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

Manual for the Development of Safe and Sustainable National Blood Programs

2021

Overview

The safety and integrity of a nation's blood supply is fundamental to a secure health system. People in all communities 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 Organisation (WHO) advocates that Ministries of Health "have ultimate responsibility for ensuring an adequate supply of safe blood and blood products"[1], the International Federation of Red Cross and Red Crescent Societies (IFRC) expects its member National Societies that are involved in blood programs to meet these obligations to the community.

This manual 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 program and directs member National Societies to relevant resources on blood program management.

By developing this manual, GAP seeks to support National Societies to manage their involvement in blood programs 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 minimum requirements and international blood service standards that National Societies need to meet in order to maintain a blood program. It includes generic guidelines to assist them in assessing the risks of blood service provision, and in transitioning to a lesser involvement in blood program delivery if this is considered appropriate.

Ultimately, it is the responsibility of individual National Societies involved in blood programs to ensure they establish sound governance and that their programs 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.

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[1] Aide-Mémoire Developing a National Blood System. Geneva, WHO, 2011

Using this Manual

The International Federation's Blood Policy (Refer Appendix 4) 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 or who are involved in collection activities **(Category A)** should find all sections of the manual relevant.

National Societies that are involved in the systematic recruitment of voluntary blood donors **(Category B)** should 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).

For those National Societies involved only in promotion and advocacy of voluntary blood donation **(Category C)**, Chapter 3 on the fundamental principles underpinning involvement in blood activities will be of particular interest. Of note - for the purposes of this manual, any reference to voluntary blood donors or voluntary blood donation assumes the donation is non-remunerated.

GAP and the International Federation are mindful that member National Societies are at different stages of development in their blood programs and acknowledges their efforts to date towards meeting their obligations. This manual is intended to serve as a resource to assist member National Societies 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.

Disclaimer

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1. Introduction

The International Federation's mission is to improve the lives of vulnerable people by mobilising the power of humanity. The IFRC recognises that health security is fundamental to global, national and individual development and is committed to capacity building and promoting sustainability.[2] Priority goals in its Strategy 2030[3] are to ensure people anticipate, respond to, and quickly recovery from crisis; lead safe, healthy and dignified lives and have opportunities to thrive; and mobilise for inclusive and peacful communities.

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' Sustainable Development Goal 3: Good Health and Wellbeing[4].

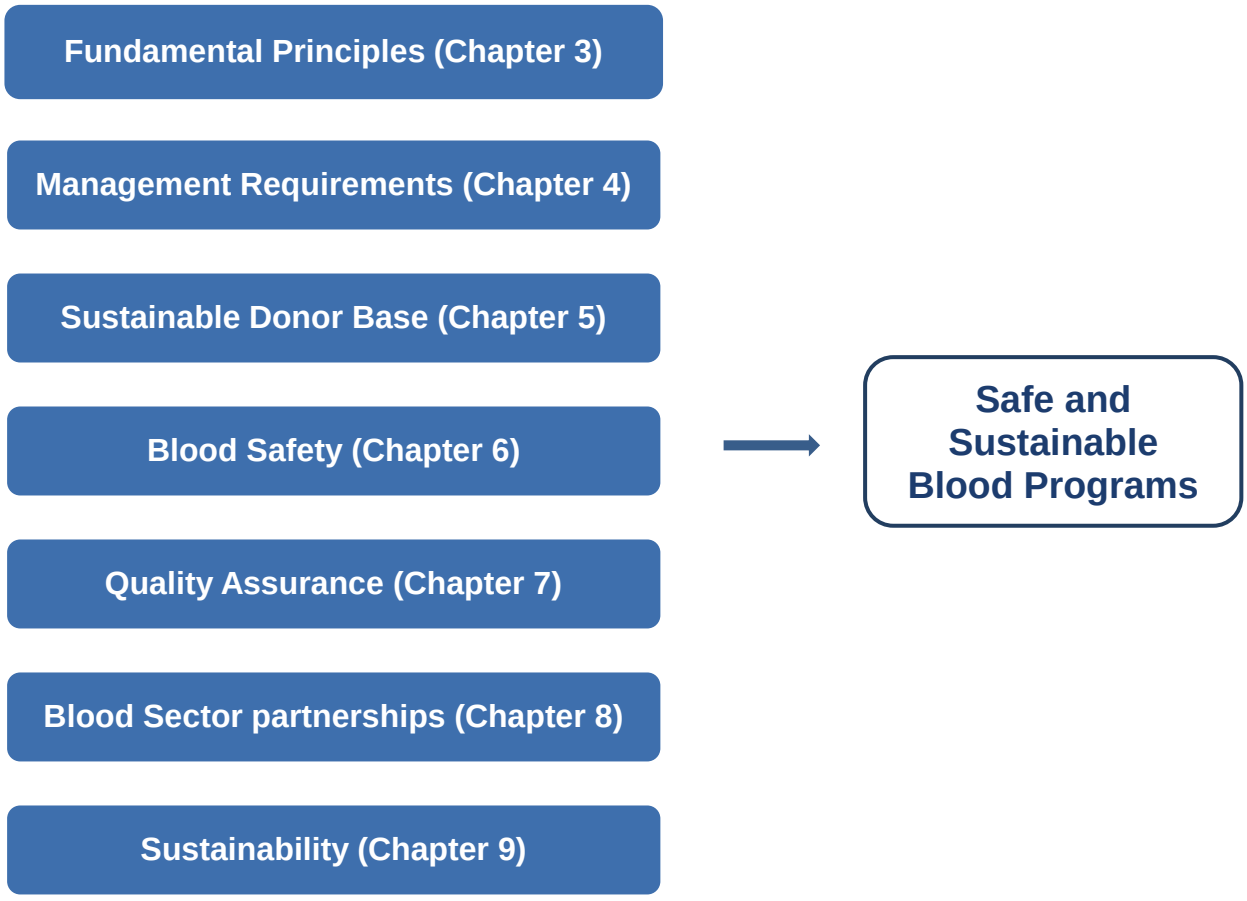
Recognizing that voluntary, non-remunerated blood donation (VNRBD)[5] provides the foundation for safe and sustainable blood systems, the International Federation has partnered with WHO to create a global framework for action for 100 per cent voluntary blood donation[6,7]. Approximately 60 nations, including 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 GAP supports the establishment of safe and sustainable blood systems through leadership, advocacy and guidance to National Societies and their blood programs. This manual has been developed by GAP with the assistance of IFRC's health department. Since its establishment in 2001, GAP has provided advice to member National 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 topics covered in this publication (Figure 1 below), 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] IFRC Strategy 2030. Geneva, 2020. IFRC.
[4] UN Sustainable Development Goal 3 https://www.un.org/sustainabledevelopment/health/
[5] "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
[6] 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.
[7] Towards 100% voluntary blood donation: A global framework for action. 2010. WHO and IFRC

Figure 1: GAP Manual Key Topics



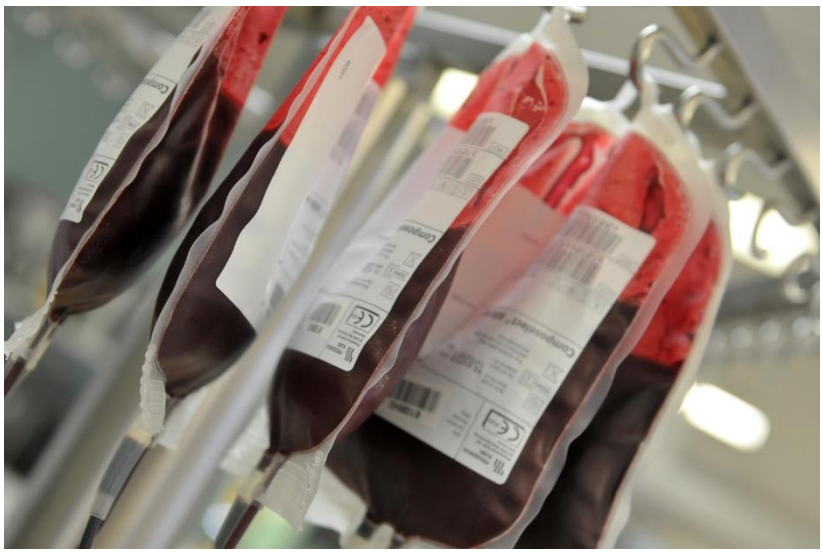


Photo courtesy of Australian Red Cross Lifeblood

2. Overview of National Society involvement in blood programs

2.1 Categories of National Society engagement

The extent of National Society engagement in blood programs ranges from non-involvement through to extensive responsibility for blood collection and supply – as demonstrated in figure 2 below.

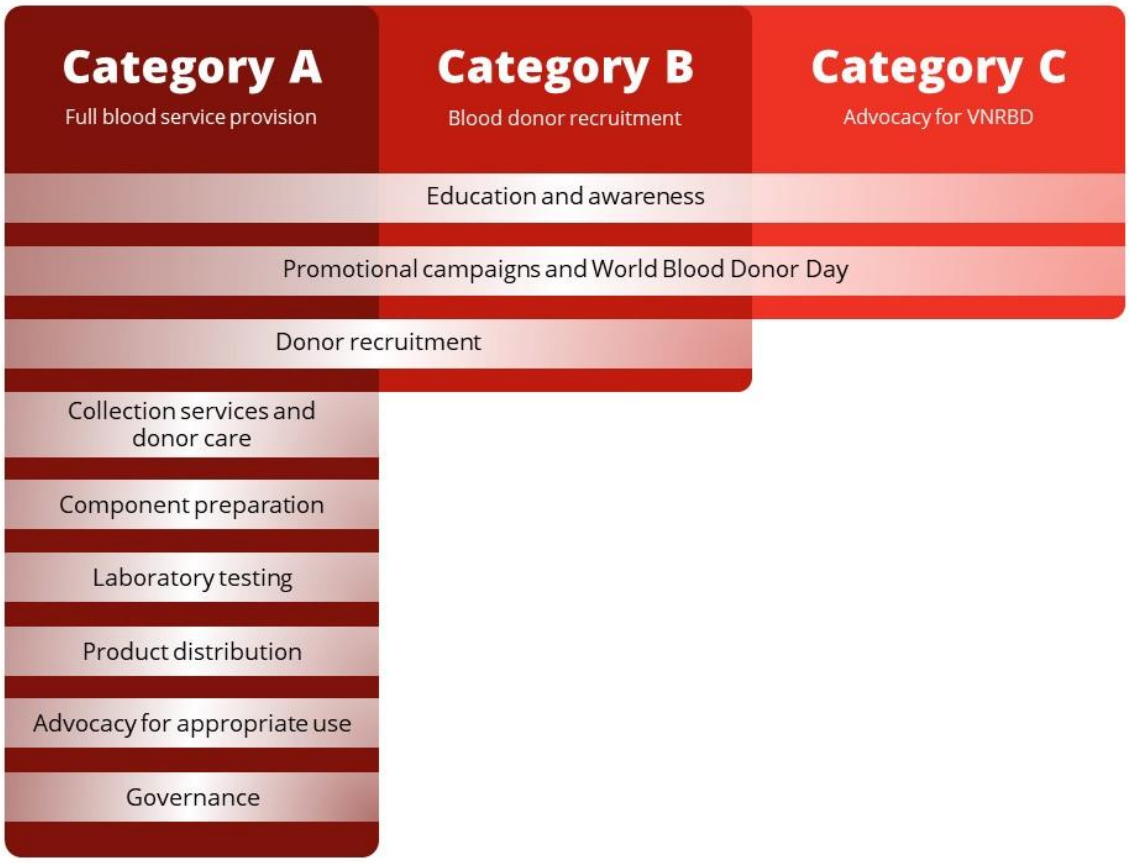


Figure 2: Categories of National Society Involvement in Blood Programs

Category A is full blood service provision, with the National Society responsible for donor recruitment, collection, testing, processing and distribution activities. These societies can reinforce positive attitudes to blood donation through excellent service, recognition and valuing of the donor gift. Category A National Societies require strong governance and risk management structures.

Note: Category A National Societies must also meet the requirements set out for Category B and C National Societies.

Category B National Societies support their domestic blood program and blood services by recruiting blood donors, with all donor collection and blood service provision activities being undertaken by a separate organisation or the government. These societies act in partnership with a blood service, actively promote non-remunerated donation, and motivate donors through information and recruitment campaigns. Category B National Societies must engage 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.

It is noted that while some Category B National Societies may predominantly focus on donor recruitment activities, they may also undertake some donor collection activities. In these cases, these National Societies are considered to be Category A National Societies and are therefore obligated to meet all the requirements for a Category A National Society in a careful and measured way.

Category C National Societies report they play a significant role in promoting VNRBD for blood programs in their countries and in generating positive attitudes to blood donation through volunteer networks, education programs and advocacy campaigns. All donor recruitment, collection and blood service provision activities are undertaken by separate organisations or governments. All National Societies are encouraged to be involved in Category C, if practicable and appropriate.

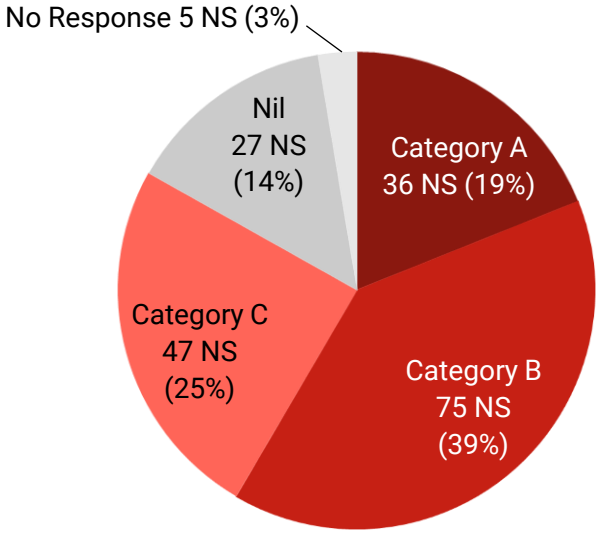


Figure 2: National Society Involvement in Blood Programs globally (total number 190). Source - 2018 GAP Global Mapping Report[8]

Nineteen percent of National Societies have some responsibility for blood service delivery in their national blood programs, while 64 percent are engaged in either systematic blood donor recruitment activities or advocacy and promotion of VNRBD.[8]

Most National Societies are well suited to contribute towards *motivating* the community to donate blood, for example, through education programs and advocacy campaigns. Feedback from many governments suggests that support for their blood services from a National Society and its volunteers in this area can be of great assistance. GAP regards this level of involvement as presenting the lowest risk for any National Society. The greater the level of engagement and responsibility that National Societies have in relation to blood programs, the more extensive their governance requirements, obligations and level of risk.

Regardless of their category of engagement in blood programs, National Societies are cautioned against any expansion of their existing activities unless they have received approval from the appropriate government authority, and have sufficient resources, capacity and expertise to do so.

[8] www.globaladvisorypanel.org/about-gap/activities/global-mapping

Should National Societies wish to move between categories, undertake more extensive involvement in donor recruitment, or significantly increase or reduce their involvement in Category A activities, **it is recommended that advice be sought from GAP at the outset**. Considerations include the capacity of a National Society to undertake additional blood program activities, the provision of sufficient government funding, access to suitable training and personnel, appropriate governance structures and risk management expertise.

To assist National Societies in understanding the extent of their commitment and the associated requirements, an overview of recommendations for each category of engagement in blood program activities is provided in Appendix 1. A list of the minimal conditions recommended for undertaking a National Society blood program can also be found in the GAP Self-Assessment under Key Issue 1: Minimum Conditions.[9]

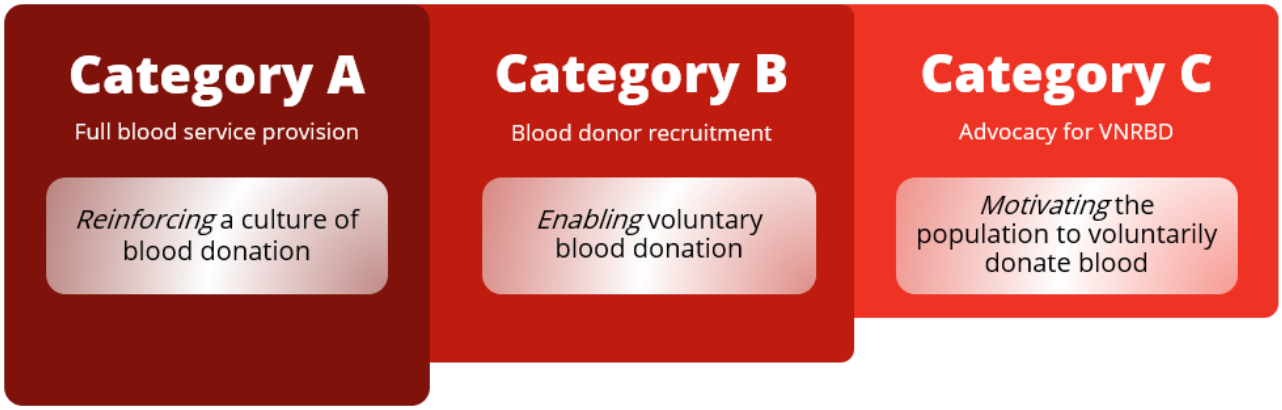
[9] GAP Self-assessment questionnaire, http://globaladvisorypanel.org/resources/Self-Assessment, GAP, 2021

2.2 Promoting a safe and sustainable blood system through VNRBD

All National Societies, irrespective of whether they are directly or indirectly involved in the administration of their national blood programs, 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 programs (Category 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 programs supported by the International Federation and its member National 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 (Category B) can further build participation in voluntary blood donation through campaigns and providing access to donation centres. Those extensively involved in blood services (Category 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 programs adhere to and promote the Fundamental Principles of humanity, impartiality, neutrality, independence, voluntary service, unity and universality.

These principles are reflected in the following commitments that underpin safe, equitable and sustainable national blood programs. National Societies should also comply with the International Society of Blood Transfusion (ISBT) *Code of Ethics for Blood Donation and Transfusion* (2017), which has been adopted by WHO (refer Appendix 4).

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) resolution[10] 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.[11] 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.[12] 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 programs aimed at recruiting and retaining voluntary blood donors from low-risk populations. Countries continue to work hard to make the transition from paid and family replacement donation to VNRBD and, as illustrated in figure 3 below, have made good progress in increasing the number of annual VNRBD, however increasing demand has meant that the overall rate of VNRBD has not increased.

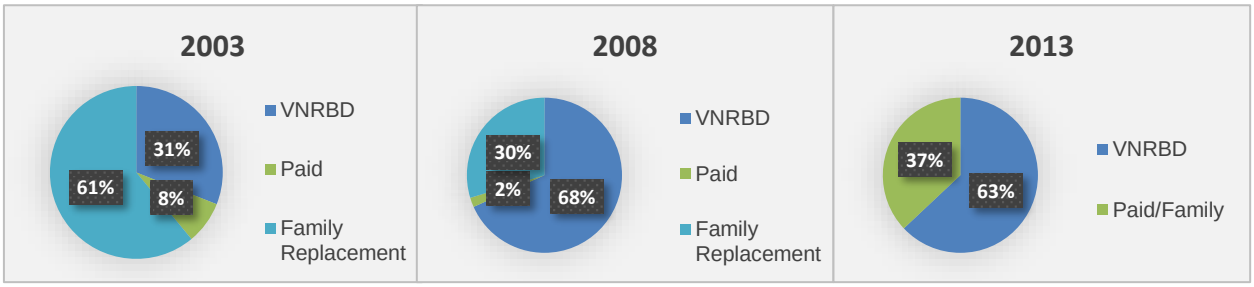


Figure 3: Developing (Low HDI) Countries' Progression towards VNRBD (WHO Global Database)

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

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

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

In countries where family and replacement donors account for a significant proportion of the donor base, an effective strategy to build a sustainable voluntary donor base may be to advocate to safe (transfusion transmissible infection negative) family and replacement donors on the need for an ongoing supply of safe blood and retain these donors as regular voluntary donors. This can be achieved by addressing the three fundamentals for donor recruitment.

Further information can be found at www.globaladvisorypanel.org/activities/vnrbd.

Figure 4: Three fundamentals for a blood donor recruitment program

3.2 Ensuring safety for donors and recipients

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 through:

☑ Recruitment focused on attracting low-risk donors,

☑ Effective donor screening and deferral processes.

☑ Appropriate donor welfare including donor health and counselling.

☑ Safety and quality processes for blood and blood components including

- 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.[13] Access to safe blood for all patients reduces morbidity and mortality, supporting the International Federation's global agenda goals and the UN Sustainable 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 percent 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.[13] 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.[13]

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 and 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 regular, voluntary and 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 program activities. Engagement in blood services and promotion of safe blood donation provides tangible and 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 program 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), 2017.

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

4. Blood program management

4.1 Organisational models

Key GAP recommendation - where possible, National Society blood programs should function under a nationwide operational model in which district and regional services form part of a central blood service managed by a national blood service director.

Blood programs can be national, regional or hospital-based. National Societies can range from being the sole provider of the national blood program 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.[14]

In the absence of national standards, GAP recommends that relevant internationally recognised standards should be applied. Standards for use in resource limited settings are available and NS should contact GAP for further information and advice on this.

WHO recommends that a national blood system should be organised and coordinated to ensure the most efficient and cost-effective use of all resources[15]. Blood transfusion services should be coordinated at national, regional and provincial levels, with critical activities such as blood screening and processing consolidated in strategic locations[15].

- ☑ 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.

Whatever model is used, it is important that the blood service has a clear organisational structure, and that the roles and responsibilities at the national, regional and district levels (if applicable) are clear, and accountabilities between the different levels, if any, are clearly defined.

The blood service 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 organisational policies and procedures in line with national regulations.

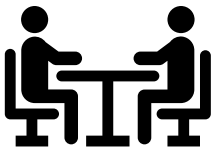
Individual Blood Transfusion Services (BTS) should be structured, staffed and managed in accordance with national regulations with suitable medical, technical and quality processes for the provision of safe blood and blood components to patients.

[14] Aide-Mémoire: Safe Blood Components. Geneva, WHO, 2005

[15] Aide-Mémoire: Developing a National Blood System. Geneva, WHO, 2011

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 reagents[14]



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

Resources

- Aide-Mémoire: Safe Blood Components, Geneva, WHO, 2005
- Aide-Mémoire: Developing a National Blood System, Geneva, WHO, 2011
- GAP Self-Assessment Category A

4.2 Governance

Key GAP recommendation - National Societies delivering blood programs should establish a separate, professional board that comprises members with blood sector, clinical and business management experience.

National Societies are expected to apply principles of good corporate governance in respect of their blood programs. Blood program management is complex and requires specialist medical, technical, and financial expertise.

The separate board should have delegated responsibility to govern the blood program, including the appointment of the director of the blood program and authority over dedicated blood program resources. There should be clearly defined roles and accountability between the blood service director and the blood service board. The chair 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 accordance 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 program and develop succession planning
- ☑ ensure that the blood service has appropriate interaction with external stakeholders

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.

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 blood service board and the National 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 Category A.

4.3 Corporate management

Key GAP Recommendation – that the roles and responsibilities of the National Society and the blood service are discussed and clarified, and then documented and respected.

Specifically:

- ☑ That National Society blood services have a separate corporate structure for the administration of the blood program, including an independent budget.
- ☑ 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 organisation and its activities. Blood service staff should have the appropriate experience and training for their positions.[16]
- ☑ A clear vision and mission should be in place for the blood service or blood donor recruitment program 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 these remain relevant.

Resources
GAP Self-Assessment Categories A and B.

[16] Aide-Mémoire: Blood Safety. Geneva, WHO, 2002

4.4 Financial management

Key GAP Recommendation – that National Societies involved in blood programs of any category should develop and implement a financial management system, with blood program activities appropriately costed, effectively managed, and supported by government to ensure the ongoing financial sustainability of their blood program.

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.[16] 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 program activities.

The WHO and IFRC Global Framework[17] provides National Societies operating Category B or C blood programs (recruitment and motivation only) with information and action points to secure sustainable financing for their blood programs. National Societies operating at Category 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 regarding the cost to safely collect, process, test and distribute 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 fully support the seemingly high cost of blood.

It is very important that National Societies actively engage and advocate with funders on the issue of sustainable blood service funding either through cost recovery or annual budget allocation. Additionally, they must ensure that both capital and recurrent costs[18] are included, and that the financial model[19] allows 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.)

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 also recommended that there should be a dedicated resource person (chief financial officer) for blood service financial management who is accountable to the blood program 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

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

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

[19] The WHO Blood Costing Model is an example of a tool that can be used by National Societies with full blood programs for costing their blood services. Costing Blood Transfusion Services. Geneva, WHO, 1998

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

4.5 Risk management

Key GAP Recommendation - that National Societies consult with local legal experts to clarify the risk management benefits of securing government assurance for its blood program 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.

There are inherent risks in collecting and supplying blood and blood components. Blood services need to ensure the health of donors, manage the risk of transfusion-transmitted infection and other transfusion-related complications, ensure blood and blood components are stored and handled appropriately and 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 blood program delivery risks results in improved outcomes for donors and 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 (Category A) and VNRBD recruitment (Category B) can be found in Appendix 2, and a full checklist can be found in the GAP Self-Assessments.

It should be recognised, 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.

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[20]. These recommend a **risk management framework** that integrates risk management into the culture of the organisation, including governance, planning, decision-making and reporting.

A **risk management framework** promotes understanding of the context in which the organisation operates, sets out a risk management policy and processes to address and manage risk, and assigns 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. A risk matrix can then be developed to categorise risks, and criteria agreed for which type of risk would need to

[20] International Standard ISO 31000 Risk Management — Principles and Guidelines. International Organisation for Standardisation (ISO), 2009. Available from the ISO web site, www.iso.org

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 organisational 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.

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.

The GAP Self-Assessment questionnaire enables National Societies to ascertain:

- ☑ 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. 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 in all Categories of blood program activity. Participating Category A blood services receive an individual feedback report from GAP that analyses their Self-Assessment results and provides them with specific risk management recommendations. Depending upon the number of Self-Assessments received by GAP, blood services may receive an additional report comparing their Self-Assessment results with those of other Category A blood services in their region. Category B National Societies may complete the Self-Assessment and receive a feedback report upon request, according to 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.

GAP endeavours to respond to the many requests for corporate governance and risk management assistance received from National Society blood services. Specific technical support is provided as resources allow; those seeking assistance should first contact the GAP secretariat to discuss what assistance is required.

Resources

- GAP Self-Assessment, Category A, B and C.
- 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 rather than waiting 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, considering 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 Category A, B and C.
- Aide-Mémoire: Good Policy Process for Blood Safety and Availability. Geneva, WHO, 2008

5. Building a sustainable donor base

The capacity of a blood program to provide sufficient blood and blood products is ultimately determined by the availability and commitment of healthy, regular VNRB 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 positive, long-term relationships with donors that recognise their commitment, promote good donor health, foster repeat donations and encourage referrals of colleagues, family and friends.

5.1 Voluntary, Non-Remunerated blood collection

Key GAP recommendation – that National Societies involved in blood programs in any Category base their program on the achievement of 100% VNRBD.

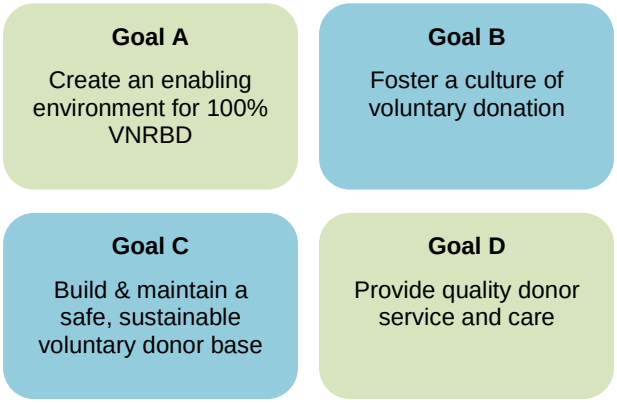
Voluntary, non-remunerated donors who regularly give blood are the foundation of a safe and adequate blood supply. Blood collection from well-selected voluntary donors from low-risk populations provides the first line of defense in minimising the risk of transfusion-transmitted infection.[21]

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.[22]

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 programs internationally.[22] The global framework outlines strategies for progressing towards this goal in each of the areas illustrated in the figure.



[21] Screening Donated Blood for Transfusion-Transmissible Infections. Geneva. WHO, 2009, p. 6.

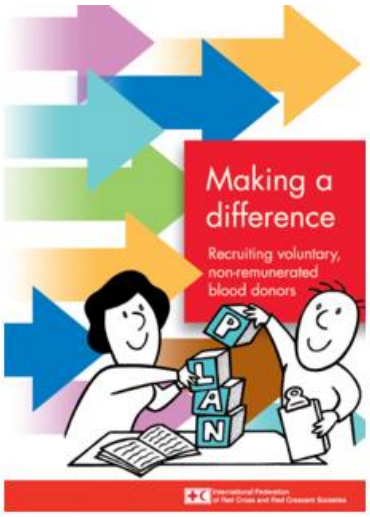
[22] Towards 100 per cent voluntary blood donation: A global framework for action. Geneva, WHO/IFRC, 2010, p. 14.

5.2 Attracting and Retaining Donors

Key GAP recommendation - that blood services appoint an officer responsible for the national blood donor program to lead a group trained in relevant aspects of donor education, motivation, recruitment and retention

To provide for even the most basic blood supply requirements a country needs at least 1 percent of the population to donate, with requirements in most countries far exceeding this.[23] 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.[24]

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.[25]



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 programs, recruiting and retaining target groups, engaging young people, approaches to quality service provision, and national and global partnerships in support of donor recruitment.

Resources

- Blood Donation Training Program E-learning, IFRC Learning Platform 2019
- 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

[23] Towards 100 per cent voluntary blood donation: A global framework for action. Geneva, WHO/IFRC, 2010, p. 10.
[24] Aide-Mémoire: Safe Blood Components. Geneva, WHO, 2005
[25] 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
- ☑ 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

Key GAP recommendation - that blood services 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
- ☑ providing post-donation information, counselling and referral when appropriate[26]

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 victimisation from their community.

Minimum checklist for blood donor counselling:[26]

- ☑ 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.
- ☑ 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.

[26] Blood Donor Counselling Implementation Guidelines. Geneva, WHO-CDC-IFRC, 2014

- ☑ 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. Where possible, refer to external provider for confirmatory testing.

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

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

6. Blood Safety

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 programs to minimise 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 un-disclosed risk factor. Finally, donated blood is laboratory tested for markers of TTI prior to release.

Blood Safety strategies should include 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

Key GAP recommendation - that blood services develop and implement an overall blood safety screening strategy to manage blood safety and specifically reduce the risk of TTIs, ensuring the provision of safe blood to the community.

Minimum checklist for blood safety screening strategy:

- ☑ Be consistent nationally and described strategy in national policies and regulations.
- ☑ Reflect international good practice (WHO, Council of Europe, AABB etc.) and consider 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 Program Implementation

The effectiveness of the screening strategy depends upon the consistent implementation of all aspects of the strategy into blood programs at the local level.

Minimum checklist for screening strategy:

- ☑ 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 programs are operated within the context of a well-supported and well managed quality system.
- ☑ The screening program incorporates all blood screening requirements specified in country-specific regulations/standards (where these exist) or other internationally recognised 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 blood components, human tissues and human cellular therapy products. Canberra, Therapeutic Goods Administration, 2013
- 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. World Health Organisation (WHO), Council of Europe, AABB guidelines) as well as national and local epidemiological data on infectious diseases, prevalent risk behaviours and other local variables[27].

The donor questionnaire must be designed to obtain the donor's medical and travel history, and any behaviours that may result in an 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.

b.) Laboratory screening of blood donations

Testing for markers of transfusion-transmissible infections:

The blood screening program 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 *tremonema 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.

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

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 program 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, HTLVI/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 stigmatisation may undermine the development of a base of regular VNRBD donors, all of which can adversely affect the sustainability of the blood program[28]. Post donation screening (as per the minimum screening requirements) is essential to allow release labeling of the final product.

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 considered 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.

[28] Screening donated blood for transfusion transmissible infections. Geneva, WHO, 2009, section 5.8

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

Key GAP recommendation - that the blood screening program is supported by, and operated within a well-managed quality system.

Quality system oversight of the screening program 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 (e.g. from national reference laboratories)
- ☑ the participation in independent quality assurance panels.

Quality systems are discussed in further detail in Section 7.

6.2.6 Result, donor and product management

Key GAP recommendation - 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.

Only blood donations that have been screened and found negative for TTIs are suitable for release for supply and ultimately transfusion. 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 management[29].

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.

[29] Safe management of wastes from healthcare activities. Geneva, WHO, 1999

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).

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

Key GAP recommendation - 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.

7. Quality management

Key GAP recommendation - 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:

1. The Quality System
2. Good Manufacturing Practice
3. 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 consider the structure, needs and capabilities of the blood service.[30] It should be guided by a quality policy (preferably national) and operate under the direction of a national quality 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 Organisation for Standardisation's ISO 9001 Standard which is generic to all industries. The AABB, the African Society for Blood Transfusion, 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, and works towards obtaining a third-party accreditation.

[30] Aide-Mémoire: Quality Systems for Blood Safety. Geneva, WHO, 2002

A starting point for National Societies yet to implement standards and achieve accreditation is to adopt existing standards such as the AABB Fundamental Standards or the African Society for Blood Transfusion Stepwise Standards. These provide the minimum requirements for a blood service, with the view that the blood service would progress to implementation of full standards at a future point, when resources allow.

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.
- 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
- AABB Fundamental Standards
- African Society for Blood Transfusion Stepwise Accreditation Programme Standards
- Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular therapy products. Canberra, Therapeutic Goods Administration, 2013

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:

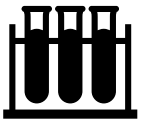
☑ **Implementation (or introduction) of a quality system:** Quality system structures and procedures should be in place and a quality manager who is independent of the manufacturing process should be appointed.

☑ **Monitoring the effectiveness of the quality system:** An internal audit program 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.

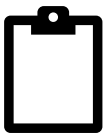
☑ **Staff training and performance:** Staff should be trained in and be able to follow the quality system requirements and GMP principles applicable to their role, and their work performance evaluated regularly. This should be documented and the records should be made available to staff and for audit 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 organised 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 program 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 program 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.

Resources: As per Section 7.1, plus:

- WHO Guidelines on good manufacturing practices for blood establishments. Geneva, WHO, 2011
- 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 and Accreditation

Key GAP recommendation - 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 be existing industry standards or locally developed.

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. Category A National Societies are encouraged to be working towards accreditation status, provided by an appropriate third party.

Suitable existing industry standards include: the AABB *Fundamental Standards or Standards for Blood Banks and Transfusion Services, African Society for Blood Transfusion Stepwise Standards* or Council of Europe *Guide to the preparation, use and quality assurance of blood components*.

In the absence of country specific technical standards please contact GAP for advice on relevant internationally recognised standards.

Resources

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

7.4 Auditing

Key GAP recommendation - An internal audit program should be established to periodically review the operation and effectiveness of the quality system.

The audit program 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.

8. Partnerships

The UN Sustainable Development Goal 17 states that "a successful development agenda requires inclusive partnerships – at a global, regional, national and local levels"[31]. There are limits to the capacity of individual organisations 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 program. WHO recognises 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 non-governmental blood service organisation, governments should provide effective leadership and governance and sufficient resources to establish and maintain a sustainable national blood system[32].

This should include:

- ☑ providing adequate financial resources with which to develop and maintain a viable blood program
- ☑ formalising government support and commitment to the blood program
- ☑ 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 emphasises the principle of VNRBD[33]
- ☑ 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 commission[34] or national blood authority with executive functions.[35]

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 agreement[35] 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 program.

[31] Sustainable Development Goals 2015 United Nations. https://www.un.org/sustainabledevelopment/globalpartnerships/
[32] Aide-Mémoire: Developing a National Blood System. Geneva, WHO, 2011
[33] Processes for effective blood policy and policy considerations are outlined in Aide-Mémoire: Good Policy Process for Blood Safety and Availability. Geneva, WHO, 2008
[34] Aide-Mémoire: Blood Safety. Geneva, WHO, 2002
[35] Aide-Mémoire: Developing a National Blood System. Geneva, WHO, 2011

National Societies and their blood services have a responsibility to practice humanitarian diplomacy[36] 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 appropriately funding and supporting the national blood program.

National Society communications and interactions with government should stress the need for a national policy of VNRBD, action to minimise 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[37]).*

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 program activities, particularly with regard to 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 program first contacts 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

8.2 Community Engagement

Blood services are encouraged to engage with government health, education and community agencies, the media, other voluntary and educational organisations and the business community in promoting VNRBD and community support for the national blood program. 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

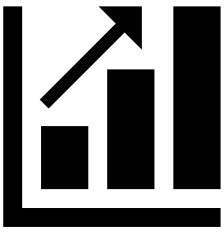
- Towards 100 per cent voluntary blood donation: A global framework for action. Geneva, WHO/IFRC, 2010

[36] IFRC Humanitarian Diplomacy Policy, adopted by the 19th session of the IFRC Governing Board in Paris, May 2009.
[37] Aide-Mémoire: Developing a National Blood System. Geneva, WHO, 2011

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, and manage known and emerging risks. 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 recognise that there are significant benefits in engaging in blood sector networks. These benefits include supporting performance improvement and operational efficiency through benchmarking, the exchange of knowledge and information, and the development of consistent policies, standards and processes across countries and regions. Networks may be international or regional, wide-ranging in their focus or tailored specific to an area of blood operational focus. Blood sector networks also provide additional assistance when responding to an emergency or local disaster event.



Benchmarking operational performance against other comparable blood services supports the identification of best practice, and continuous improvement opportunities. It also identifies partner blood services to assist with making local changes.

Exchanging knowledge and information supports local decision making and policy setting, through recognition of how others have approach similar decisions, or a collaborative approach to forming policy in response to a common area of focus.

Examples of existing regional and international blood sector networks include the following: Alliance of Blood Operators (ABO), European Blood Alliance (EBA), Asia-Pacific Blood Network (APBN), Asian Association of Transfusion Medicine (AATM), AABB, African Society for Blood Transfusion (AfSBT), ISBT, International Plasma Fractionation Association (IPFA), International Haemovigilance Network (IHN), International Society of Thrombosis and Haemostasis (ISTH), and International Federation of Blood Donor Organisations (FIODS).

8.4 Hospitals and Clinicians

Key GAP recommendation - that blood services have in place formal agreements for the supply of blood to hospitals.

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.

The formal agreements should include provisions such as:

- ☑ a commitment from the hospital that it adheres to WHO recommendations on the clinical transfusion process and patient safety[38] and PBM,[39]
- ☑ the appropriate levels of stock,
- ☑ systems for ordering and supply,
- ☑ monitoring and reporting of appropriate use, wastage and expiry, and
- ☑ 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 minimising wastage from 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 Programs (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. Category B and C National Societies could also focus on hospitals and clinicians in their advocacy efforts to change family replacement donation to 100 percent VNRBD.

[38] Aide-Mémoire: Clinical Transfusion Process and Patient Safety. Geneva, WHO, 2010

[39] Aide-Mémoire: The Clinical Use of Blood. Geneva, WHO, 2004

Resources

- Aide-Mémoire: Clinical Transfusion Process and Patient Safety. Geneva, WHO, 2010
- Aide-Mémoire: The Clinical Use of Blood. Geneva, WHO, 2004
- 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

GAP supports cooperation between National Societies involved in blood program 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. GAP's Regional Coordinators can also provide advice to National Societies seeking priority assistance with the organisation of their blood program.

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

The International Federation encourages National Societies involved in donor recruitment to share their experiences; some regions hold regular meetings for National Societies involved in blood program activities, including VNRBD recruitment. National Societies should contact GAP or their IFRC Regional Office for more information.

9. Sustainability

9.1 Adoption of New Technologies and Practices

Key GAP recommendation - that Category A National Societies leverage knowledge exchange and shared learning opportunities with other blood services for identification of best practice opportunities in blood management, testing, manufacturing and distribution.

Blood services benefit from shared learning with other blood services. This includes evaluation 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 standardisation, 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 minimise 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

Key GAP recommendation - National Societies should have in place a disaster management plan to ensure the ongoing availability and supply of blood in a disaster situation, including protocols for:

1. Including blood in the IFRC / NS appeal if the blood service is affected by a disaster,
2. A protocol for the affected NS to contact GAP and the IFRC for assistance if required

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 may 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 details.

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, and
- ☑ 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 and collecting convalescent plasma in the context of the COVID-19 pandemic. WHO, Feb 2021
- Pandemic Influenza Planning for Blood Organisations. European Blood Alliance Emergency Planning Action Group, 2009
- Disaster Operations Handbook: Coordinating the Nation's Blood Supply during Disasters and Biological Events**.** AABB, 2008.
- 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 minimise 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.[40]

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 minimise 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, and
- ☑ communicate the environmental policy and environmental requirements to contractors and suppliers and seek to influence, as far as possible, their environmental practices.

Resources

- ISO 14000, Environmental Management. ISO, 2007.
- Safe management of wastes from healthcare activities. Geneva, WHO, 1999
- Aide-Memoire: Safe health-care waste management. Geneva, WHO, September 2000

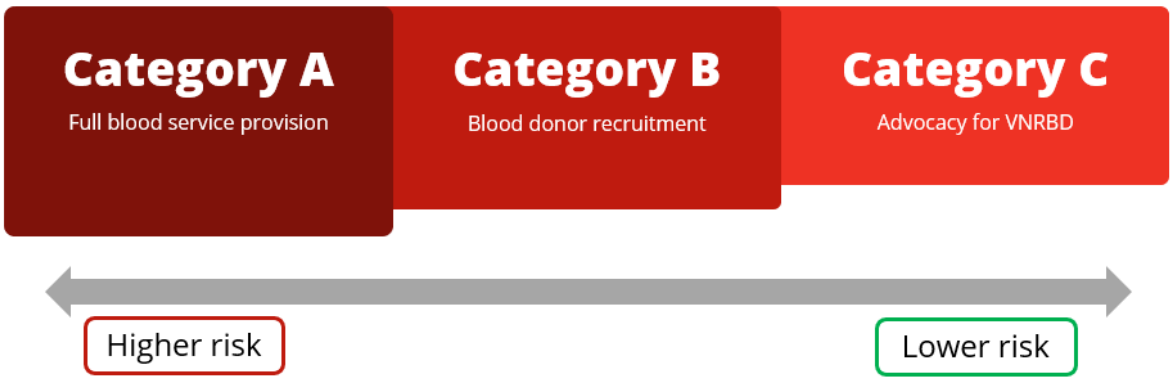
[40] See IS web site, www.iso.org.

10. Transition and exit strategies

Key GAP recommendation - National Societies that are considering either building their capacity and ability to operate their blood service in a safe and sustainable manner or withdrawing to a lesser involvement in blood activities are encouraged to contact GAP for advice.

As previously highlighted, involvement in blood service delivery (Category 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.

If a National Society involved in a blood program determines that it has insufficient capacity to manage the associated risks, or if the government is prepared to take over the blood program, it could consider reducing its level of involvement in blood activities, as in the diagram below.



Decisions to reduce involvement in blood programs 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.

Likewise, National Societies who are considering increasing their level of activity, for example, Category B Societies who may want to commence blood collection must carefully consider and mitigate the risks associated with becoming a Category A society and are encouraged to contact GAP for further advice and support.

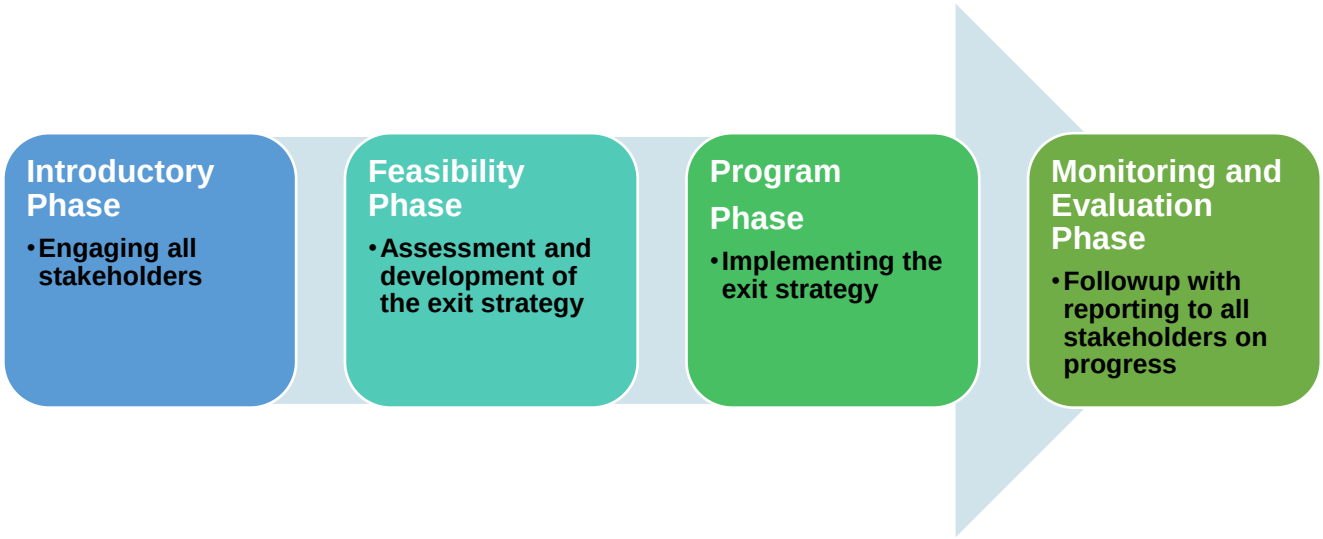
It is important that the National Society engages key stakeholders (the government, the International Federation, WHO, GAP and others) before it initiates action to exit from its blood service. The result of the negotiations might be that an alternative provider is identified, making it easier for the 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 GAP or WHO, the blood service can improve its operations to meet the required standards and remain the national blood program provider.

The following pages (Exit Strategy Framework) present generic guidelines for blood service National Societies contemplating a transition from Category 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 program. Blood services cannot function effectively without adequate financing and appropriate infrastructure. GAP can provide guidance to National Societies when engaging with government and other stakeholders regarding the extent of their involvement in blood program 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.

Introductory Phase

Objective: To facilitate the gradual implementation of an exit strategy by consulting key stakeholders and identifying requirements for effective transition.

Activities:

1. Hold **discussions** between the:
   a. National Society blood service and the ministry of health, and
   b. National Society blood service, the ministry of health and the appropriate GAP Regional Coordinator (focal point), if necessary.
2. Share information arising from the **GAP Self-Assessment report**.
3. Clarify the **new role** of the National Society (Category B or C).
4. Discuss **options** and a **time frame** for the exit strategy/change plan (recommended minimum of two years).
5. 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.

Feasibility Phase

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.

Activities

1. 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).
2. The project team (including government authorities) should develop a project/exit plan that ensures:
   a. A clear **governance regime** for the handover, and for **each area** of blood service operations the following are identified:
      i. *what* is required to properly effect a handover,
      ii. *who* is responsible,
      iii. *how* those tasks will be done by the responsible party, and
      iv. *when* those tasks will be done by the responsible party.
   b. The following are incorporated as areas for attention (as applicable):
      i. **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.
      ii. **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.
   c. The **safety** of blood donors and recipients through the application of the **fundamental principles** of VNRBD and equity in access to blood and blood products (see Section 3).
   d. The **integration** of international standards in quality assurance and good manufacturing practice (GMP) (see Section 6) into **national regulations** as recommended by WHO.
   e. **Blood donors** are aware of and **confident** in the transition process, so they continue to donate blood.
   f. A **costing analysis** is completed to ensure that the future blood program operation is **financially sustainable** (see Section 4.4).
   g. Appropriate **compensation** is given to the National Society for **transfer of any assets.**
   h. **Risks** are identified and managed throughout the process of transition and beyond (see Section 4.5).
   i. Sufficient resources are put towards **communicating** with government, key stakeholders (e.g. media, regulators, suppliers, hospital staff and clinicians), donors and general public.
   j. A contingency plan is in place to manage either:
      i. lack of preparedness to exit according to the initial time frame,
      ii. a local disaster which may result in the necessity to re-establish the National Society blood service temporarily to deal with the crisis.
3. Agree on a **Memorandum of Understanding** that clarifies each party's role and responsibilities subsequent to the handover (see Appendix 3).
4. **A GAP review[41] 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).

[41] Subject to the availability of resources

Program Phase

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

Activities:

1. Implementation of the project/exit plan and Memorandum of Understanding with scaling down of National Society involvement during the transition, ensuring:
   a. The **systematic transfer** of blood service functions and operational products and services.
   b. The establishment of **national regulations** for the blood program based upon international standards, if they are not in place already.
   c. Blood safety is maintained through the **application of quality assurance and GMP systems** (as per WHO recommendations).
   d. Progress is being made towards **100 per cent VNRBD.**
   e. Ongoing **collaboration** with partners, patient organisations, professional societies and other stakeholders to ensure supply plans are set up to meet the nation's need for blood.
   f. The supply of blood and blood products is on a **non-for-profit basis.**
   g. Changes and updates are **communicated** to stakeholders through key spokespersons.
   h. A system and process is established to manage the ongoing requirement for **donor lookback and counselling** once the exit is complete.
2. If withdrawing to Category B or C, in parallel, the National Society should consider:
   a. Appointing a **team** with a focus on **donor recruitment** or **community education** and setting up training programs based on:
      i. the IFRC toolkit *Making a difference…Recruiting voluntary, non-remunerated blood donors,*
      ii. the workshop materials compiled jointly by WHO and IFRC, entitled *DONOR,*
      iii. *Towards 100 per cent voluntary blood donation: A global framework for action, and*
      iv. the requirements and basic checklists found in this manual in Appendix 1.
   b. 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 recipients.[42]
   c. Providing ongoing **capacity building and mentoring** to the new blood service operator.
3. 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.

[42] 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.

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:

1. Report on **agreed targets** (e.g. blood donation, blood component production).
2. Review the new **system's impact**, if any, on wider health and care priorities (maternal health, child mortality).
3. **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.
4. Report back to **GAP** with full **'case study'** details for the benefit of other National Societies and ministries of health.
5. Conduct a **'Learning Review'** to identify what:
    a. was done well and would be done again
    b. was not done well and would be improved on next time

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

Appendices

Appendix 1: Checklists for Category A, B and C National Societies

Category A: National Society blood service checklist		
Level of Risk: High ***Refer to Chapter 4, Appendix 2 and the GAP Self-Assessment Category A***		
1. Fundamental Principles		
1.1	Adherence to IFRC blood policy and the minimal conditions described in the GAP Self-Assessment (Category A).	☐
1.2	The blood service is integrated as part of a national health policy and plan.	☐
1.3	The blood service operates under a quality assurance program and adheres to a national regulatory framework or, if necessary, an international regulatory framework[43].	☐
1.4	The blood service is based upon voluntary, non-remunerated blood donation.	☐
1.5	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.	☐
1.6	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).	☐
1.7	The blood service has a long-term and sustainable source of revenue.	☐
1.8	The blood service has sufficient facilities, supplies, equipment and trained staff and volunteers to meet operational and regulatory requirements.	☐
1.9	Training programs are in place to develop and maintain operational skills for all staff.	☐
1.10	The donor is treated ethically and his or her privacy and confidentiality are assured.	☐
2. Blood Program Management		
2.1	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.	☐
2.2	There is a well-defined system of delegation that provides clarity on authority and accountability between the: • National Society council and blood service board • Blood service board and blood service management	☐

[43] For example, the AABB's 'Standards for Blood Banks and Transfusion Services', or the Council of Europe's 'Guide to the preparation, use and quality assurance of blood components'.

2.3	A policy is in place to ensure there are no conflicts of interest for board members, senior staff and major suppliers.	☐
2.4	The blood service is under the direction of an appropriately qualified professional who has authority over the necessary resources.	☐
2.5	A separate corporate structure for the administration of the blood service has been established.	☐
2.6	There is a nationwide organisational model for the blood service.	☐
2.7	The blood service has a clear vision and mission, and a strategic plan that meets the needs of donors, recipients and clinicians.	☐
2.8	Performance goals and key performance indicators have been established to monitor progress against the strategic plan.	☐
2.9	Training programs are in place to develop and maintain management and leadership skills.	☐
3. Financial Management		
3.1	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.	☐
4. Risk Management		
4.1	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.	☐
4.2	Systems are in place to identify emerging threats to the safety of the blood supply relevant to the local environment.	☐
4.3	Mechanisms are in place for supporting recipients of infected blood, including record-keeping policies for potential future claims.	☐
4.4	If undertaking fractionation, the appropriate risk management measures described in the GAP Self-Assessment are in place.	☐
5. Donor care and counselling		
5.1	The health and well-being of the donor and recipient are paramount	☐
5.2	The blood service maintains donor records and a donor register.	☐
5.3	National donor selection and deferral criteria are defined and a deferral system relevant to the local environment has been implemented.	☐
5.4	A counselling system for donors, especially those that have been deferred, is in place.	☐
6. Blood Safety		
6.1	A national screening strategy is developed and implemented by the blood service that:	☐
6.1.1	reflects international good practice and considers local variables and national regulations;	☐
6.1.2	describes minimal requirements for pre-donation screening (including donor eligibility), laboratory testing and product management;	☐
6.1.3	ensures 100% of blood donations are tested and only those found negative for specified transfusion transmitted infections (TTIs) are released; and	☐

6.1.4	includes a system to manage the disposal of ‘at risk’ product in accordance with national regulations for bio-hazardous waste	☐
7. Quality Assurance		
7.1	The blood service adheres to a national regulatory framework, or there is national acknowledgement that an international regulatory framework (such as AABB, African Society for Blood Transfusion or Council of Europe) should be applied.	☐
7.2	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.	☐
7.3	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.	☐
7.4	Staff are continually trained in all aspects of quality assurance.	☐
8. Stakeholder Partnerships		
8.1	The blood service participates with government in the development of national regulatory standards.	☐
8.2	A system is in place for performing a cost-benefit analysis, with government, on all safety-enhancement proposals.	☐
8.3	The government is educated on the importance of adequately funding blood safety.	☐
8.4	A national system is established to report Haemovigilance/serious adverse events to the National Society blood program where a donor might be implicated. If there is no national system, hospital-based reporting should be encouraged.	☐
8.5	There are systems in place to educate the public on the safety of the blood supply and the risks of blood transfusion.	☐
8.6	Clinicians are educated on the appropriate use of blood and blood components, the risks of blood transfusion and relevant aspects of Patient Blood Management	☐
8.7	Hospitals are encouraged to develop a system that monitors and works towards reducing wastage and advocates appropriate blood product use.	☐
8.8	The blood service has formal agreements with end users (e.g. hospitals) on inventory holdings, ordering and supply systems.	☐
8.9	Hospitals are encouraged to set up multidisciplinary transfusion committees.	☐
8.10	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.	☐
9. Sustainability		
9.1	A clear disaster preparedness and contingency plan is in place.	☐
9.2	The blood service has an appropriate environmental and hazardous waste management policy.	☐
Key Resources for Category A blood programs – refer Appendix 4		

Category B:
National Society VNRBD recruitment program checklist

Level of Risk: Medium
Refer to Chapter 4, Appendix 2 and the GAP Self-Assessment Category B

1. Fundamentals		
1.1	Adherence to the IFRC's blood policy and the minimal conditions described in the GAP Self-Assessment (Category B).	☐
1.2	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 programs (see Category A information - Appendix 1).	☐
1.3	The blood donor recruitment program is based on VNRBD.	☐
1.4	Roles and responsibilities between the National Society and government have been clarified and there is a documented service agreement for VNRBD recruitment activities.	☐
1.5	A long-term and sustainable source of revenue for the donor recruitment program has been secured.	☐
1.6	The donor recruitment program is evaluated regularly to assess whether a) it is meeting demands or b) it is grossly exceeding requirements.	☐
1.7	The donor is treated ethically and his or her privacy and confidentiality are assured.	☐
1.8	The IFRC toolkit *Making a difference…Recruiting VNRBD* is used.	☐
1.9	Completion of the Online Blood Donation Training Program: Course 2 (volunteers) or Course 3 (staff), available on the IFRC Learning Platform (log-in/registration required): www.ifrc.org/learning-platform	☐
2. Blood Donor Recruitment Program Management		
2.1	There is a clear vision, mission and strategic plan for the donor recruitment program.	☐
2.2	Performance goals and key performance indicators have been established to monitor progress against the strategic plan.	☐
2.3	The program 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.	☐
2.4	The director organises, manages, trains, monitors and evaluates the staff, volunteers and procedures involved in blood donor recruitment and retention.	☐
2.5	Staff are continually trained in all aspects of blood donor recruitment and retention.	☐
3. Donor Care and Counselling		
3.1	A donor register and records are maintained.	☐

3.2	The National Society's donor recruitment and deferral practices reflect national donor selection and deferral criteria.	☐
3.3	Counselling for donors, especially those that have been deferred, is provided by the National Society or blood service, as appropriate.	☐
3.4	Good customer service and donor care is the responsibility of all staff members.	☐
3.5	Staff performance is subject to monitoring and evaluation.	☐
4. Promotion		
4.1	A community education program develops positive attitudes to VNRBD.	☐
4.2	Donor populations at low risk of transfusion-transmitted infections (TTIs) are targeted.	☐
4.3	The worth of blood donations and blood donors is recognised.	☐
4.4	The National Society works with clinicians (through education, awareness etc.) to promote VNRBD.	☐
5. Sustainability		
5.1	There is a risk management framework in place to identify, prioritize and manage risks relevant to the local environment.	☐
5.2	A clear disaster preparedness and contingency plan is in place.	☐

Key Resources

- IFRC Blood Policy Promoting Safe and Sustainable Blood Systems Policy. Geneva, IFRC, 2011.
- GAP Self-Assessment Category B.
- GAP VNRBD Resources
- IFRC Community-Based Health and First Aid: Voluntary Non-Remunerated Blood Donation primary Prevention Module (community awareness)
- Towards 100 per cent voluntary blood donation: A global framework for action. Geneva, WHO and IFRC, 2010.
- Making a difference…Recruiting voluntary, non-remunerated blood donors. Toolkit, Geneva, IFRC, 2008.
- Developing a Voluntary Blood Donor Program for Blood Safety (DONOR). Geneva, WHO and IFRC.
- Aide-Mémoire: Blood Safety. Geneva, WHO, 2002.
- Aide-Mémoire: Safe Blood Components. Geneva, WHO, 2005.
- Making the most of World Blood Donor Day**.** WHO/IFRC/FIODS/ISBT.

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

Category C:
National Society VNRBD motivation and advocacy checklist

Level of Risk: Low

1. National Society Expectations		
1.1	Bring to public attention the role of voluntary blood donors in meeting the needs of the most vulnerable.	☐
1.2	Undertake occasional, broad-based community education and awareness programs.	☐
1.3	Participate in World Blood Donor Day events (14 June).	☐
2. Basic Checklist		
2.1	National Societies involved in the occasional promotion and advocacy of blood donation should:	☐
2.1.1	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	☐
2.1.2	Remind its own membership about the need for securing a safe blood supply through voluntary and unpaid blood donation	☐
2.1.3	Have clarified its roles and responsibilities and those of other stakeholders in setting up viable youth donor programs, whereby youth assist by giving blood on a regular basis and also help with peer education in health promotion	☐
2.1.4	Explore with the government ways to phase out family replacement donation and move towards 100 per cent voluntary blood donation	☐
2.1.5	Completion of the IFRC Online Blood Donation Training Program: Course 1 (health delegates and volunteers), available on the IFRC Learning Platform (log-in/registration required): www.ifrc.org/learning-platform	☐

Key Resources

- *IFRC Blood Policy Promoting Safe and Sustainable Blood Systems Policy. Geneva, IFRC, 2011.*
- GAP Self-Assessment Category C.
- IFRC Community-Based Health and First Aid: Voluntary Non-Remunerated Blood Donation primary Prevention Module (community awareness)
- *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 and IFRC, 2010.
- *Developing a Voluntary Blood Donor Program for Blood Safety (DONOR).* Geneva, WHO and IFRC, 2010.
- *Making the most of World Blood Donor Day.* WHO/IFRC/FIODS/ISBT.

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

Appendix 2: National Society blood risk summary

There are a number of risk issues facing Category A and Category B National Societies. For a full list of risk management recommendations, please refer to the GAP Self-Assessment questionnaire.

Main risks for National Society blood services (Category A)	
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 organisation

Main risks for National Societies involved in blood donor recruitment (Category B)	
Risk issue	**Consequence**
Lack of 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.
Inadequate knowledge of the criteria for blood donor selection	There is a risk of mobilising groups of people, some of whom may not be eligible to donate blood, which could result in the National Society being criticized as unprofessional
Inappropriate 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 (VNRBD only - Category B) or all (Category A, including just collections) of a national blood program 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 program 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:

- ☑ Title
- ☑ Mission / Objective
- ☑ Purpose and Scope
- ☑ Responsibilities
- ☑ Terms of Understanding

The **title** 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 program of work e.g. implementation of the national blood program/provision of the blood donor recruitment program*]*'*

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 program 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 program. 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 **Category A** blood program.

Government obligations:
• 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 program • The provision of an appropriate legislative framework for the blood program 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 program on its behalf, particularly regarding incidents of 'no fault' transfusion transmitted infection.
National Society/blood service obligations:
• 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 • 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 program • Provide a technical, financial and administrative structure to ensure the appropriate management of the blood program • 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

A number of the examples above could also apply for **Category B** National Society's entering into partnership with a blood centre. Additional suggestions are included below:

Government/Blood Centre obligations:
• 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 program, in liaison with those responsible for donor recruitment program (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)

National Society/blood donor recruitment program obligations:
• 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 program, implementing wherever possible the IFRC's standard toolkit 'Making a Difference …recruiting voluntary, non-remunerated blood donors' • Develop and implement a continuous national awareness program 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 programs 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 organise 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 maximise the impact of the donor recruitment program

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.

Appendix 4: Resources

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

- GAP website
  https://globaladvisorypanel.org

- GAP Self-Assessment questionnaire
  https://globaladvisorypanel.org/resources/Self-Assessment

- GAP VNRBD resources
  https://globaladvisorypanel.org/resources/tools/vnrbd-resources

International Federation of Red Cross and Red Crescent Societies (IFRC)

- IFRC Blood Policy
  https://www.ifrc.org/PageFiles/40636/IFRC%20Policy%20on%20blood%20systems.pdf

- Blood Donation Training Program E-learning, IFRC Learning Platform 2019
  https://ifrc.csod.com/client/ifrc/default.aspx

- Developing a Voluntary Blood Donor Program for Blood Safety (DONOR). Geneva, WHO and IFRC.

- IFRC Community-Based Health and First Aid: Voluntary Non-Remunerated Blood Donation primary Prevention Module (community awareness)
  http://ifrc-ecbhfa.org/guides-and-tools

- Making a difference…Recruiting voluntary, non-remunerated blood donors. Toolkit, Geneva, IFRC, 2008
  https://www.rcrc-resilience-southeastasia.org/document/making-a-difference-recruiting-voluntary-non-remunerated-blood-donors/

- Making the most of World Blood Donor Day**.** WHO/IFRC/FIODS/ISBT,
  http://www.who.int/worldblooddonorday/resources/making_the_most_of_wbdd.pdf

World Health Organisation (WHO)

- Blood cold chain: guide to the selection and procurement of equipment and accessories (2002)
  https://www.who.int/publications/i/item/9241545798

- Blood Donor Counselling Implementation Guidelines 92014)
  https://www.who.int/bloodsafety/voluntary_donation/Blooddonorcounselling.pdf

- Blood donor selection: guidelines on assessing donor suitability for blood donation (2012)
  https://www.who.int/publications/i/item/9789241548519

- Costing Blood Transfusion Services (1998)
  https://www.who.int/bloodsafety/transfusion_services/en/Costing_BTS_Eng.pdf

- Design guidelines for blood centres (2010)
  https://www.who.int/publications/i/item/9789290613190

- Developing a National Policy and Guidelines on the Clinical Use of Blood (2001) https://www.who.int/publications/i/item/WHO-BCT-BTS-01.3

- Establishing external quality assessment programmes for screening of donated blood for transfusion-transmissible infections: Implementation guide (2016) https://www.who.int/publications/i/item/9789241515832

- External quality assessment of transfusion laboratory practice: guidelines on establishing an EQA Scheme in blood group serology https://www.who.int/publications/i/item/9241591250

- Guidance on centralization of blood donation testing and processing (2021) https://www.who.int/publications/i/item/9789240020825

- Guide to establishing a national haemovigilance system (2016) https://www.who.int/publications/i/item/9789241549844

- Guidelines on good manufacturing practices for blood establishments (2011) https://www.who.int/bloodproducts/publications/GMP_Bloodestablishments.pdf

- Maintaining a Safe and Adequate Blood Supply and collecting convalescent plasma in the context of the COVID-19 pandemic (2021) https://www.who.int/publications/i/item/WHO-2019-nCoV-BloodSupply-2021-1

- Making the most of World Blood Donor Day**.** WHO/IFRC/FIODS/ISBT, http://www.who.int/worldblooddonorday/resources/making_the_most_of_wbdd.pdf

- Manual on the management, maintenance and use of blood cold chain equipment (2005) https://www.who.int/publications/i/item/92-4-154673-5

- Safe Blood and Blood Products Distance Learning Material (2002) https://apps.who.int/iris/handle/10665/61622

- Safe management of wastes from healthcare activities (1999) https://apps.who.int/iris/bitstream/handle/10665/42175/9241545259.pdf

- Screening donated blood for transfusion-transmissible infections: Recommendations (2009) https://www.who.int/publications/i/item/9789241547888

- Towards 100% voluntary blood donation: a global framework for action (2010) https://www.who.int/publications/i/item/9789241599696

- Quality Assurance of Pharmaceuticals: A Compendium of Guidelines and Related Materials, Volume 2, Good Manufacturing Practices and Inspection (2007) https://www.who.int/medicines/areas/quality_safety/quality_assurance/QualityAssurancePharmVol2.pdf

WHO Aide-Memoir

- Blood Cold Chain (2011) https://www.who.int/publications/i/item/WHO-EHT-11.04
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- Blood Safety (2002) https://www.who.int/publications/i/item/WHO-BCT-02.03

- Clinical Use of Blood (2004)
  https://www.who.int/publications/i/item/WHO-EHT-04.07

- Clinical transfusion process and patient safety (2010)
  https://www.who.int/publications/i/item/WHO-EHT-10.05

- Developing a National Blood System (2011)
  https://www.who.int/publications/i/item/WHO-EHT-11.01

- Good policy process for blood safety and availability (2008)
  https://www.who.int/publications/i/item/WHO-EHT-08.02

- Quality Systems for Blood Safety (2002)
  https://www.who.int/publications/i/item/WHO-BCT-02.02

- Safe Blood Components (2005)
  https://www.who.int/publications/i/item/WHO-EHT-05.01

- Safe health-care waste management (2000)
  https://www.who.int/occupational_health/activities/2amhcw_en.pdf

- Safe management of wastes from healthcare activities (2014)
  https://www.euro.who.int/__data/assets/pdf_file/0012/268779/Safe-management-of-wastes-from-health-care-activities-Eng.pdf

International Society of Blood Transfusion (ISBT)

- ISBT Code of Ethics
  https://www.isbtweb.org/about-isbt/code-of-ethics

AABB

- Standards for Blood Banks and Transfusion Services.
  https://www.aabb.org/standards-accreditation/standards

- AABB Fundamental Standards
  https://www.aabb.org/standards-accreditation/standards

- Disaster Operations Handbook: Coordinating the Nation's Blood Supply during Disasters and Biological Events (2008).
  https://www.aabb.org/about-aabb/organization/disaster-response

African Society for Blood Transfusion (AfSBT)

- AfSBT Step-wise Accreditation Programme Standards
  https://afsbt.org/accreditation-standards/

Australian Therapeutic Goods Administration

- Australian Code of Good Manufacturing Practice for human blood and blood components, human tissues and human cellular therapy products (2013)
  https://www.tga.gov.au/publication/australian-code-good-manufacturing-practice-human-blood-and-blood-components-human-tissues-and-human-cellular-therapy-products

Council of Europe (CoE)

- Guide to the Preparation, Use and Quality Assurance of Blood Components. European Directorate for the Quality of Medicine (EDQM) – 20th edition. https://www.edqm.eu/en/blood-guide

European Commission

- Principles of Good Manufacturing Practice in Respect of Medicinal Products for Human Use and Investigational Medicinal Products for Human Use. EC Directive 2003/94/EC https://ec.europa.eu/health/human-use/good_manufacturing_distribution_practices_en

European Blood Alliance

- Pandemic Influenza Planning for Blood Organisations. European Blood Alliance Emergency Planning Action Group (2009) http://europeanbloodalliance.eu/wp-content/uploads/2012/09/EBA-Planning-Document-on-Pandemic-Influenza-1.pdf

ISO www.iso.org

- ISO 9001 Quality Management Systems – Requirements (2015)
- ISO 19011: Guidelines for quality and/or environmental management systems auditing (2002)
- ISO 14000, Environmental Management (2007)

John Hopkins Bloomberg School of Public Health and IFRC

- Public health guide in emergencies (2008) https://reliefweb.int/sites/reliefweb.int/files/resources/Forward.pdf