

INTERNATIONAL FEDERATION OF RED CROSS AND
RED CRESCENT SOCIETIES

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Item 11.1 of the agenda

Policy on “Promoting Safe and Sustainable National Blood Systems”

It is recommended that:

The Governing Board,

approves the draft policy on “Promoting Safe and Sustainable National Blood Systems” and refers it to the upcoming General Assembly for final decision

Executive summary.

The attached version of the revised policy includes modifications to the text submitted to the Governing Board in December 2010. More specifically there are some substance additions to the version proposed by the Advisory Body on Health And Sustainable Development - especially in the list of points describing “an integrated approach to blood safety” (just below the description of “Level B” programmes) - and there is clarification of roles and responsibilities related to risk management at global and other levels. The key modifications related to risk management are to be found in the section on “Specific Responsibilities arising out of this policy”. In summary, it is underlined that the primary responsibility for managing safety and risks of blood programmes lies with national governments. The remainder of the text remains largely largely unchanged in substance over the version presented to the Governing Board in December last year.

What is the issue

The need for a new blood policy was in part triggered by a comprehensive report submitted by the Global Advisory Panel on Blood (GAP) on the “Review of risks associated with blood service delivery for National Societies engaged in blood programmes” to the Governing Board in September 2009. While there was subsequently relatively quickly agreement on the main technical substance, it took a while longer to find consensus around the definition of roles and responsibilities related to the management of the various risks associated with different forms of engagement of the membership in blood related activities.

The relation to previous governance decision(s)

Following the December 2010 Governing Board decision asking the Secretariat to conduct further consultations with National Societies on the draft blood policy as well as the April 2011 decision supporting the proposal of the Secretary General to continue consultations on the blood policy specifically in the area of risk management, a final draft is now presented to the Governing Board for endorsement and for transmission to the General Assembly for final decision.

The relation to existing policies

This policy replaces the 1999 policy on “Quality Provision of Blood Services”

The relation to strategic objectives

Red Cross Red Crescent work on blood issues is in particular covered by strategic aim 2 of Strategy 2020.

How does this decision solve the issue

The new policy provides clarity on the scope of Red Cross Red Crescent blood related activities as well as roles and responsibilities related to management of associated risks

Research, analysis and consultations carried out

Various key stakeholders have been consulted, including the Advisory Body for Health and Sustainable Development, GAP (Global Advisory Panel on Blood), the Risk and Audit Committee and senior managers and leaders of National Societies. In addition the Secretariat took into consideration pro bono work of a British law firm.

Any other relevant information: to be referred in annexes

Not applicable

Resource implications

There are at this stage no specific resource implications for the Secretariat. The membership at large is being continuously asked to support the

Recommended options

The Secretariat orally updated the Governing Board at its April 2011 session on its perspective on possible legal liabilities and the various options of managing risk at the global level as well as options for the future legal structure of GAP. There are separate terms of reference for GAP, and discussions and work are being carried out towards establishing GAP as a separate legal entity.

Any potential risks to the Federation

Red Cross and Red Crescent engagement in blood activities will always come with reputational and other risks. Adherence to the policy will significantly contribute to effective management of risks.

Implementation and Monitoring and how implementation will be monitored and reported to the Governing Board

The Secretariat is a member of the GAP Board, and will update the Governing Board through the Secretary General on material issues and risks that are brought to its attention in relation to implementation of the blood policy.



POLICY

Promoting Safe and Sustainable National Blood Systems

Introduction:

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

The International Federation recognises that “health security is a fundamental and indispensable prerequisite to global, national and individual development”¹ and it supports the advancement of global health security by promoting voluntary non-remunerated blood donation (VNRBD), and advocating for the safe provision of blood and products².

While the World Health Organisation (WHO) recognises that it is the responsibility of governments to ensure a safe and adequate supply of blood³, Red Cross/Red Crescent Societies in many countries, as auxiliaries to their governments, play an important role in promoting safe and sustainable blood programmes. National Society activities range from the provision of the national blood service, to systematic recruitment of voluntary blood donors, to promotion of blood donation and advocacy for VNRBD, for example annual participation in World Blood Donor Day.

Scope of policy

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

Importance of blood services

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

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

4. the reduction of child mortality;
5. the improvement of maternal health; and

¹ Health Policy adopted at the 15 session of the General Assembly of the IFRC, Seoul, November 2005.

² *Strategy 2020*, p 15, IFRC

³ *Blood Safety*, Aide-Memoire for National Blood programme, WHO, 2002

6. combating HIV/AIDS, malaria and other diseases.

It is recognised that a sufficient supply of safe blood and blood components based on voluntary non-remunerated blood donation (VNRBD), and the security of that supply, are important national goals to prevent blood shortages and meet the transfusion needs of the patient population⁴.

VNRBD is a critical component in ensuring a safe and sustainable blood supply that meets the needs of all recipients. VNRBD was enshrined as a fundamental principle of blood service when the 1975 World Health Assembly (WHA) resolution called for member states to “promote the development of national blood services based upon voluntary non-remunerated donation of blood”⁵.

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

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

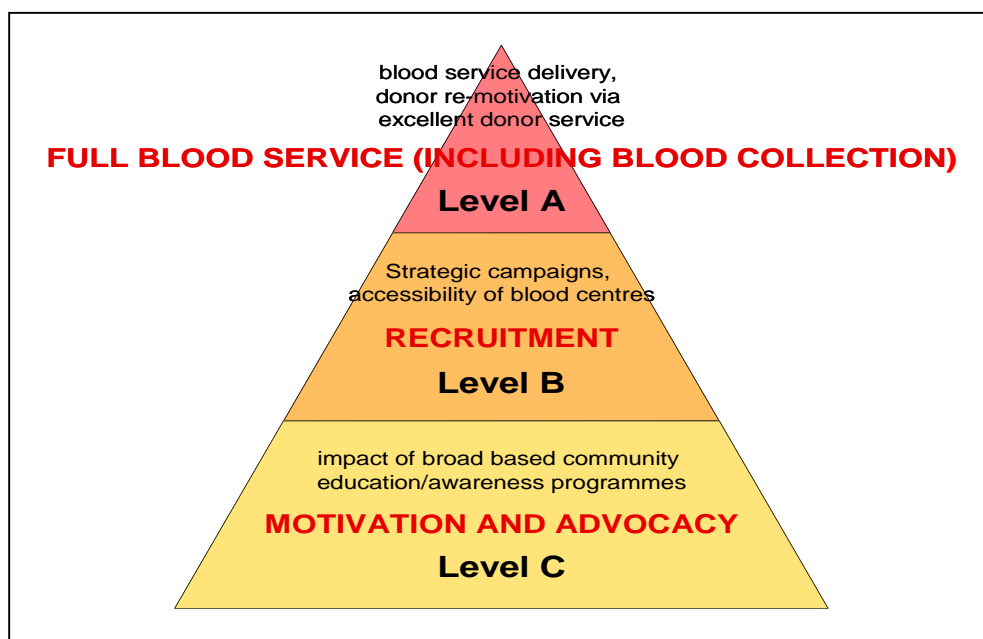
Characteristics of well-functioning RC/RC blood programmes

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

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

These levels are reflected in the figure below.

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



⁴ WHA resolution 63.12.

⁵ WHA resolution 28.72 This principle was reasserted again by the WHA in 2005 (WHA58.13) and 2010 (WHA28.72)

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

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

For both Levels A and B:

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

At Level A:

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

At Level B:

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

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

- The establishment of a nationally coordinated blood service
- Formalization of government commitment and support.
- Contribute where appropriate to the Development of National blood policy and plans.
- Advocacy of necessary legislation/regulation for the Blood Transfusion Service .
- Establishment of nationwide quality systems, including guidelines, standard operating procedures, accurate records, monitoring and evaluation aligning to Government policy.
- Collection of blood only from vnrbd from low risk populations
- Haemovigilance system for monitoring, reporting and investigating adverse events.
- Trained staff and continuing professional development and upgrading for latest technology as a prerequisite.
- Ensure efficient and good laboratory practices in screening for transfusion transmissible infections, blood grouping, compatibility testing, blood component production, storage and transportation
- Reduction of unnecessary transfusions through effective clinical use of blood

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

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

Framework of support to RC/RC blood programmes

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

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

The International Federation's main toolkit, designed to assist key stakeholders in best practice, in donor recruitment and advocacy for 100 per cent vnrbd is the package *"Making a*

Difference...recruiting voluntary, non-remunerated blood donors". This is a self-help manual empowering personnel in the field to motivate, recruit and retain vnrbd and to phase-out any dependence on family/replacement donors.

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

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

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

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

Specific Responsibilities – arising out of this policy:

The International Federation, GAP and National Societies engage to:

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

National Societies have a responsibility to:

- work to ensure their Governments accept their responsibility to ensure a safe and adequate blood supply within their jurisdictions
- identify their role in the overall strategy of blood service delivery in their country in accordance with their capacity, technical know-how, available resources, local priorities and in liaison with government
- promote safe, sustainable and equitable practices in the development and administration of blood programmes
- ensure their blood programme has an adequate governance structure with a well-defined system for delegation of authority and accountability.
- support the aspiration of national self-sufficiency, including ensuring adequate blood and blood products to meet domestic health needs
- undertake Humanitarian Diplomacy as necessary to seek government action to minimise risk in blood services and to help ensure that Government alerts the public to any reasonably preventable inadequacy in blood service delivery which places them at risk

- implement the GAP Self-assessment and adhere to the *Development of Safe and Sustainable National Blood Programmes Manual*, which may necessitate a more detailed analysis, assessment and development of an exit strategy
- respect the confidentiality and privacy of all information relating to blood donors and blood donation
- administer any blood programmes in compliance with this position; inform all staff, volunteers and blood sector partners participating in blood programmes of this position
- where practical, provide support to other National Societies and blood services in achieving a safe and sustainable blood system in ways that enable self-empowerment and long-term sustainability
- take steps in consultation with GAP and other partners to ensure that appropriate risk management measures are implemented; this includes ensuring that its senior management and governing leaders are alerted to any material risks and that appropriate action is subsequently taken
- ensure that all blood programmes comply with this policy

The International Federation has a responsibility to:

- focus on the promotion of voluntary blood donor recruitment and to liaise and work in close collaboration with GAP, WHO and other partners in implementing the WHO/IFRC Global Framework for action-towards 100 per cent voluntary blood donation
- share knowledge and exchange information with GAP at a strategic, regional and country level.
- ensure this policy is reviewed after five years
- work with the GAP membership to help ensure necessary GAP resourcing
- keep – through the International Federation Secretary General – International Federation Governance appropriately informed of major material risks for the International Federation it becomes aware of

The GAP has a responsibility to:

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

Review and Reference:

This policy was drawn up in 2010 and it is designed to replace the previously established policy on Quality Provision in Blood Services. IFRC will ensure this policy is reviewed after five years, with

any proposed amendments to be submitted to the Federation for approval. The review is to be initiated no later than 30 Dec 2014.

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

Further Reference Texts:

Decision 34, 8th session of the General Assembly, Budapest, 25-28 Nov 1991. Voluntary 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

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

Code of Ethics for Blood Donation and Transfusion. International Society of Blood Transfusion, General Assembly, 12 July 2000; amended by the ISBT General Assembly, 5 September 2006.

Decision 36, Blood Quality Programme. Seville, Spain: 11th Session of the General Assembly, November 1997.

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

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