**GAP Self-Assessment Questionnaire**

For Category A National Society Blood Services

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**Who is GAP?**

GAP is a global network of Red Cross/Red Crescent Blood Services with expertise in risk management and corporate governance of blood programs. Read more on GAP [here](https://globaladvisorypanel.org/).

**Benefits to completing the Self-Assessment**

The Self-Assessment is considered to be a valuable tool to assist National Society (NS) blood programs to:

* Identify areas of challenge with regard to blood program risk management;
* Implement, manage and measure progress of blood program related risk management strategies;
* Reflect on the effectiveness of their governance;
* Evaluate themselves against relevant international benchmarks;
* Fulfil the National Society’s obligations under the IFRC Blood Policy;
* Support IFRC Strategy 2030 (outcome 3.2).

**Who should complete the questionnaire?**

It is recommended that, as a first step, the Self-Assessment is completed separately by the blood service senior management team and board (if a board exists). The board and the senior management team could then meet to evaluate their responses and finalise a single Self-Assessment result to be used for their country. This evaluation could be repeated from time to time to review progress. An internal review, possibly on an annual basis, is recommended.

**How to complete the questionnaire?**

Select either a ‘Yes’ or ‘No’ response for each question (or % where indicated). An optional comment can be provided where further clarification is required.

If the blood service response is ‘No’ for a particular question, but another organisation has the delegated responsibility for risk management for this aspect, please note this in the comments.

For assistance, please contact the GAP Secretariat: gapsecretariat@redcrossblood.org.au.

**Next steps?**

GAP will provide a Self-Assessment feedback report to each National Society blood service that has completed and submitted the questionnaire. This individual report enables the National Society blood service to develop practical steps towards achieving GAP’s key recommendations for risk management, and may also assist with advocacy and funding applications.

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| *For your information, GAP treats the information shared by National Societies in the Self-Assessment as strictly confidential. This is to encourage open responses so we can provide the most appropriate and useful advice.  However, the National Society may share this information at their discretion.*  |

**Name of National Society blood service:**

**Name(s) of person(s) completing the survey:**

**Title:**

Date completed:

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| **Background information** |
| Please provide a brief overview of your blood service, with the most recent data available to you. This section will help set an overall picture of blood service activities in your National Society, and assist in evaluating progress over time. |
| 1 | What percentage (%) of the total national blood supply does your National Society blood service provide? |       % |
| 2 | If your National Society blood service provides less than 100% of the national blood supply, please list the top five providers of blood in your country with the approximate % share of overall supply. | 1.      2.      3.      4.      5.       |
| 3 | Please provide the total number of collections by your National Society blood service annually of:Whole bloodApheresis plasmaApheresis plateletsOther (please specify) |                      |
| 4 | Please provide the number of fixed collection sites operated by your National Society blood service: |       |
| 5 | Please provide the percentage (%) of total blood collections by your National Society blood service that are undertaken at mobile sites / camps? |       % |
| 6 | Is the amount of plasma collected for fractionation in your country enough to meet the national requirement for self-sufficiency? | [ ]  **YES** | **[ ]  NO** |
| 7 | Are you aware of any other organisations in your country that use the Red Cross/Red Crescent emblem, that carry out blood services? | [ ]  **YES** | **[ ]  NO** |
| If Yes, please give details:      |
| 8 | Would you be willing to share some of your local success stories with other Red Cross / Red Crescent blood services? | **[ ]  YES** | **[ ]  NO** |

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| **Key Issue 1: Minimum conditions** |
|  | **Yes** | **No** | *Comment (if required)* |
| 1.1 | Are the roles and responsibilities clearly defined, documented and adhered to, with the following?* Governments (national and local – *where applicable)*
* National Society
* Hospitals / clinics
 | [ ] [ ] [ ]  | [ ] [ ] [ ]  |                 |
| 1.2 | Does your country’s government, National society or Blood Service have a policy of securing the supply of safe blood through voluntary and non-remunerated blood donation (VNRBD)? (*Indicate all that apply)** Government
* National Society
* Blood Service
 | [ ] [ ] [ ]  | [ ] [ ] [ ]  |                 |
| 1.3a | Approximately what percentage (%) of blood collected by your blood service is from VNRBD donors? *(Please note: VNRBD does not include replacement donations from family or friends)* |       % |
| 1.3b | *If your answer to Q1.3a is not 100%:*Is there a plan in place to increase to 100% VNRBD? | [ ]  | [ ]  |       |
| 1.4a | Is your blood service a separate legal entity from the National Society? | [ ]  | [ ]  |       |
| 1.4b | *If your answer to Q1.4a is NO*:Does your blood service and National Society have sufficient protections in place to limit the transfer of liability between both entities? *(e.g. through equivalent structural/governance arrangements and / or separate insurance)* | [ ]  | [ ]  |       |
| 1.5 | Does the blood service assure the privacy and confidentiality of donor information? | [ ]  | [ ]  |       |
| 1.6 | Does your blood service have a long-term, sufficient and sustainable source of revenue / funding? | [ ]  | [ ]  |       |

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|  | **Yes** | **No** | *Comment (if required)* |
| 1.7 | Does the blood service have sufficient of the following resources to meet regulatory requirements and minimum standards?* Facilities
* Supplies
* Equipment
* Trained staff / volunteers
 | [ ] [ ] [ ] [ ]  | [ ] [ ] [ ] [ ]  |                      |
| 1.8 | ***If you answered NO to Q1.6 and/or Q1.7,* this could indicate a potential Major Material Risk (MMR).**Please provide further detailed information, including impact on the blood program and whether any plans are in place to improve this. |       |
| 1.9 | Does the blood service meet the following for blood programs *(please indicate which ones)*?* National quality, technical and regulatory standards
* WHO standards
* International technical standards (e.g. AABB, cGMP, EU Directives, GMP, AfSBT, AABB Fundamental Standards)

*Please indicate which standard:*       | [ ] [ ] [ ]  | [ ] [ ] [ ]  |                 |
| 1.10 | Where the blood service does NOT operate according to international or national standards in blood programme delivery, is the reason documented and accepted by government? | [ ]  | [ ]  |       |
| 1.11 | Is your blood service assessed for compliance to these standards through accreditation, certification or an independent assessment? | [ ]  | [ ]  |       |
| Additional comments for Key Issue 1 (if required):       |

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| **Key Issue 2: Organisation and management** |
|  | **Yes** | **No** | *Comment (if required)* |
| 2.1a | Does the blood service have a separate management structure from the National Society including a separate board of governance or equivalent committee with authority for blood program strategic, operational, financial management and planning? | [ ]  | [ ]  |       |
| 2.1b | *If your answer to Q2.1a is YES*Are the delegations of authority and accountability well-defined and documented between the?* National Society and blood service board/committee
* Blood service board/committee and blood service management
 | [ ] [ ]  | [ ] [ ]  |            |
| 2.2 | Does the blood service management and board/committee have the expertise to perform its responsibilities and manage change? | [ ]  | [ ]  |       |
| 2.3 | Does the blood service have training programmes in place to maintain and develop management and leadership skills? | [ ]  | [ ]  |       |
| 2.4 | Does the blood service have a strategic plan with a vision/mission, strategic objectives and key performance goals and indicators? | [ ]  | [ ]  |       |
| 2.5 | Is your National Society Blood Service centrally co-ordinated at a national level? | [ ]  | [ ]  |       |
| 2.6 | Are there any National Society Blood Service operations that are controlled at a state or provincial level? | [ ]  | [ ]  |       |
| 2.7 | Does the blood service have contingency plans or systems in place to maintain blood service delivery in the event of disaster? *(e.g. a business continuity plan or disaster preparedness procedures in place for the blood program)* | [ ]  | [ ]  |       |
| Additional comments for Key Issue 2 (if required):       |

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| **Key Issue 3: Liability and protection** |
|  | **Yes** | **No** | *Comment (if required)* |
| 3.1 | Does the government provide legal and/or financial liability protection to the blood service? | [ ]  | [ ]  |       |
| 3.2 | Does the blood service receive either government or commercial indemnity protection for blood-borne disease liabilities? | [ ]  | [ ]  |       |
| 3.3 | Does the blood service maintain insurance cover against the following potential liabilities?* property loss
* public liability
* blood and blood products liability
* directors' and officers' liability
* professional indemnity
* internal fraud
* donor injury
* malicious product tamper
 | [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  | [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  |                                          |
| 3.4 | Does the blood service obtain regular professional advice on the levels and type of insurance cover? | [ ]  | [ ]  |       |
| 3.5 | Does the blood service retain donor and donation records according to a defined policy? | [ ]  | [ ]  |       |
| 3.6 | Does the blood service, National Society, government (or another agency) provide any compassionate / practical support to recipients of infected blood? *Examples may include:**Psychological (availability of counselling), medical (facilitating access to doctors) and social (facilitating access to authorities)* | [ ]  | [ ]  |       |
| If Yes, please provide details: |       |
| Additional comments for Key Issue 3 (if required):       |

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| **Key Issue 4: Safety vs cost** |
|  | **Yes** | **No** | *Comment (if required)* |
| 4.1 | Does the blood service conduct a cost/benefit analysis of new safety-enhancement proposals? *(e.g. Nucleic Acid Testing)* | [ ]  | [ ]  |       |
| 4.2 | Does the blood service advise the government on the importance of sufficient funding for new blood safety initiatives and the consequences of not funding these? | [ ]  | [ ]  |       |
| 4.3 | Does the blood service have systems in place to monitor emerging threats to the safety of the blood supply *(e.g. regional disease surveillance and haemovigilance programs)*? | [ ]  | [ ]  |       |
| 4.4 | Does the blood service participate with relevant health authorities in the development of national standards? | [ ]  | [ ]  |       |
| 4.5 | Does the blood service aim to influence hospitals/clinics in the appropriate use of blood components including storage, handling and minimising waste?  | [ ]  | [ ]  |       |
| 4.6 | Does the blood service have a written agreement in place with all major hospitals regarding appropriate blood use? | [ ]  | [ ]  |       |
| 4.7 | Does the blood service have systems in place to ensure?* The correct blood is being provided to hospitals.
* Mechanisms to enable lookback and recall
 | [ ] [ ]  | [ ] [ ]  |            |
| 4.8 | Does the blood service aim to influence hospitals/clinics in ensuring the following?* The right product is being transfused or administered to the correct patient
* Traceability (for patient lookback)

*(If the blood service is directly involved in blood transfusion/administration, please indicate if the blood service has these systems in place)* | [ ] [ ]  | [ ] [ ]  |            |
| 4.9 | Do all major hospitals that use blood components from your blood service have active multi-disciplinary transfusion committees? | [ ]  | [ ]  |       |
| 4.10 | Does the blood service participate in multi-disciplinary transfusion committees? | [ ]  | [ ]  |       |
| Additional comments for Key Issue 4 (if required):       |
| **Key Issue 5: Funding** |
|  | **Yes** | **No** | *Comment (if required)* |
| 5.1 | Please indicate where your blood service funding comes from (%):* government
* hospitals
* cost recovery charge to hospitals/clinics
* internal funding activities
* your National Society
* other National Societies
* NGOs (non-governmental organisations) & international funds
* public/private health insurance system
* Other
 |       %      %      %      %      %      %      %      %      % *Please specify:*       |
| 5.2 | Do the National Society and blood service have separate accounting systems? | [ ]  | [ ]  |       |
| 5.3 | Is a formal agreement in place to manage National Society access to blood service funds? | [ ]  | [ ]  |       |
| 5.4 | Are blood service funds used only by the blood service? | [ ]  | [ ]  |       |
| 5.5 | Does the blood service ensure that 'for profit' organisations or suppliers have no equity share or management control in the blood programme?*(For example: Ensuring that suppliers of equipment/reagents do not influence blood service decision making)* | [ ]  | [ ]  |       |
| 5.6 | Does the blood service manage potential conflict of interest for:* Board members
* Senior staff
* Volunteers
* Major suppliers

*A potential conflict of interest is a situation in which a person is in a position to personally benefit from decisions made in their official capacity. Some examples of ways to manage conflict of interest are: a) board members with a conflict of interest are required to abstain from decision making where a conflict exists or b) policies are implemented that ensure suppliers are not influencing blood service decision making.* | [ ] [ ] [ ] [ ]  | [ ] [ ] [ ] [ ]  |                      |
| Additional comments for Key Issue 5 (if required):       |
| **Key Issue 6: Education and Patient Blood Management** |
|  | **Yes** | **No** | *Comment (if required)* |
| 6.1 | Do donors have to provide written informed consent prior to blood donation? | [ ]  | [ ]  |       |
| 6.2 | In your country, do patients have to provide written informed consent prior to transfusion? | [ ]  | [ ]  |       |
| 6.3 | Does the blood service conduct regular campaigns to educate the public on the need for regular blood donations? | [ ]  | [ ]  |       |
| 6.4 | Has the blood service developed and implemented strategies aimed at improving public education in relation to the safety of the blood supply and risks of blood transfusion?*(Examples may include: school programmes, media (including social media), information on a website, brochures/leaflets, informal networks, donor education, placing representatives on appropriate decision-making bodies)* | [ ]  | [ ]  |       |
| 6.5 | Does the blood service provide education on the risks of blood transfusion to clinicians and other stakeholders? *(Including National Society, Government, Hospitals & clinical colleges, Blood service staff, Participation on hospital transfusion committees)* | [ ]  | [ ]  |       |
| Additional comments for Key Issue 6 (if required):  |

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| **Key Issue 7: Fractionation** |
| **Question 7.1** - Is the blood service involved in any of the following activities related to plasma fractionation? *(please indicate below)* |

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| **a) Collection of plasma for fractionation into plasma derived medicinal products and sending it to a plasma fractionator**  |
| [ ]  **YES** If yes, for these activities,  does the blood service **🡪** | Have approval from government? | [ ]  **Yes**  | [ ]  **No** |
| Have insurance / indemnity? | [ ]  **Yes** | [ ]  **No** |
| Meet relevant national/ international technical standards and accreditation requirements? | [ ]  **Yes** | [ ]  **No** |
| [ ]  **NO** If no, does the blood  service **🡪** | Plan to be involved in this activity in the future? | [ ]  **Yes** | [ ]  **No** |
| *If yes, please provide details:*       |

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| **b) Operation of a plasma fractionation facility or directly performing plasma fractionation***Please note - Fractionation refers to the process where the proteins in plasma are separated, purified and concentrated to make plasma derived medicinal products (e.g. immunoglobulins).* |
| [ ]  **YES** If yes, for these activities,  does the blood service **🡪** | Have approval from government? | [ ]  **Yes**  | [ ]  **No** |
| Have insurance / indemnity? | [ ]  **Yes** | [ ]  **No** |
| Meet relevant national/ international technical standards and accreditation requirements? | [ ]  **Yes** | [ ]  **No** |
| [ ]  **NO** If no, does the blood  service **🡪** | Plan to be involved in this activity in the future? | [ ]  **Yes** | [ ]  **No** |
| *If yes, please provide details:*       |

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| **c) Receiving income from the sale of plasma to commercial plasma fractionators** |
| [ ]  **Yes** If yes **🡪** | Are donors informed about the blood service's commercial arrangements for plasma? | [ ]  **Yes**  | [ ]  **No** |
| Are financial arrangements transparent and consistent with the ethical considerations for blood products *(Oviedo convention and IFRC Blood Policy)* | [ ]  **Yes** | [ ]  **No** |
| [ ]  **No** |

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| **d) Receiving income from the sale of plasma derived medicinal products to hospitals/clinics/patients** |
| [ ]  **Yes** If yes **🡪** | Are donors informed about the blood service's commercial arrangements for plasma? | [ ]  **Yes**  | [ ]  **No** |
| Are financial arrangements transparent and consistent with the ethical considerations for blood products *(Oviedo convention and IFRC Blood Policy)* | [ ]  **Yes** | [ ]  **No** |
| [ ]  **No** |

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| Additional comments for Key Issue 7 (if required):       |

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| **Key Issue 8: Other activities** |
| **Question 8.1** - Is the blood service involved in any of the following activities? *(please indicate all that apply)* |

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| **a) Transfusion or administration of blood products to patients (e.g. whole blood, components, plasma derived products, or cell therapies)** |
| [ ]  **YES** If yes, for these activities,  does the blood service **🡪** | Have approval from government? | [ ]  **Yes**  | [ ]  **No** |
| Have insurance / indemnity? | [ ]  **Yes** | [ ]  **No** |
| Meet relevant national/ international technical standards and accreditation requirements? | [ ]  **Yes** | [ ]  **No** |
| [ ]  **NO** If no, does the blood  service **🡪** | Plan to be involved in this activity in the future? | [ ]  **Yes** | [ ]  **No** |
| *If yes, please provide details:*       |

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| **b) Therapeutic collection of whole blood or plasma** |
| [ ]  **YES** If yes, for these activities,  does the blood service **🡪** | Have approval from government? | [ ]  **Yes**  | [ ]  **No** |
| Have insurance / indemnity? | [ ]  **Yes** | [ ]  **No** |
| Meet relevant national/ international technical standards and accreditation requirements? | [ ]  **Yes** | [ ]  **No** |
| [ ]  **NO** If no, does the blood  service **🡪** | Plan to be involved in this activity in the future? | [ ]  **Yes** | [ ]  **No** |
| *If yes, please provide details:*       |

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| **c) Compatibility testing / cross-matching and/or antibody identification services for hospitals** |
| [ ]  **YES** If yes, for these activities,  does the blood service **🡪** | Have approval from government? | [ ]  **Yes**  | [ ]  **No** |
| Have insurance / indemnity? | [ ]  **Yes** | [ ]  **No** |
| Meet relevant national/ international technical standards and accreditation requirements? | [ ]  **Yes** | [ ]  **No** |
| [ ]  **NO** If no, does the blood  service **🡪** | Plan to be involved in this activity in the future? | [ ]  **Yes** | [ ]  **No** |
| *If yes, please provide details:*       |

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| **d) Blood inventory management for hospitals / clinics** |
| [ ]  **YES** If yes, for these activities,  does the blood service **🡪** | Have approval from government? | [ ]  **Yes**  | [ ]  **No** |
| Have insurance / indemnity? | [ ]  **Yes** | [ ]  **No** |
| Meet relevant national/ international technical standards and accreditation requirements? | [ ]  **Yes** | [ ]  **No** |
| [ ]  **NO** If no, does the blood  service **🡪** | Plan to be involved in this activity in the future? | [ ]  **Yes** | [ ]  **No** |
| *If yes, please provide details:*       |

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| **e) Clinical advice or approval for blood and blood products for transfusion or administration (e.g. plasma derived products such as IVIg or FVIII)** |
| [ ]  **YES** If yes, for these activities,  does the blood service **🡪** | Have approval from government? | [ ]  **Yes**  | [ ]  **No** |
| Have insurance / indemnity? | [ ]  **Yes** | [ ]  **No** |
| Meet relevant national/ international technical standards and accreditation requirements? | [ ]  **Yes** | [ ]  **No** |
| [ ]  **NO** If no, does the blood  service **🡪** | Plan to be involved in this activity in the future? | [ ]  **Yes** | [ ]  **No** |
| *If yes, please provide details:*       |
| **f) Cord blood banking and peripheral blood stem cells (including collection, storage, testing, distribution and/or administration)** |
| [ ]  **YES** If yes, for these activities,  does the blood service **🡪** | Have approval from government? | [ ]  **Yes**  | [ ]  **No** |
| Have insurance / indemnity? | [ ]  **Yes** | [ ]  **No** |
| Meet relevant national/ international technical standards and accreditation requirements? | [ ]  **Yes** | [ ]  **No** |
| [ ]  **NO** If no, does the blood  service **🡪** | Plan to be involved in this activity in the future? | [ ]  **Yes** | [ ]  **No** |
| *If yes, please provide details:*       |

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| **g) Other activities involving cells and tissues (including collection, storage, testing, distribution and/or administration)** |
| Please indicate which:       |
| [ ]  **YES** If yes, for these activities,  does the blood service **🡪** | Have approval from government? | [ ]  **Yes**  | [ ]  **No** |
| Have insurance / indemnity? | [ ]  **Yes** | [ ]  **No** |
| Meet relevant national/ international technical standards and accreditation requirements? | [ ]  **Yes** | [ ]  **No** |
| [ ]  **NO** If no, does the blood  service **🡪** | Plan to be involved in this activity in the future? | [ ]  **Yes** | [ ]  **No** |
| *If yes, please provide details:*       |

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| **h) Consumables or invitro diagnostics manufacture** |
| [ ]  **YES** If yes, for these activities,  does the blood service **🡪** | Have approval from government? | [ ]  **Yes**  | [ ]  **No** |
| Have insurance / indemnity? | [ ]  **Yes** | [ ]  **No** |
| Meet relevant national/ international technical standards and accreditation requirements? | [ ]  **Yes** | [ ]  **No** |
| [ ]  **NO** If no, does the blood  service **🡪** | Plan to be involved in this activity in the future? | [ ]  **Yes** | [ ]  **No** |
| *If yes, please provide details:*       |

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| **i) Other biomedical activities (e.g. milk bank, microbiome)** |
| Please indicate which:       |
| [ ]  **YES** If yes, for these activities,  does the blood service **🡪** | Have approval from government? | [ ]  **Yes**  | [ ]  **No** |
| Have insurance / indemnity? | [ ]  **Yes** | [ ]  **No** |
| Meet relevant national/ international technical standards and accreditation requirements? | [ ]  **Yes** | [ ]  **No** |
| [ ]  **NO** If no, does the blood  service **🡪** | Plan to be involved in this activity in the future? | [ ]  **Yes** | [ ]  **No** |
| *If yes, please provide details:*       |

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| Additional comments for Key Issue 8 (if required):       |

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| **Final comments or feedback on the Self-Assessment (optional):** |

Thank you, please send your completed questionnaire to: gapsecretariat@redcrossblood.org.au.