system
- Reliable supply of blood collection bags and reagents.

BTS infrastructural requirements include:

- Suitable working environment for donor selection, blood collection, processing, testing and storage
- Reliable water and power supplies with back-up systems
- Waste management system
- Reliable transportation systems
- Effective communication systems.

An effective planning and communication system should be established to set and evaluate targets for donor recruitment,

blood collection and component preparation.

A quality system should be in place in all areas to ensure good manufacturing and laboratory practices. This should include:

- Specifications for blood components, equipment and materials
- Validation of processes, procedures, equipment and materials
- Regular maintenance and calibration of equipment to ensure quality and minimize down-time
- Standardized procedures
- Hygiene and safety of environment, equipment, blood donors and staff
- Documentation of all processes and accurate labelling to ensure traceability
- Ongoing training of staff
- Monitoring of all activities to ensure continuous quality improvement.

Blood donors and blood collection

A reliable base of regular voluntary non-remunerated blood donors is a prerequisite for a safe and effective blood component programme that can meet the transfusion requirements of all patients. Effective donor recruitment, call-up and retention strategies are needed to promote regular donation by suitable donors. This requires:

- National donor selection and deferral criteria, including criteria specific to component preparation
- Mechanism for setting blood collection targets to meet component preparation targets and clinical demand.

Effective blood collection requires:

- Systematic planning and preparation for fixed and mobile sessions
- Planning of number and type of collections per session from whole blood/apheresis donors
- Appropriate staffing, equipment and materials, including blood bags.

Component preparation, testing and distribution

The centralization or regionalization of blood processing and testing in major centres permits more efficient, cost-effective use of technology and resources. It also facilitates uniform standards of performance, resulting in improved quality and safety.

Safe component preparation requires:

- Preparation of components only from whole blood or apheresis donors who meet standard selection criteria

- Testing of all donated units and discard of all blood and components that test positive for any transfusion-transmissible infection
- Quality system and good manufacturing practices for all aspects of component preparation and distribution
- Compliance with specifications for components, equipment and materials
- Labelling system for untested, quarantined and available stock
- Mechanisms for quarantine and release
- System for recall of defective components
- Cleaning and maintenance of all areas and equipment to minimize the risk of contamination of components
- Quality monitoring of components, including statistical process control.

Storage and transportation

Correct storage and transportation conditions are required at all times for blood donations and specimens, blood bags, reagents and other materials, especially in extremes of temperature. This entails:

- Storage and transportation of collected units and specimens to processing centres and testing laboratories within prescribed temperature and time limits
- Separate storage areas for untested, quarantined and available units
- Suitable areas and equipment for storage and transportation that meet specifications for time and temperature

- Monitoring and recording of temperatures in all blood cold chain equipment
- Corrective and preventive action in cases of deviation from specified temperature ranges and time limits.

Blood component stock management

Efficient stock management systems are needed in the BTS and hospitals, including:

- Formal agreement and ongoing communication between the BTS and hospitals on optimum stocks, order and supply
- Monitoring and evaluation of component availability and utilization, including shortfalls and outdated.

Blood component therapy

The optimum use of blood as a scarce national resource requires:

- National and hospital guidelines on the use of blood and blood products and alternatives to blood transfusion
- Hospital transfusion committees to develop local policies and guidelines, and monitor component utilization
- Training of clinical staff involved in the prescription and administration of components
- Accurate transfusion records to ensure the traceability of component usage
- Haemovigilance system for monitoring, investigation and reporting of adverse transfusion events
- Ongoing assessment of current and future clinical needs for components.